TITLE PAGE

Title	Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice
Version Identifier of the Final Study Report	20110132, Version 1.0
Date of Last Version of the Study Report	Not Applicable
Clinicaltrials.gov Identifier No:	NCT01652690
Active Substance	Denosumab (ATC code M05BX04 for Prolia)
Medicinal Product	Prolia® (denosumab 60 mg)
Product Reference:	EMEA/H/C/001120
Marketing Authorization Holder	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, The Netherlands
Research Question and Objectives	This was a noninterventional study in postmenopausal osteoporosis patients who received at least 1 injection of Prolia 60 mg once every 6 months subcutaneously in the Czech Republic and Slovakia. The objective of this study was to describe by country the characteristics of patients treated with Prolia in routine clinical practice and their clinical management during the first 2 years of treatment. The decision to treat patients with Prolia was made independent of and before their enrolment in the study. No study drug was administered as part of the study.
Countries of Study	Czech Republic, Slovakia
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Marketing Authorization Holder

Marketing Authorization Holder (MAH)	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, The Netherlands
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1. ABSTRACT

- **Title**

Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice

Date: 04 January 2016

Author: Maurille Tepie Feudjo, Observational Research Director, Amgen, UK

- **Keywords**

Prolia, postmenopausal osteoporosis, clinical practice, noninterventional

- **Rationale and Background**

Prolia has been approved for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

After regulatory approval is granted for pharmaceutical products, many countries request post-launch population use characteristics to ensure that each drug is being used in the population for which it was intended, especially for injectable drugs like Prolia.

- **Research Question and Objective**

The objective of this study was to describe characteristics of postmenopausal women treated with Prolia® (denosumab) in routine clinical practice and to describe the clinical management of osteoporosis in these patients during the first 2 years of treatment with Prolia in the Czech Republic and Slovakia.

- **Study Design**

The decision to treat patients with Prolia was made independent of and before their enrolment in the study. Patients were to receive their scheduled Prolia injection every 6 months.

No study drug was administered as part of the study. Detailed data obtained as part of routine clinical practice were collected at the initial visit and for up to approximately 2 years after entering the study, either directly or from medical records, to characterize Prolia-treated patients.

- **Setting**

The study was conducted at various study centres in the Czech Republic and Slovakia. The recruitment period was from 26 June 2012 to 15 May 2013. The last patient last visit was in May 2015 and the database lock was on 20 July 2015.

- **Subjects and Study Size, Including Dropouts**

Patients were eligible if they were women with a clinical diagnosis of postmenopausal osteoporosis (PMO), a decision was made to treat them with Prolia 60 mg once every 6 months (Q6M), and they had received their first injection of Prolia within 8 weeks before enrolling in this study.

To characterize this Prolia population, a sample size of approximately 300 patients per country (Czech Republic and Slovakia) was planned.

- **Variables and Data Sources**

Available clinical information obtained for routine clinical practice (including those already recorded on the patient medical records for baseline characteristics) were

recorded, including Prolia administration, previous and current therapies, medical history (including fractures), adverse drug reactions and serious adverse drug reactions, and comorbidities.

- **Results**

A total of 600 patients (300 each from the Czech Republic and Slovakia) were enrolled in the study. In the Czech Republic and Slovakia, most of the patients (> 98.0%) received all their injections of Prolia from the initial prescribing study centre, irrespective of the total number of injections received on study. In both Czech Republic and Slovakia, reasons for prescribing Prolia to most of the PMO patients were: history of osteoporotic fracture, multiple risk factors for fracture, failure to respond to other available osteoporosis therapy, intolerance to other osteoporosis therapy, and/or low BMD T-score. A total of 35 patients (11.7%) in the Czech Republic and 21 patients (7.05) in Slovakia discontinued the study. In the Czech Republic and Slovakia, Prolia injections were always administered by a health care professional to all patients. A total of 82.0% of the patients in the Czech Republic and 81.0% of the patients in Slovakia received all 4 postbaseline injections. Dual-energy X-ray absorptiometry (DXA) assessment was done for 99.0% (95% confidence interval [CI]: 97.1, 99.8) of patients prebaseline and 84.3% (79.7, 88.3) of patients postbaseline in the Czech Republic; and 99.7% (98.2, 100.0) of patients prebaseline and 72.0% (66.6, 77.0) of patients postbaseline in Slovakia.

The percentages of patients reporting new fractures and clinical/osteoporotic fractures were 6.0% and 5.0%, respectively in the Czech Republic and 1.3% and 1.0%, respectively in Slovakia. The adverse reactions reported in 2 patients each were musculoskeletal pain in the Czech Republic and alopecia, rash, and hypocalcaemia in Slovakia. All other adverse drug reactions were reported in 1 patient each. One patient in Slovakia had a serious adverse drug reaction of myocardial infarction. One patient sustained an event consistent with the definition of atypical femoral fracture. There were no fatal adverse drug reactions in any of the patients.

- **Discussion**

The reasons for prescribing Prolia in the Czech Republic and Slovakia were as per the approved local labels for most of the patients. Prolia was always administered by a health care professional in both the countries. The percentage of patients reporting new fractures was 6.0% in the Czech Republic and 1.3% in Slovakia. No new safety risks were identified as the reported adverse drug reactions were either consistent with the known safety profile of Prolia or reflected common diseases observed in elderly women.

- **Marketing Authorization Holder**

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- **Names and Affiliations of Principal Investigator**

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2. LIST OF ABBREVIATIONS

Abbreviation or Term	Definition/Explanation
BMD	bone mineral density
CI	confidence interval
DXA	dual-energy X-ray absorptiometry
MAH	Marketing Authorization Holder
MedDRA	Medical Dictionary for Regulatory Activities
PMO	postmenopausal osteoporosis
PT	preferred term
Q6M	once every 6 months
RANKL	RANK ligand
SAP	statistical analysis plan
SC	subcutaneously
SD	standard deviation
SOC	system organ class

3. INVESTIGATORS

National coordinating investigator details are as follows:

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A list of all collaborating institutions and investigators will be made available upon request.

4. OTHER RESPONSIBLE PARTIES

The Amgen and Marketing Authorization Holder (MAH) contact person for this study is Rachel Wagman.

5. MILESTONES

The milestones for this study are provided in Table 5-1.

Table 5-1. Study 20110132 Milestones

Milestone	Planned Date	Actual Date
Start of data collection	27 June 2012	26 June 2012
End of data collection	24 June 2015	15 May 2015
Registration on clinicaltrials.gov	17 July 2012	26 July 2012
Final report of study results	10 December 2015	04 January 2016

6. RATIONALE AND BACKGROUND

Osteoporosis is characterized by low bone mass and compromised bone strength predisposing individuals to an increased risk of fracture (NIH Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy, 2001). The morbidity and mortality associated with osteoporosis-related fractures result in significant clinical, human, and economic costs (Cree et al, 2003).

Clinical studies have demonstrated the efficacy of the bisphosphonate class of drugs in reducing the risk of osteoporosis-related fractures (Papapoulos, 2005). However, difficult dosing regimens, lack of patient satisfaction, and medication side effects may limit drug adherence (Sambrook and Cooper, 2006).

Prolia® (denosumab) is a fully human monoclonal antibody that inhibits the RANK ligand (an essential regulator of osteoclast differentiation) activation and survival. Administration of denosumab (Prolia) 60 mg subcutaneously (SC) once every 6 months (Q6M) has been shown to decrease bone remodelling with consequent increases in bone mineral density (BMD) and a decreased risk for new vertebral, nonvertebral, and hip fractures (Cummings et al. 2009). It has been approved in all 27 European Union (EU) member states plus Iceland, Liechtenstein, Norway, and Switzerland for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

After regulatory approval is granted for pharmaceutical products, many countries request post-launch population use characteristics to ensure that each drug is being used in the population for which it was intended. Moreover, for injectable drugs like Prolia, countries seek information on the manner of administration to ensure proper use.

By collecting information on patient characteristics including demographics, comorbid conditions, and use of concomitant medications, study findings would help describe patients receiving Prolia for osteoporosis in the Czech Republic and Slovakia. Data from this study provide information about management practice patterns in patients for whom, in the opinion of the prescribing physician, Prolia was deemed to be appropriate.

7. RESEARCH QUESTION AND OBJECTIVES

The objective of this observational study was to describe the characteristics of postmenopausal patients treated with Prolia® (denosumab) in routine clinical practice and to describe the clinical management of osteoporosis in these patients during the first 2 years of treatment in the Czech Republic and Slovakia.

The study was descriptive and no formal hypothesis testing was performed in this prospective, observational study.

8. AMENDMENTS AND UPDATES

The original study protocol, dated 28 February 2012, was superseded once. The key change made in the superseded version is summarized in Table 8-1.

The final amended protocol is provided in Annex 2.

Table 8-1. Protocol Amendment Summary Table

Amendment or Update Number	Date	Section of Study Protocol	Amendment or Update	Reason
Superseding Version	14 December 2012	Section 9, Safety Data Collection, Recording, and Reporting	Safety reporting requirements were updated	Superseded to make the safety reporting requirements consistent with the new European Union pharmacovigilance directive for noninterventional studies.

9. RESEARCH METHODS

9.1 Study Design

This was a multicentre, noninterventional, observational study in patients with postmenopausal osteoporosis (PMO) who received at least 1 injection of Prolia 60 mg SC Q6M in the Czech Republic and Slovakia. This observational study did not alter the routine clinical management of patients.

Patients were eligible to enrol within 8 weeks after receiving their first Prolia injection. The decision to treat the patients with Prolia was made independent of and before their enrolment in the study. However, Prolia prescription, the first Prolia injection, and/or administration of informed consent (as applicable by local country laws and regulations) could have occurred at the same visit. It was expected that patients would receive their scheduled Prolia injection every 6 months as part of their routine clinical care.

Approximately 300 patients each were enrolled in the Czech Republic and Slovakia. The estimated duration of enrolment was approximately 12 months. No study drug was administered as part of the study. Investigators offered participation in the study to all patients treated with Prolia during the enrolment period until the contracted number of patients was reached. Detailed data obtained as part of the routine clinical practice were collected at the initial visit, either directly or from medical records, to characterize the patient population. It was anticipated that patients would return to the clinic every 6 months to receive their Prolia prescription and/or injections. After the initial visit, information regarding Prolia prescription and administration, procedures pertaining to Prolia administration and osteoporosis, concomitant medication use, and nonserious and serious adverse drug reactions were obtained during routine clinical visits and recorded for up to approximately 2 years after entering the study.

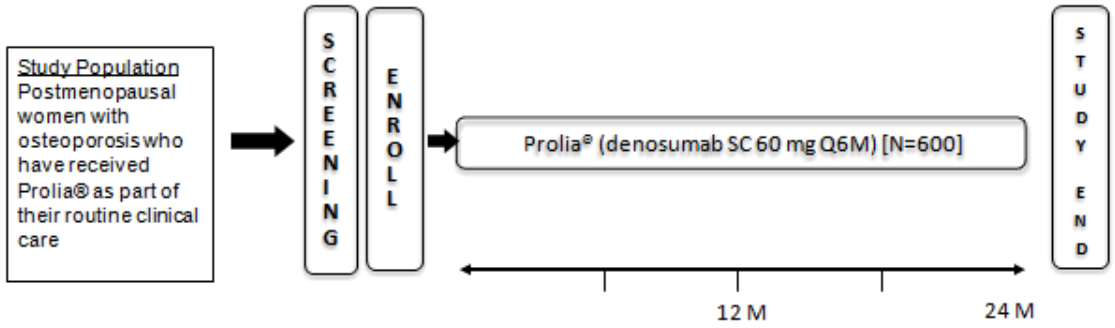
The study was to describe the profile of patients treated with Prolia and the clinical management of osteoporosis in these patients during the first 2 years of treatment. Patient and study centre characteristics were collected at baseline according to the following 4 dimensions, when available:

- sociodemographic-related
- condition-related (osteoporosis)
- patient-related
- physician-related (including geographic region, specialty)

In this observational study, adverse drug reactions and serious adverse drug reactions related to Prolia were collected and reported. Adverse drug reactions were coded using the Medical Dictionary for Regulatory Activities (MedDRA; version 14.1 or later). Given that the frequency of Prolia administration was every 6 months, a 2-year observation period was thought appropriate to ascertain treatment practices and document adverse drug reactions and serious adverse drug reactions.

The overall study design is provided in Figure 9-1.

Figure 9-1. Study Design and Treatment Schema



Source: Protocol Study Design and Treatment Schema (Annex 2 of this report)

9.2 Setting

The study was conducted at various study centres in the Czech Republic and Slovakia. The recruitment period was from 26 June 2012 to 15 May 2013. The last patient last visit was in May 2015 and the database lock was on 20 July 2015.

9.3 Subjects

Postmenopausal women with osteoporosis who received an injection of Prolia and met the inclusion/exclusion criteria were eligible to participate in the study.

The patients who were included in the study:

- had a clinical diagnosis of PMO
- were prescribed Prolia 60 mg Q6M for treatment of osteoporosis
- had received their first injection of Prolia within 8 weeks before enrolling in this study

- had an appropriate written informed consent (as required per local country regulations)

Patients were excluded from the study if they had:

- participated in previous denosumab clinical trials or were participating in any ongoing trial
- participated in other clinical or device trials in the last 6 months
- been contraindicated for treatment with Prolia according to the approved applicable local product label.
- any kind of disorder that, in the opinion of the investigator, compromised the ability of the patient to give written informed consent

9.4 Variables

The following outcomes characterized the clinical management of patients during the first 2 years of treatment with Prolia:

- occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia from the initial prescribing physician's office
- occurrence (yes/no) of patient receiving an individual prescription and injection of Prolia from the initial prescribing physician office by each individual injection
- occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia, whether or not the injections were given at the initial prescribing physician's office
- occurrence (yes/no) of patient with a referral by the prescribing physician to other health care providers for continuation or follow up of care by type of physician
- types of health care professionals administering an individual injection of Prolia inside or outside the initial prescribing office by individual injection
- number of Prolia injections received by each patient during the follow-up period
- occurrence (yes/no) of patient having radiologic bone assessments pretreatment with Prolia, and during the study
- occurrence (yes/no) of patient having osteoporosis-related laboratory examinations pretreatment with Prolia, and during the study

The following outcomes characterized the safety of patients during the first 2 years of treatment with Prolia:

- incidence (yes/no) of patients with adverse drug reactions to Prolia
- incidence (yes/no) of patients with serious adverse drug reactions to Prolia

A summary of the profile of patients treated with Prolia and the clinical management of these patients during the first 2 years of treatment included factors within the following 4 dimensions: sociodemographic-related, condition-related (osteoporosis), patient-related, and physician-related (including geographic region, specialty). Each

dimension is further elaborated in the statistical analysis plan (SAP) Section 6.6 (Annex 4 of this report).

9.5 Data Sources and Measurement

The study was to be conducted in approximately 30 representative (country specific) study centres (15 each in the Czech Republic and Slovakia). After feasibility assessment, the selected study centres represented those providing PMO care in each country and region, with regards to type (eg hospital, non-hospital) and location of study centre.

This study was designed to follow and observe patients who had recently (within 8 weeks) initiated treatment with Prolia in routine clinical practice. No study-specific treatment was provided and no additional clinical procedures or assessments were required as part of this observational study.

Patients were observed for a period of up to 2 years after their entry in the study unless they discontinued the study or were lost to follow up. Information regarding the clinical management of the patients receiving Prolia was collected whenever available, even after treatment discontinuation.

There were no procedures or changes to the routine clinical management of patients. It was anticipated that the patients were to return to the clinic every 6 months to receive their Prolia prescription and/or injections. Available clinical information obtained for routine clinical practice (including those already recorded on the patient's medical records; ie, baseline characteristics) were recorded, including Prolia administration, previous and current therapies, medical history (including fracture history), adverse drug reactions and serious adverse drug reactions, and comorbidities.

9.6 Bias

The study results were to reflect the patient characteristics and prescribing patterns of Prolia treatment for Czech Republic and Slovakia only.

Patients were eligible to enrol within 8 weeks after receiving their first Prolia injection. Moreover, patients were only asked to enrol into the study after they had agreed to receive Prolia. There were no mandated study procedures, so the study was as close to a patient's routine clinical setting as possible. However, the prospective observational nature of the study could have impacted the investigator and patient's subjective response to treatment.

It has been documented that patients' participation in a study may alter their behaviour as a result of knowing they are being observed (Hawthorne effect) (McCarney et al, 2007). This is considered to be unavoidable and the proposed type of study in routine clinical practice is considered the best option to achieve the proposed objectives with acceptable levels of precision.

The absence of a control group in the study prevents formal comparisons of the adherence to Prolia with other (standard of care) osteoporosis treatments. Descriptive summaries of outcomes from this study could be informally compared with estimates for similar outcomes reported in the literature for similar patient populations.

The study may have been carried out with nonrepresentative study centres and patients. Summary statistics of study centre characteristics and the patients enrolled in the study were provided to investigate the representativeness relative to the patient population for osteoporosis treatment although limited information was provided on patients who refused to participate in the study.

9.7 Study Size

This was an observational study for which the analysis was descriptive in nature. Country commitments require that patients and management of patients receiving Prolia be characterized and described, and safety (Prolia-related adverse and serious adverse drug reactions) be reported.

To characterize this Prolia population, a sample size of approximately 300 patients per country (Czech Republic and Slovakia) was planned. The sample size was proposed based on the chances of capturing any patient-related characteristics that had a prevalence of approximately 1% or more in the population. The chances of observing at least 1 event with a prevalence rate of 1% or more was ≥ 90% when the sample size was at least 250 patients. A sample size of approximately 300 patients was suggested based on the precision of 95% confidence interval (CI) provided around selected percentage point estimates. The sample size of approximately 300 patients per country provided a maximum half width (based on an estimate of prevalence rate of 50%) for the 95% CIs around the percentage point estimates of approximately 6%. Further details are provided in the SAP Section 3.3 (Annex 4 of this report).

9.8 Data Transformation

Programs were developed and maintained, and output was verified in accordance with the current risk-based quality control procedures. Tables, figures, and listings were

produced with validated standard macro programs where possible. The production environment for statistical analyses consisted of Amgen-supported versions of statistical analysis software, for example the SAS System and S-plus.

9.9 Statistical Methods

Details of the statistical analyses for this study are provided in the SAP in Annex 4.

9.9.1 Main Summary Measures

Frequency distributions were described for categorical variables. Continuous variables were summarized by the number of nonmissing values, mean, standard deviation, median, lower and upper quartiles, and minimum and maximum values.

All study outcomes and baseline characteristics were summarized overall and by country. For selected study outcomes related to the clinical management of these patients, point estimate and 95% CIs were provided by country as well.

Detailed statistical methods used in this study are provided in the SAP Section 10 (Annex 4 of this report).

9.9.2 Main Statistical Methods

This was an observational study for which the analysis was descriptive in nature and no formal hypothesis was tested.

All outcomes related to the clinical management of the patients, as specified in the SAP Section 4 (Annex 4 of this report), were summarized overall, by country, and by the baseline variables at 12 and 24 months. For each outcome, the point estimate and 95% CI (based on binomial distribution) were provided.

Dual-energy X-ray absorptiometry (DXA) BMD T-score was summarized in descriptive statistics by location and visit. Percent change from baseline in BMD T-score by location and visit were to be summarized when a patient provided a baseline and a post baseline measurement at the same location. However, percentage change from baseline in BMD (lumbar spine/femoral neck/total hip) was not tabulated since DXA machine type was not collected. Bone mineral density values were collected only when BMD was assessed by DXA during the study as per local clinical practice and or guidelines. The DXA BMD assessments were assigned to a study visit as detailed in the SAP Section 9.4 (Annex 4 of this report).

Safety data were summarized overall and by country. The MedDRA version 14.1 or later was to be used to code all adverse events to a system organ class (SOC) and a

preferred term (PT). All serious and non-serious clinical fractures were also coded using MedDRA.

Unless otherwise mentioned, data in the results section are presented by country in text for each outcome as n (x%, 95% CI), where n is the number of respondents, x is the percentage of respondents, and 95% CI is the associated 2-sided CI.

9.9.3 Missing Values

Missing data, except for adverse drug reaction start dates, were maintained as missing.

Partial start date for serious and nonserious adverse drug reactions was imputed as follows:

- Missing day was set to "01" unless an event started the same month and year as first dose date then set to first dose date.
- Missing day/month was set to "01 Jan" unless an event started the same year as first dose date then set to first dose date.

9.9.4 Sensitivity Analyses

Not applicable.

9.9.5 Amendments to the Statistical Analysis Plan

The following analyses were not as planned in the SAP amendment 1, dated 11 June 2015:

- Changes in BMD are usually reported as percent change, calculated from the absolute BMD measurements. As they differ by DXA machine type, they can only be calculated, when the the same machine types are being used for the individual measurement. As DXA machine type was not collected on the eCRF, this approach was not possible for this study.

  For Study 20110132, the SAP mentions that percent change from baseline in BMD T-score by location and visit were to be summarized when a patient provides a baseline and a postbaseline measurement at the same location. As percent change in BMD T-score could be either negative or positive due to baseline BMD T-scores being either negative or positive, and a positive percent change in BMD T score would not always mean improvement, this was not considered to be the most appropriate way to report the results. Therefore, change from baseline in BMD T-score was summarized instead as a more reliable measure of assessing improvement in this study.
- The SAP states that patient incidence of clinical fractures and serious clinical fractures were to be tabulated by SOC and PT. The final tables presented patient incidence for clinical fractures only, as serious clinical fractures are not clinically relevant. In addition, because multiple fracture locations are coded to the same PT, it was more informative to report fractures by location instead of by PT.

9.10 Quality Control

To ensure the quality of clinical data across all patients and study centres, a clinical data management review was performed on patient data received at Amgen. During this review, patient data were checked for consistency, omissions, and any apparent discrepancies. In addition, the data were reviewed for adherence to the protocol and Good Clinical Practice guidelines (as applicable by local law). To resolve any questions arising from the clinical data management review process, data queries and/or study centre notifications were created in the electronic data capture system database for study centre resolution and closed by an Amgen reviewer.

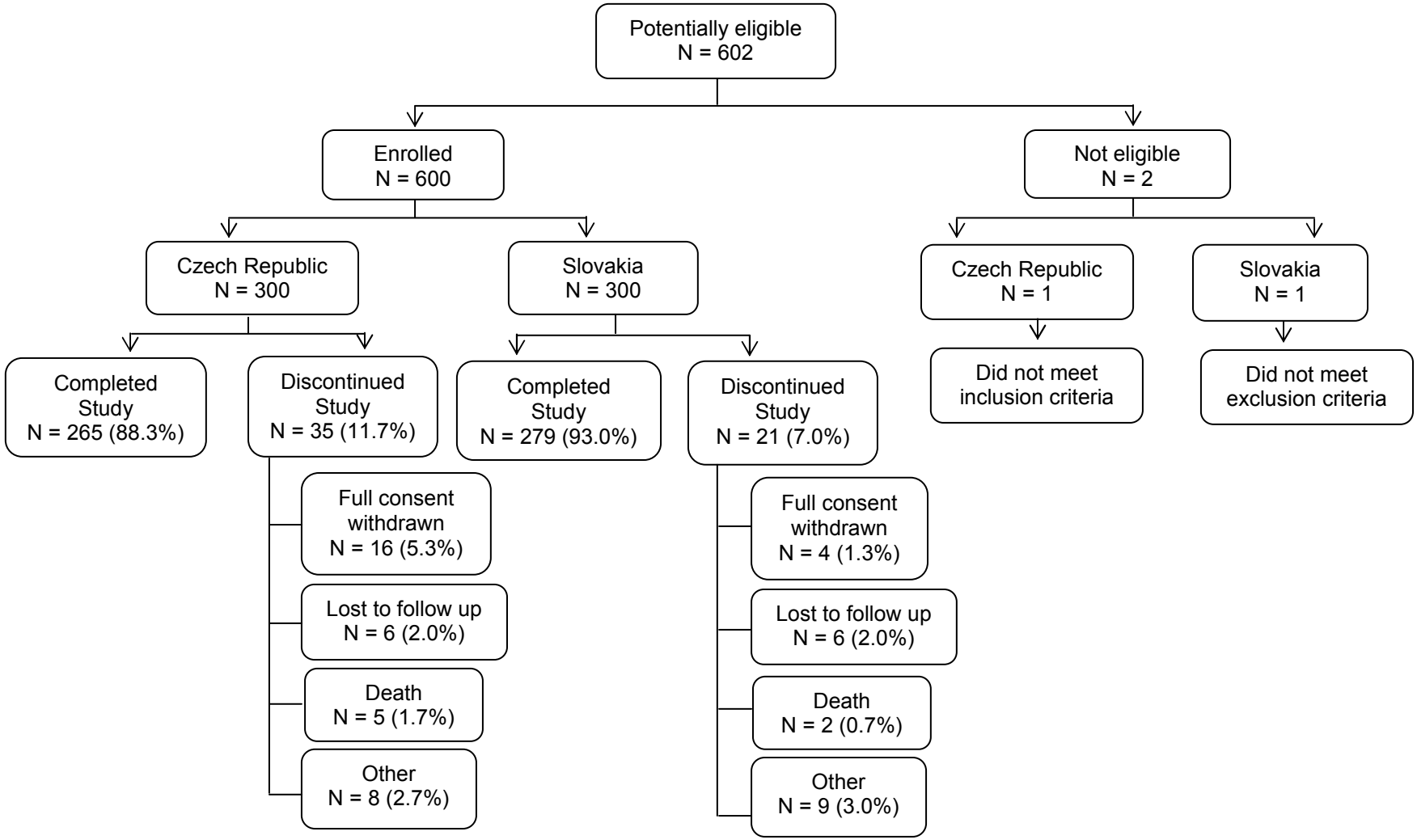
10. RESULTS

10.1 Participants

A total of 300 patients each enrolled in the study in the Czech Republic and Slovakia (Figure 10-1). In the Czech Republic, 35 patients (11.7%) discontinued the study; in Slovakia, 21 patients (7.0%) discontinued the study (Table 14-1.2.1).

All enrolled patients received at least 1 injection of Prolia and were included in the 24-month final analysis set. The reasons for discontinuation of Prolia in this study are provided in Table 10-1.

Figure 10-1. Patient Disposition and Reasons for Discontinuation



Source: Table 14-1.1.1 and Table 14-1.2.1

Table 10-1. Reasons for Discontinuation of Prolia Administration (All Enrolled Patients)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Patients who never received Prolia®	0 (0.0)	0 (0.0)	0 (0.0)
Patients who received Prolia®	300 (100.0)	300 (100.0)	600 (100.0)
Patients who completed Prolia®	257 (85.7)	266 (88.7)	523 (87.2)
Patients who discontinued Prolia®	43 (14.3)	34 (11.3)	77 (12.8)
Reasons for Prolia® discontinuation			
Other	7 (2.3)	19 (6.3)	26 (4.3)
Patient request	19 (6.3)	2 (0.7)	21 (3.5)
Lost to follow-up	5 (1.7)	5 (1.7)	10 (1.7)
Adverse event	2 (0.7)	5 (1.7)	7 (1.2)
Death	5 (1.7)	2 (0.7)	7 (1.2)
Noncompliance	2 (0.7)	1 (0.3)	3 (0.5)
Requirement for alternative PMO	3 (1.0)	0 (0.0)	3 (0.5)

PMO = postmenopausal osteoporosis
Percentages based on number of enrolled patients
Source: Table 14-1.2.2

10.2 Descriptive Data

All the enrolled patients were women (Table 14-2.1.1). A summary of baseline demographics and disease characteristics is provided in Table 10-2.

A detailed list of the prior osteoporosis medications by type, route, and frequency is provided in Table 14-2.7.1.

Table 10-2. Summary of Baseline Demographics and Disease Characteristics (Full Analysis Set)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Age (years)			
n	300	300	600
Mean	69.0	64.3	66.7
SD	8.7	8.6	9.0
Body mass index (kg/m^2)[a]			
n	296	268	564
Mean	25.39	26.78	26.05
SD	4.30	4.74	4.57
Age at menopause (years)			
n	300	300	600
Mean	48.3	48.3	48.3
SD	5.6	5.2	5.4
Median	50.0	50.0	50.0
Q1, Q3	46.0, 52.0	45.0, 52.0	45.0, 52.0
Min, Max	21, 60	29, 62	21, 62
Years since menopause			
n	300	300	600
Mean	20.7	15.9	18.3
SD	9.2	9.4	9.6
Median	21.0	15.0	17.0
Q1, Q3	13.5, 28.0	9.0, 22.0	11.0, 25.0
Min, Max	0, 44	0, 53	0, 53
Time since PMO diagnosis to enrolment (years)			
n	300	300	600
Mean	5.3	3.0	4.1
SD	5.2	4.1	4.8
Median	4.7	1.0	2.6
Q1, Q3	0.7, 8.2	0.1, 4.6	0.2, 6.8
Min, Max	0, 37	0, 20	0, 37
Cause of menopause - n (%)			
Natural onset	248 (82.7)	244 (81.3)	492 (82.0)
Clinically/surgically induced	51 (17.0)	53 (17.7)	104 (17.3)
Not available	1 (0.3)	3 (1.0)	4 (0.7)
Hospitalized for osteoporotic fracture - n (%)			
Yes	63 (21.0)	11 (3.7)	74 (12.3)
No	237 (79.0)	289 (96.3)	526 (87.7)
≥ 1 Fall in the last 12 months - n (%)			
Yes	61 (20.3)	24 (8.0)	85 (14.2)
No	239 (79.7)	276 (92.0)	515 (85.8)

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N = number of patients in the full analysis set
[a] Includes the closest height, weight, and BMI data up to 1 year before or at baseline Prolia injection. If there was no preinjection data the earliest postinjection data up to study day 91 was included.
[b] Protocol-specified comorbidities or conditions reported within 12 months before baseline.
Percentages based on number of patients in the full analysis set
Source: Table 14-2.1.1, Table 14-2.2.1, Table 14-2.3.1, Table 14-2.5.1, Table 14-2.6.1, and Table 14-2.8.1

Table 10-2. Summary of Baseline Demographics and Disease Characteristics (Full Analysis Set)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
≥ 1 Occurrence of immobility in the last 12 months - n (%)			
Yes	19 (6.3)	6 (2.0)	25 (4.2)
No	281 (93.7)	294 (98.0)	575 (95.8)
Secondary osteoporosis - n (%)			
Yes	45 (15.0)	23 (7.7)	68 (11.3)
No	255 (85.0)	277 (92.3)	532 (88.7)
Number of patients reporting a history of at least 1 comorbidity[b]	290 (96.7)	272 (90.7)	562 (93.7)
Modified-Wolfe comorbidity index			
n	300	300	600
Mean	1.9	1.4	1.6
SD	1.5	1.2	1.4
Was the patient ever exposed to prior PMO therapy?			
Yes	255 (85.0)	146 (48.7)	401 (66.8)
No	45 (15.0)	154 (51.3)	199 (33.2)
Did the patient receive any PMO therapy during the 12 months prior to enrollment?			
Yes	240 (80.0)	119 (39.7)	359 (59.8)
No	60 (20.0)	181 (60.3)	241 (40.2)
Did the patient receive any prior calcium and/or vitamin D supplement?			
Yes	151 (50.3)	19 (6.3)	170 (28.3)
No	149 (49.7)	281 (93.7)	430 (71.7)

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N = number of patients in the full analysis set
[a] Includes the closest height, weight and BMI data up to 1 year prior to or at baseline Prolia injection. If there is no pre-injection data the earliest post injection data up to study day 91 is included.
[b] Protocol specified comorbidities or conditions reported within 12 months before baseline.
Percentages based on number of patients in the full analysis set
Source: Table 14-2.1.1, Table 14-2.2.1, Table 14-2.3.1, Table 14-2.5.1, Table 14-2.6.1, and Table 14-2.8.1

Approximately 74% of patients in the Czech Republic and 33% of patients in Slovakia had a history of fracture (Table 10-3).

Table 10-3. Fracture History (Full Analysis Set)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Any historical fracture - n (%)	221 (73.7)	100 (33.3)	321 (53.5)
Osteoporotic[a]	203 (67.7)	90 (30.0)	293 (48.8)
Vertebral	93 (31.0)	21 (7.0)	114 (19.0)
Nonvertebral	153 (51.0)	74 (24.7)	227 (37.8)
Major nonvertebral[b]	119 (39.7)	62 (20.7)	181 (30.2)
Hip	18 (6.0)	5 (1.7)	23 (3.8)
More than one	97 (32.3)	21 (7.0)	118 (19.7)
Patients aged 50 years or older	296 (98.7)	294 (98.0)	590 (98.3)
Any historical fracture at 50 years or older	204 (68.9)	76 (25.9)	280 (47.5)
Osteoporotic[a]	186 (62.8)	67 (22.8)	253 (42.9)
Vertebral	86 (29.1)	14 (4.8)	100 (16.9)
Nonvertebral	136 (45.9)	55 (18.7)	191 (32.4)
Major nonvertebral[b]	103 (34.8)	44 (15.0)	147 (24.9)
Hip	16 (5.4)	4 (1.4)	20 (3.4)
More than one	85 (28.7)	12 (4.1)	97 (16.4)
Time since most recent fracture (years)			
n	221	92	313
Mean	5.5	6.7	5.8
SD	7.9	9.6	8.4
Median	2.0	3.0	2.0
Q1, Q3	0.0, 8.0	0.0, 10.0	0.0, 8.0
Min, Max	0, 57	0, 44	0, 57
Time since most recent fracture - n (%)			
< 12 Months	63 (21.0)	29 (9.7)	92 (15.3)
≥ 12 Months	158 (52.7)	63 (21.0)	221 (36.8)
Missing	0 (0.0)	8 (2.7)	8 (1.3)
Not applicable	79 (26.3)	200 (66.7)	279 (46.5)

N = number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
Table displays self-reported data captured on the historical fracture CRF page since adulthood.
Patients may have more than 1 fracture
[a] Any fracture recorded on the CRF not including skull, facial bones, fingers, and toes and not associated with known high trauma severity or pathological fractures.
[b] A subset of nonvertebral fractures including the following locations: pelvis, hip, upper leg (not hip), lower leg (not knee or ankle), ribs, shoulder, forearm, and wrist and not associated with known high trauma severity or pathological fractures.
Source: Table 14-2.9.1 and Table 14-2.9.2

A total of 160 patients (53.3%) were prescribed Prolia in the Czech Republic following their intolerance to other therapies for osteoporosis and 178 patients (59.3%) were prescribed Prolia in Slovakia, primarily because they had a low BMD T-score. Details on Prolia prescriptions are provided in Table 14-2.10.1.

Most of the patients (272 [90.7%] Czech Republic, 275 [91.7%] Slovakia) in the study had at least 1 baseline DXA assessment; of these, 122 patients (40.7%) in the Czech Republic and 140 patients (46.7%) in Slovakia had their assessment done up to 3 months before the first Prolia dose (Table 14-2.11.1). In the Czech Republic, 267 patients (89.0%) satisfied the reimbursement criteria for PMO patients (Table 14-2.15.1). Relevant data were not required to be collected in Slovakia since there were no such requirements for reimbursement in Slovakia.

In the Czech Republic, most of the physicians were either internists (46.7%) or rheumatologists (40.0%); in Slovakia, most of them were rheumatologists (47.1%). In both the countries, most of the physicians had ≥ 10 years of experience. The study centres in this study were mostly nonhospital type (66.7% Czech Republic, 58.8% Slovakia), nonacademic (93.3% Czech Republic, 58.8% Slovakia), and located in urban regions (93.3% Czech Republic, 100% Slovakia) (Table 14-2.13.1).

Patient-reported outcomes at baseline on living situation, education, employment, and osteoporosis medication usage are provided in Table 14-2.14.1.

10.3 Outcome Data

The full analysis set included all 600 patients (300 Czech Republic, 300 Slovakia) who enrolled in the study (Table 14-1.3.1). This set was used to analyse all the outcomes in this study.

10.4 Main Results

10.4.1 Occurrence (yes/no) of Patient Receiving all Prescriptions and Injections of Prolia From the Initial Prescribing Physician's Office

In the Czech Republic, 295 of the 300 patients (98.3%, [96.2, 99.5]) received all injections of Prolia from the initial study centre, irrespective of the total number of injections received on study. In Slovakia, 296 of the 300 patients (98.7%, [96.6, 99.6]) received all injections of Prolia from the initial study centre, irrespective of the total number of injections received on study (Table 14-4.1.1).

The characterisation of this outcome based on the 4 dimensions (sociodemographic-related, condition-related, patient-related, and physician-related) is provided in Table 14-4.1.2 to Table 14-4.1.5.

10.4.2 Occurrence (yes/no) of Patient Receiving an Individual Prescription and Injection of Prolia From the Initial Prescribing Physician's office by Each Individual Injection

Most of the patients received their individual Prolia injections from the initial prescribing study centre at baseline and the subsequent 4 postbaseline visits (Table 10-4).

Table 10-4. Summary of Individual Prolia Injections Received From the Initial Prescribing Study Centre (Full Analysis Set)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Yes	300/300	100.0 (98.8, 100.0)	298/300	99.3 (97.6, 99.9)	598/600	99.7 (98.8, 100.0)
No	0/300	- (-, -)	2/300	0.7 (0.1, 2.4)	2/600	0.3 (0.0, 1.2)
First post-baseline injection						
Yes	282/283	99.6 (98.0, 100.0)	291/293	99.3 (97.6, 99.9)	573/576	99.5 (98.5, 99.9)
No	1/283	0.4 (0.0, 2.0)	2/293	0.7 (0.1, 2.4)	3/576	0.5 (0.1, 1.5)
Second post-baseline injection						
Yes	275/276	99.6 (98.0, 100.0)	282/283	99.6 (98.0, 100.0)	557/559	99.6 (98.7, 100.0)
No	1/276	0.4 (0.0, 2.0)	1/283	0.4 (0.0, 2.0)	2/559	0.4 (0.0, 1.3)
Third post-baseline injection						
Yes	260/262	99.2 (97.3, 99.9)	274/276	99.3 (97.4, 99.9)	534/538	99.3 (98.1, 99.8)
No	2/262	0.8 (0.1, 2.7)	2/276	0.7 (0.1, 2.6)	4/538	0.7 (0.2, 1.9)
Fourth post-baseline injection						
Yes	245/246	99.6 (97.8, 100.0)	240/243	98.8 (96.4, 99.7)	485/489	99.2 (97.9, 99.8)
No	1/246	0.4 (0.0, 2.2)	3/243	1.2 (0.3, 3.6)	4/489	0.8 (0.2, 2.1)

CI = confidence interval; N = number of patients in the full analysis set; n = number of patients who received the corresponding injection from the initial prescribing study centre; N1 = number of patients who received the corresponding injection
Percentages based on N1
Source: Table 14-4.2.1

The characterisation of this outcome based on the 4 dimensions (sociodemographic-related, condition-related, patient-related, and physician-related) is provided in Table 14-4.2.2 to Table 14-4.2.5.

10.4.3 Occurrence (yes/no) of Patient Receiving all Prescriptions and Injections of Prolia, Whether or Not the Injections Were Given at the Initial Prescribing Physician's Office

In the Czech Republic, the percentage of patients receiving Prolia injections, whether or not they were given at the initial prescribing study centre, was approximately 94% at the first postbaseline injection and 82% at the fourth postbaseline injection. In Slovakia, the percentage of patients was approximately 98% at the first postbaseline injection and 81% at the fourth postbaseline injection (Table 10-5).

Table 10-5. Summary of Patients Receiving All Individual Prolia Injections Whether or Not at the Initial Prescribing Study Centre (Full Analysis Set)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N	% (95% CI)	n/N	% (95% CI)	n/N	% (95% CI)
First post-baseline injection	283/300	94.3 (91.1, 96.7)	293/300	97.7 (95.3, 99.1)	576/600	96.0 (94.1, 97.4)
Second post-baseline injections	276/300	92.0 (88.3, 94.8)	283/300	94.3 (91.1, 96.7)	559/600	93.2 (90.8, 95.1)
Third post-baseline injections	262/300	87.3 (83.0, 90.9)	276/300	92.0 (88.3, 94.8)	538/600	89.7 (86.9, 92.0)
Fourth post-baseline injections	246/300	82.0 (77.2, 86.2)	243/300	81.0 (76.1, 85.3)	489/600	81.5 (78.2, 84.5)

CI = confidence interval; N = number of patients in the full analysis set; n = number of patients who received the corresponding post-baseline injection(s)
Percentages based on number of patients in the full analysis set
Source: Table 14-4.3.1

The characterisation of this outcome based on the 4 dimensions (sociodemographic-related, condition-related, patient-related, and physician-related) is provided in Table 14-4.3.2 to Table 14-4.3.5.

10.4.4 Occurrence (yes/no) of Patient With a Referral by the Prescribing Physician to Other Health Care Providers for Continuation or Follow Up of Care by Type of Physician

A total of 35 patients in the Czech Republic and 21 patients in Slovakia had discontinued the study. Of these, none of the patients in the Czech Republic and 2 patients in

Slovakia were referred to other health care providers (rheumatologist) at the end of the study (Table 14-4.4.1).

10.4.5 Types of Health Care Professionals Administering an Individual Injection of Prolia Inside or Outside the Initial Prescribing Office by Individual Injection

Most of the injections (baseline and 4 postbaseline injections), in both Czech Republic and Slovakia, were administered by other health care professionals (ie a nurse) (Table 10-6).

Table 10-6. Summary of the Types of Health Care Professionals Administering Injections of Prolia by Visit (Full Analysis Set)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Prescribing Physician	54/300	18.0 (13.8, 22.8)	84/300	28.0 (23.0, 33.4)	138/600	23.0 (19.7, 26.6)
Physician other than prescribing Physician	19/300	6.3 (3.9, 9.7)	21/300	7.0 (4.4, 10.5)	40/600	6.7 (4.8, 9.0)
Other health care professional	227/300	75.7 (70.4, 80.4)	195/300	65.0 (59.3, 70.4)	422/600	70.3 (66.5, 74.0)
Nurse[a]	227/227	100.0 (98.4, 100.0)	195/195	100.0 (98.1, 100.0)	422/422	100.0 (99.1, 100.0)
1st post-baseline injection						
Prescribing Physician	70/283	24.7 (19.8, 30.2)	109/293	37.2 (31.7, 43.0)	179/576	31.1 (27.3, 35.0)
Physician other than prescribing Physician	8/283	2.8 (1.2, 5.5)	0/293	0.0 (0.0, 1.3)	8/576	1.4 (0.6, 2.7)
Other health care professional	205/283	72.4 (66.8, 77.6)	184/293	62.8 (57.0, 68.3)	389/576	67.5 (63.5, 71.3)
Nurse[a]	205/205	100.0 (98.2, 100.0)	184/184	100.0 (98.0, 100.0)	389/389	100.0 (99.1, 100.0)
2nd post-baseline injection						
Prescribing Physician	75/276	27.2 (22.0, 32.8)	104/283	36.7 (31.1, 42.7)	179/559	32.0 (28.2, 36.1)
Physician other than prescribing Physician	0/276	0.0 (0.0, 1.3)	0/283	0.0 (0.0, 1.3)	0/559	0.0 (0.0, 0.7)
Other health care professional	201/276	72.8 (67.2, 78.0)	179/283	63.3 (57.3, 68.9)	380/559	68.0 (63.9, 71.8)
Nurse[a]	201/201	100.0 (98.2, 100.0)	179/179	100.0 (98.0, 100.0)	380/380	100.0 (99.0, 100.0)

CI = confidence interval; N = number of patients in the full analysis set; n = number of patients in the sub-group; N1 = number of patients in the full analysis set within each sub-group at the corresponding visit
Percentages based on N1
[a] Derives from free text provided when chosen Other health care professional.
Source: Table 14-4.5.1

Table 10-6. Summary of the Types of Health Care Professionals Administering Injections of Prolia by Visit (Full Analysis Set)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection						
Prescribing Physician	69/262	26.3 (21.1, 32.1)	113/276	40.9 (35.1, 47.0)	182/538	33.8 (29.8, 38.0)
Physician other than prescribing Physician	4/262	1.5 (0.4, 3.9)	1/276	0.4 (0.0, 2.0)	5/538	0.9 (0.3, 2.2)
Other health care professional	189/262	72.1 (66.3, 77.5)	162/276	58.7 (52.6, 64.6)	351/538	65.2 (61.0, 69.3)
Nurse[a]	189/189	100.0 (98.1, 100.0)	162/162	100.0 (97.7, 100.0)	351/351	100.0 (99.0, 100.0)
4th post-baseline injection						
Prescribing Physician	76/246	30.9 (25.2, 37.1)	93/243	38.3 (32.1, 44.7)	169/489	34.6 (30.3, 39.0)
Physician other than prescribing Physician	0/246	0.0 (0.0, 1.5)	6/243	2.5 (0.9, 5.3)	6/489	1.2 (0.5, 2.7)
Other health care professional	170/246	69.1 (62.9, 74.8)	144/243	59.3 (52.8, 65.5)	314/489	64.2 (59.8, 68.5)
Nurse[a]	170/170	100.0 (97.9, 100.0)	144/144	100.0 (97.5, 100.0)	314/314	100.0 (98.8, 100.0)

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CI = confidence interval; N = number of patients in the full analysis set; n = number of patients in the sub-group; N1 = number of patients in the full analysis set within each sub-group at the corresponding visit
Percentages based on N1
[a] Derives from free text provided when chosen Other health care professional.
Source: Table 14-4.5.1

10.4.6 Number of Prolia Injections Received by Each Patient During the Follow-up Period

Most of the patients in the Czech Republic (82.0%) and Slovakia (81.0%) received all 4 postbaseline injections (Table 10-7).

Table 10-7. Number of Postbaseline Prolia Injections Received (Full Analysis Set)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of post-baseline Prolia injections received			
0	17 (5.7)	7 (2.3)	24 (4.0)
1	7 (2.3)	10 (3.3)	17 (2.8)
2	14 (4.7)	7 (2.3)	21 (3.5)
3	16 (5.3)	33 (11.0)	49 (8.2)
4	246 (82.0)	243 (81.0)	489 (81.5)

N = number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
Source: Table 14-4.6.1

10.4.7 Occurrence (yes/no) of Patient Having Radiologic Bone Assessments Pretreatment With Prolia, and During the Study

In the Czech Republic, a total of 297 patients (99.0%, [97.1, 99.8]) prebaseline and 253 patients (84.3%, [79.7, 88.3]) postbaseline (during the study) had a DXA assessment performed. In Slovakia, 299 patients (99.7%, [98.2, 100.0]) prebaseline and 216 patients (72.0%, [66.6, 77.0]) postbaseline had a DXA assessment performed (Table 14-4.7.1).

The characterisation of this outcome based on the 4 dimensions (sociodemographic-related, condition-related, patient-related, and physician-related) are provided in Table 14-4.7.2 to Table 14-4.7.5.

Details on DXA BMD T-score and change from baseline at month 24 by location and visit are provided in Table 10-8. The terms “improving”, “unchanged”, and “worsening” are defined by values of change from baseline in T-score: 0 indicated unchanged, > 0 indicated improving, and < 0 indicated worsening.

Table 10-8. DXA BMD T-score and Change From Baseline at Month 24 by Location and Visit (Full Analysis Set)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Lumbar spine BMD T-score			
n	147	160	307
Mean	-2.19	-1.91	-2.04
SD	1.00	0.97	0.99
Median	-2.30	-2.10	-2.20
Q1, Q3	-2.80, -1.80	-2.50, -1.45	-2.60, -1.70
Min, Max	-4.4, 1.4	-4.0, 2.3	-4.4, 2.3
Change in lumbar spine BMD T-score			
n	145	155	300
Mean	0.58	0.63	0.61
SD	0.47	0.53	0.50
Median	0.60	0.60	0.60
Q1, Q3	0.30, 0.80	0.40, 0.90	0.30, 0.80
Min, Max	-0.8, 2.5	-1.9, 2.6	-1.9, 2.6
Improving - n (%)	133 (44.3)	144 (48.0)	277 (46.2)
Unchanged - n (%)	4 (1.3)	2 (0.7)	6 (1.0)
Worsening - n (%)	8 (2.7)	9 (3.0)	17 (2.8)
Total Hip BMD T-score			
n	146	151	297
Mean	-1.77	-1.07	-1.41
SD	0.90	0.85	0.94
Median	-1.90	-1.10	-1.40
Q1, Q3	-2.40, -1.20	-1.70, -0.40	-2.10, -0.80
Min, Max	-4.2, 0.7	-3.5, 1.0	-4.2, 1.0
Change in total hip BMD T-score			
n	145	139	284
Mean	0.21	0.21	0.21
SD	0.25	0.45	0.36
Median	0.20	0.20	0.20
Q1, Q3	0.10, 0.30	0.10, 0.40	0.10, 0.40
Min, Max	-0.6, 1.4	-2.4, 1.8	-2.4, 1.8
Improving - n (%)	112 (37.3)	111 (37.0)	223 (37.2)
Unchanged - n (%)	18 (6.0)	11 (3.7)	29 (4.8)
Worsening - n (%)	15 (5.0)	17 (5.7)	32 (5.3)

N = number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
Source: Table 14-4.9.1, Table 14-4.9.2

Table 10-8. DXA BMD T-score and Change From Baseline at Month 24 by Location and Visit (Full Analysis Set)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Femoral neck BMD T-score			
n	146	160	306
Mean	-1.96	-1.67	-1.81
SD	0.77	0.80	0.80
Median	-2.10	-1.70	-1.90
Q1, Q3	-2.50, -1.50	-2.20, -1.15	-2.40, -1.30
Min, Max	-4.4, 0.4	-3.9, 0.7	-4.4, 0.7
Change in femoral neck BMD T-score			
n	145	155	300
Mean	0.20	0.24	0.22
SD	0.36	0.36	0.36
Median	0.20	0.20	0.20
Q1, Q3	0.00, 0.40	0.00, 0.40	0.00, 0.40
Min, Max	-0.9, 1.7	-0.5, 1.7	-0.9, 1.7
Improving - n (%)	101 (33.7)	104 (34.7)	205 (34.2)
Unchanged - n (%)	16 (5.3)	21 (7.0)	37 (6.2)
Worsening - n (%)	28 (9.3)	30 (10.0)	58 (9.7)

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N = number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
Source: Table 14-4.9.1, Table 14-4.9.2

10.4.8 Occurrence (yes/no) of Patient Having Osteoporosis-related Laboratory Examinations Pretreatment With Prolia, and During the Study

The percentage of patients with postbaseline osteoporosis-related laboratory examinations ranged from 52% to 66% in the Czech Republic and 70% to 85% in Slovakia (Table 10-9).

Table 10-9. Osteoporosis-related Laboratory Examinations (Full Analysis Set)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection	230/300	76.7 (71.5, 81.3)	260/300	86.7 (82.3, 90.3)	490/600	81.7 (78.3, 84.7)
First post-baseline injection	148/285	51.9 (46.0, 57.9)	207/294	70.4 (64.8, 75.6)	355/579	61.3 (57.2, 65.3)
Second post-baseline injection	162/280	57.9 (51.8, 63.7)	224/286	78.3 (73.1, 83.0)	386/566	68.2 (64.2, 72.0)
Third post-baseline injection	163/270	60.4 (54.3, 66.2)	226/280	80.7 (75.6, 85.2)	389/550	70.7 (66.7, 74.5)
Fourth post-baseline injection	174/262	66.4 (60.3, 72.1)	223/263	84.8 (79.9, 88.9)	397/525	75.6 (71.7, 79.2)

CI = confidence interval; N = number of patients in the full analysis set; n = number of patients who had osteoporosis-related laboratory examination; N1 = number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia injection when they attended corresponding visit.
Source: Table 14-4.8.1

The characterisation of this outcome based on the 4 dimensions (sociodemographic-related, condition-related, patient-related, and physician-related) is provided in Table 14-4.8.2 to Table 14-4.8.5.

10.5 Other Analyses

Not Applicable.

10.6 Adverse Reactions

Sixteen of the 600 enrolled patients (2.7%) had adverse drug reactions (4 [1.3%] Czech Republic, 12 [4.0%] Slovakia) (Table 14-6.1.1). Of these, only 1 patient (0.3%) in Slovakia had a serious adverse drug reaction (myocardial infarction) (dataset aae.sas7bdat, 22 July 2015). The serious adverse event of myocardial infarction occurred in a 62-year-old woman approximately 7 months following the first dose of Prolia with a last dose latency of 2 weeks from the second dose. No medical history or concomitant medications were provided for this patient. Following treatment with acetylsalicylic acid, the myocardial infarction resolved within 1 week. The subject remained on Prolia. With no medical history nor concomitant medications provided, the

case had insufficient information for evaluation although the patient's age was a confounding factor.

The adverse drug reactions reported in patients in the Czech Republic were musculoskeletal pain (2 patients), headache (1 patient), and skin infection (1 patient). The adverse drug reactions reported in patients in Slovakia were alopecia (2 patients), rash (2 patients), hypocalcaemia (2 patients), back pain (1 patient), myocardial infarction (1 patient), supraventricular tachycardia (1 patient), upper abdominal pain (1 patient), gingival swelling (1 patient), burning sensation (1 patient), pyrexia (1 patient), dysuria (1 patient), and dyspnoea (1 patient) (Table 14-6.3.1).

None of the adverse drug reactions were fatal. The adverse drug reactions led to the discontinuation of Prolia in 7 patients (1.2%) (Table 10-10).

Table 10-10. Adverse Drug Reaction Leading to Discontinuation of Prolia by System Organ Class and Preferred Term (Full Analysis Set)

System Organ Class Preferred Term	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting treatment-emergent adverse drug reactions	2 (0.7)	5 (1.7)	7 (1.2)
Skin and Subcutaneous Tissue Disorders	0 (0.0)	3 (1.0)	3 (0.5)
Alopecia	0 (0.0)	2 (0.7)	2 (0.3)
Rash	0 (0.0)	1 (0.3)	1 (0.2)
Cardiac Disorders	0 (0.0)	1 (0.3)	1 (0.2)
Supraventricular tachycardia	0 (0.0)	1 (0.3)	1 (0.2)
Gastrointestinal Disorders	0 (0.0)	1 (0.3)	1 (0.2)
Gingival swelling	0 (0.0)	1 (0.3)	1 (0.2)
Infections and Infestations	1 (0.3)	0 (0.0)	1 (0.2)
Skin infection	1 (0.3)	0 (0.0)	1 (0.2)
Musculoskeletal and Connective Tissue Disorders	1 (0.3)	0 (0.0)	1 (0.2)
Musculoskeletal pain	1 (0.3)	0 (0.0)	1 (0.2)

N = number of patients who received ≥ 1 dose of Prolia; n = number of patients reporting ≥ 1 event
Source: Table 14-6.4.1

Eighteen patients (6.0%) in the Czech Republic and 4 patients (1.3%) in Slovakia reported new fractures (Table 10-11).

Table 10-11. Summary of Patients Incidence of New Fractures (Full Analysis Set)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting new fractures	18 (6.0)	4 (1.3)	22 (3.7)
Clinical fractures[a]	15 (5.0)	3 (1.0)	18 (3.0)

N = number of patients who received ≥ 1 dose of Prolia; n = number of patients with ≥ 1 event
Includes only treatment-emergent fractures
Patients may have more than one type of fracture.
[a] Clinical or osteoporotic fractures are defined as all fractures excluding skull, facial bones, mandible, metacarpus, finger phalanges, toe phalanges and cervical vertebrae and not associated with known high trauma severity (fall from higher than the height of stool, chair, first rung on a ladder or equivalent (> 20 inches) or severe trauma other than a fall) or pathological fractures.
Source: Table 14-6.6.1

In the Czech Republic, there was 1 positively adjudicated case of atypical femur fracture. The 79-year-old patient slipped on the floor and fell from a standing point. An X-ray on the same day confirmed the fracture. The patient had femur midshaft fracture approximately 2 years after receiving the first dose of Prolia. The patient received bisphosphonates in the past before starting therapy with Prolia. The investigator reported that the patient's concomitant medications included a combination of calcium carbonate and colecalciferol plus additional colecalciferol, and solifenacin succinate. An X-ray done within 6 months of the fracture confirmed that it had healed and the patient was able to walk without assistance. The investigator reported that there was no reasonable possibility that the event of femur midshaft fracture was related to Prolia. No concomitant medications were considered as cosuspect.

Details on clinical fractures by location of fracture are provided in Table 10-12.

Table 10-12. Clinical Fractures by Location (Full Analysis Set)

Location	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting clinical fractures[a]	15 (5.0)	3 (1.0)	18 (3.0)
Forearm	3 (1.0)	0 (0.0)	3 (0.5)
Radius fracture	3 (1.0)	0 (0.0)	3 (0.5)
Hip	3 (1.0)	0 (0.0)	3 (0.5)
Femoral neck fracture	2 (0.7)	0 (0.0)	2 (0.3)
Femur fracture	1 (0.3)	0 (0.0)	1 (0.2)
Thorax	3 (1.0)	0 (0.0)	3 (0.5)
Clavicle fracture	1 (0.3)	0 (0.0)	1 (0.2)
Rib fracture	1 (0.3)	0 (0.0)	1 (0.2)
Sternal fracture	1 (0.3)	0 (0.0)	1 (0.2)
Foot	1 (0.3)	1 (0.3)	2 (0.3)
Foot fracture	1 (0.3)	1 (0.3)	2 (0.3)
Shoulder	1 (0.3)	1 (0.3)	2 (0.3)
Humerus fracture	1 (0.3)	1 (0.3)	2 (0.3)
Spine	2 (0.7)	0 (0.0)	2 (0.3)
Thoracic vertebral fracture	2 (0.7)	0 (0.0)	2 (0.3)
Thigh	2 (0.7)	0 (0.0)	2 (0.3)
Femur fracture	1 (0.3)	0 (0.0)	1 (0.2)
Patella fracture	1 (0.3)	0 (0.0)	1 (0.2)
Lower Leg	1 (0.3)	0 (0.0)	1 (0.2)
Fibula fracture	1 (0.3)	0 (0.0)	1 (0.2)
Pelvis	0 (0.0)	1 (0.3)	1 (0.2)
Ilium fracture	0 (0.0)	1 (0.3)	1 (0.2)

N = number of patients who received ≥ 1 dose of Prolia, n = number of patients with ≥ 1 event
Includes only new fractures
[a] Clinical fractures or osteoporotic fractures are defined as all fractures excluding skull, facial bones, mandible, metacarpus, finger phalanges, toe phalanges and cervical vertebrae and not associated with known high trauma severity (fall from higher than the height of stool, chair, first rung on a ladder or equivalent (> 20 inches) or severe trauma other than a fall) or pathological fractures.
Source: Table 14-6.6.3

11. DISCUSSION

11.1 Key Results

A total of 600 patients (300 each from the Czech Republic and Slovakia) were enrolled in the study. In the Czech Republic, considerable proportion of patients were hospitalized for osteoporotic fracture (21.0%) and had more than 1 fall in the last 12 months (20.3%) from baseline. In Slovakia, 3.7% of patients were hospitalized for osteoporotic fracture and 8.0% of patients had more than 1 fall in the last 12 months from baseline. Most of the patients also did not have any secondary osteoporosis at baseline. Of note, in the Czech Republic, there was a higher rate of exposure to prior PMO therapy (85.0%) and also a higher percentage of patients received PMO therapy in the last 12 months before enrolment (80.0%). Approximately 74.0% of patients in the Czech Republic had a history of fracture. In Slovakia, almost 50% of patients were exposed to prior PMO therapy and 39.7% received PMO therapy in the last 12 months before enrolment. Approximately 33.0% of patients in Slovakia had a history of fracture. The most common reason for prescribing Prolia to PMO patients in the Czech Republic was intolerance to other osteoporosis therapy (53.3% patients) and in Slovakia was low BMD T-score (59.3% patients).

In order to satisfy the requirement to be eligible for Prolia administration in the Czech Republic, a patient was required to have a baseline BMD T-score $\leq$ -2.5 at either lumbar spine, total hip, or femoral neck and also have at least 1 of either historical osteoporotic fractures, intolerance to other osteoporosis therapy, or failure to respond to other osteoporosis therapy. A total of 89.0% of patients in the Czech Republic had satisfied the reimbursement criteria. Relevant data were not required to be collected in Slovakia since there were no such requirements for reimbursement in Slovakia.

The main characteristics of clinical management were as follows:

- In both the countries, most patients (> 80%) received all 4 postbaseline injections, whether or not they were at the initial prescribing study centre.
- In the Czech Republic and Slovakia, most of the patients (> 98%) received all their Prolia injections from the initial prescribing study centre, irrespective of the total number of injections received on study.
- Of the 35 patients who discontinued the study in the Czech Republic, none were referred to other health care providers at the end of the study. Of the 21 patients who discontinued the study in Slovakia, 2 patients were referred to other health care providers (ie rheumatologist).
- In the Czech Republic and Slovakia, a nurse administered Prolia injections to most of the patients.

- DXA assessment was done for 99.0% patients prebaseline and 84.3% patients postbaseline (at 6, 12, 18, and 24 months) in the Czech Republic; 99.7% patients had a prebaseline and 72.0% patients had a postbaseline (at 6, 12, 18, and 24 months) DXA assessment in Slovakia.
- At 24 months, 133 patients (44.3%) in the Czech Republic and 144 patients (48.0%) in Slovakia had an improved lumbar spine BMD T-score from baseline. A total of 112 patients (37.3%) in the Czech Republic and 111 patients (37.0%) in Slovakia had an improved total hip BMD T-score from baseline. A total of 101 patients (33.7%) in the Czech Republic and 104 patients (34.7%) in Slovakia had an improved femoral neck BMD T-score from baseline.

The percentages of patients reporting new fractures and clinical/osteoporotic fractures were 6.0% and 5.0%, respectively in the Czech Republic and 1.3% and 1.0%, respectively in Slovakia.

The reported adverse drug reactions were either consistent with the known safety profile of Prolia or reflected common diseases observed in elderly women. One patient sustained an event consistent with the definition of atypical femoral fracture.

11.2 Limitations

There were no mandated study procedures in this study and therefore it was as close to a patient's natural course of clinical care as possible. The prospective observational nature of the study may have impacted the investigator and patient's subjective response to treatment. Further details are provided in Section 9.6.

A base population (national list of centres), from which the participating centres could be sampled from, was not available at the study design stage. The study relied on the country operation team's knowledge and a list of potential study centres, taking into account the practicality. It was ensured that the selected centres represented all types of centres treating PMO patients as well as the type of health care provider taking care of PMO patients in each country. However, distributionwise, this may not fully represent PMO patients treated with Prolia in each of these countries. But the probability may be quite low, particularly with respect to the distribution of patients and their characteristics.

11.3 Interpretation

In both Czech Republic and Slovakia, reasons for prescribing Prolia to most of the PMO patients were: history of osteoporotic fracture, multiple risk factors for fracture, failure to respond to other available osteoporosis therapy, intolerance to other osteoporosis therapy, and/or low BMD T-score. These reasons are as per the approved indication for Prolia in postmenopausal women with osteoporosis at high risk of fracture. A very low percentage of patients were prescribed Prolia for other reasons. In this study, Prolia

injections were always administered by a health care professional in both Czech Republic and Slovakia; most of the times the healthcare professional was a nurse.

Most of the patients received all 4 postbaseline injections, whether or not at the initial prescribing study centre and most patients showed a response as reflected by the BMD T-score.

In the Czech Republic, none of the patients who discontinued the study were referred by the prescribing physician to other healthcare providers for continuation or follow-up care at the end of study; in Slovakia, 2 of the patients who discontinued the study were referred to a rheumatologist at the end of study.

The percentage of patients reporting new fractures was generally low in the Czech Republic and Slovakia. No new safety risks were identified as the reported adverse drug reactions were either consistent with the known safety profile of Prolia or reflected common diseases observed in elderly women.

11.4 Generalizability

Despite the absence of a base population (national list of centres/patients) from which participating centres/patients could be sampled from at the design stage, we believe results from this study are generalizable to PMO patients treated with Prolia in each of these countries, at least at the time of execution of the study. We leveraged our country operation team's knowledge and list of potential study centres, taking into account the practicality of the study. It was ensured that the selected centres represented all types of centres treating PMO patients as well as the type of health care provider treating PMO patients in each country. So, while it was still possible that, distributionwise, this may not fully represent PMO patients treated with Prolia in each of these countries, we believe that probability is quite small, particularly with respect to the distribution of patients and their characteristics and the clinical management.

12. OTHER INFORMATION

Not Applicable.

13. CONCLUSIONS

The main conclusions from this study are:

- The reasons for prescribing Prolia in the Czech Republic and Slovakia were as per the approved local labels for most of the patients.
- Prolia was always administered by a health care professional in both the countries.
- The percentage of patients reporting new fractures was 6.0% in the Czech Republic and 1.3% in Slovakia.
- No new safety risks were identified as the reported adverse drug reactions were either consistent with the known safety profile of Prolia or reflected common diseases observed in elderly women.

14. REFERENCES

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15. SUMMARY TABLES, FIGURES, AND LISTINGS

Table 14-1.1.1. Patients Not Meeting Eligibility Criteria (All Enrolled Patients) (24-month Final Analysis)

	Czech Republic n (%)	Slovakia n (%)	Overall n (%)
Number of enrolled patients	300	300	600
Number of patients not meeting eligibility criteria	1 (0.3)	1 (0.3)	2 (0.3)
Patients not meeting the following inclusion criteria	1 (0.3)	0 (0.0)	1 (0.2)
Have received their first injection of Prolia within 8 weeks prior to enrolling in this study	1 (0.3)	0 (0.0)	1 (0.2)
Patients meeting the following exclusion criteria	0 (0.0)	1 (0.3)	1 (0.2)
Participating in ongoing or have participated in previous denosumab clinical trials	0 (0.0)	1 (0.3)	1 (0.2)

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Percentages based on number of enrolled patients

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-disp-failcrit.sas
Output: t14-01-001-001-base-disp-failcrit-p.rtf (Date Generated: 14AUG2015: 0:01:22) Source Data: adam.aie, adam.aslinfo

Table 14-1.2.1. Patient Disposition and Reasons for Study Discontinuation (All Enrolled Patients) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Patients who completed study	265 (88.3)	279 (93.0)	544 (90.7)
Patients who discontinued study	35 (11.7)	21 (7.0)	56 (9.3)
Full consent/agreement withdrawn	16 (5.3)	4 (1.3)	20 (3.3)
Other	8 (2.7)	9 (3.0)	17 (2.8)
Lost to follow-up	6 (2.0)	6 (2.0)	12 (2.0)
Death	5 (1.7)	2 (0.7)	7 (1.2)
Patients who discontinued study	35 (11.7)	21 (7.0)	56 (9.3)
Patients who discontinued Prolia®	35 (11.7)	19 (6.3)	54 (9.0)
Patients who remained on Prolia®	0 (0.0)	2 (0.7)	2 (0.3)

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Percentages based on number of enrolled patients

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-accnt-disp-study.sas
Output: t14-01-002-001-accnt-disp-study-l.rtf (Date Generated: 13AUG15:23:57:27) Source Data: adam.aslinfo

Table 14-1.2.2. Reasons for Discontinuation of Prolia® Administration (All Enrolled Patients) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Patients who never received Prolia®	0 (0.0)	0 (0.0)	0 (0.0)
Patients who received Prolia®	300 (100.0)	300 (100.0)	600 (100.0)
Patients who completed Prolia®	257 (85.7)	266 (88.7)	523 (87.2)
Patients who discontinued Prolia®	43 (14.3)	34 (11.3)	77 (12.8)
Reasons for Prolia® discontinuation			
Other	7 (2.3)	19 (6.3)	26 (4.3)
Patient request	19 (6.3)	2 (0.7)	21 (3.5)
Lost to follow-up	5 (1.7)	5 (1.7)	10 (1.7)
Adverse event	2 (0.7)	5 (1.7)	7 (1.2)
Death	5 (1.7)	2 (0.7)	7 (1.2)
Noncompliance	2 (0.7)	1 (0.3)	3 (0.5)
Requirement for alternative PMO	3 (1.0)	0 (0.0)	3 (0.5)

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Percentages based on number of enrolled patients

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-accnt-disp-ip.sas
Output: t14-01-002-002-accnt-disp-ip-l.rtf (Date Generated: 13AUG15:23:57:10) Source Data: adam.aslinfo

Table 14-1.3.1. Analysis Sets (All Enrolled patients) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Full analysis set[a]	300 (100.0)	300 (100.0)	600 (100.0)

N = Number of patients enrolled
Percentages based on number of patients enrolled
[a] Full analysis set is defined as all enrolled patients who provided informed consent and received at least one injection.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-accnt-disp-analsets.sas
Output: t14-01-003-001-accnt-disp-analsets-p.rtf (Date Generated: 13AUG15:23:56:48) Source Data: adam.aslinfo

Table 14-2.1.1. Baseline Demographics (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Sex - n (%)			
Female	300 (100.0)	300 (100.0)	600 (100.0)
Age (years)			
n	300	300	600
Mean	69.0	64.3	66.7
SD	8.7	8.6	9.0
Median	69.0	63.0	66.0
Q1, Q3	63.0, 76.0	58.0, 70.0	60.0, 73.0
Min, Max	35, 87	33, 88	33, 88
Age group - n (%)			
< 65 years	90 (30.0)	164 (54.7)	254 (42.3)
≥ 65 - < 75 years	121 (40.3)	98 (32.7)	219 (36.5)
≥ 75 years	89 (29.7)	38 (12.7)	127 (21.2)

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N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-demog.sas
Output: t14-02-001-001-base-demog-p.rtf (Date Generated: 14AUG15:00:00:32) Source Data: adam.aslinfo

Table 14-2.2.1. Baseline Medical History (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Number of prescription medications taken at baseline			
n	300	300	600
Mean	4.0	1.3	2.7
SD	2.9	1.7	2.7
Median	3.0	1.0	2.0
Q1, Q3	2.0, 6.0	0.0, 2.0	1.0, 4.0
Min, Max	0, 15	0, 13	0, 15
Number of comorbidities			
n	300	300	600
Mean	4.0	3.2	3.6
SD	2.3	2.1	2.2
Median	4.0	3.0	3.0
Q1, Q3	2.0, 5.0	2.0, 4.0	2.0, 5.0
Min, Max	0, 12	0, 10	0, 12
Modified-Wolfe comorbidity index			
n	300	300	600
Mean	1.9	1.4	1.6
SD	1.5	1.2	1.4
Median	2.0	1.0	1.0
Q1, Q3	1.0, 3.0	0.0, 2.0	1.0, 2.0
Min, Max	0, 7	0, 6	0, 7

N = Number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-medhis.sas
Output: t14-02-002-001-base-medhis-p.rtf (Date Generated: 14AUG15:00:03:29) Source Data: adam.aslbase

Table 14-2.3.1. Summary of Baseline Disease Characteristics
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Age at menopause (years)			
n	300	300	600
Mean	48.3	48.3	48.3
SD	5.6	5.2	5.4
Median	50.0	50.0	50.0
Q1, Q3	46.0, 52.0	45.0, 52.0	45.0, 52.0
Min, Max	21, 60	29, 62	21, 62
Years since menopause			
n	300	300	600
Mean	20.7	15.9	18.3
SD	9.2	9.4	9.6
Median	21.0	15.0	17.0
Q1, Q3	13.5, 28.0	9.0, 22.0	11.0, 25.0
Min, Max	0, 44	0, 53	0, 53
Time since PMO diagnosis to enrollment (years)			
n	300	300	600
Mean	5.3	3.0	4.1
SD	5.2	4.1	4.8
Median	4.7	1.0	2.6
Q1, Q3	0.7, 8.2	0.1, 4.6	0.2, 6.8
Min, Max	0, 37	0, 20	0, 37
Cause of menopause - n (%)			
Natural onset	248 (82.7)	244 (81.3)	492 (82.0)
Clinically/surgically induced	51 (17.0)	53 (17.7)	104 (17.3)
Not available	1 (0.3)	3 (1.0)	4 (0.7)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-disease.sas Output: t14-02-003-001-base-disease-p.rtf (Date Generated: 14AUG15:00:01:10) Source Data: adam.aslbase

Table 14-2.3.1. Summary of Baseline Disease Characteristics
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Parental hip fracture - n (%)			
Yes	36 (12.0)	20 (6.7)	56 (9.3)
No	219 (73.0)	222 (74.0)	441 (73.5)
Unknown	45 (15.0)	58 (19.3)	103 (17.2)
Parent fractures hip - n (%)			
Mother	30 (10.0)	17 (5.7)	47 (7.8)
Father	5 (1.7)	2 (0.7)	7 (1.2)
Both mother and father	1 (0.3)	1 (0.3)	2 (0.3)
Neither mother nor father	219 (73.0)	222 (74.0)	441 (73.5)
Unknown	45 (15.0)	58 (19.3)	103 (17.2)
Hospitalized for osteoporotic fracture - n (%)			
Yes	63 (21.0)	11 (3.7)	74 (12.3)
No	237 (79.0)	289 (96.3)	526 (87.7)
≥ 1 Fall in the last 12 months - n (%)			
Yes	61 (20.3)	24 (8.0)	85 (14.2)
No	239 (79.7)	276 (92.0)	515 (85.8)
≥ 1 Occurrence of immobility in the last 12 months - n (%)			
Yes	19 (6.3)	6 (2.0)	25 (4.2)
No	281 (93.7)	294 (98.0)	575 (95.8)
Glucocorticoid use - n (%)			
Yes	33 (11.0)	12 (4.0)	45 (7.5)
No	267 (89.0)	288 (96.0)	555 (92.5)
Secondary osteoporosis - n (%)			
Yes	45 (15.0)	23 (7.7)	68 (11.3)
No	255 (85.0)	277 (92.3)	532 (88.7)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-disease.sas Output: t14-02-003-001-base-disease-p.rtf (Date Generated: 14AUG15:00:01:10) Source Data: adam.aslbase

Table 14-2.3.1. Summary of Baseline Disease Characteristics
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Alcoholic beverages - n (%)			
None	200 (66.7)	273 (91.0)	473 (78.8)
≤ 2 units per day	100 (33.3)	26 (8.7)	126 (21.0)
≥ 3 units per day	0 (0.0)	1 (0.3)	1 (0.2)
Tobacco use - n (%)			
Never	226 (75.3)	248 (82.7)	474 (79.0)
Former	35 (11.7)	23 (7.7)	58 (9.7)
Currently	39 (13.0)	29 (9.7)	68 (11.3)

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N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-disease.sas Output: t14-02-003-001-base-disease-p.rtf (Date Generated: 14AUG15:00:01:10) Source Data: adam.aslbase

Table 14-2.4.1. Chronic Medical Conditions (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting at least 1 chronic medical condition of which the patient is taking medications regularly	278 (92.7)	242 (80.7)	520 (86.7)
Diabetes	20 (6.7)	23 (7.7)	43 (7.2)
Osteoporosis	253 (84.3)	86 (28.7)	339 (56.5)
Hypertension	149 (49.7)	159 (53.0)	308 (51.3)
Other	186 (62.0)	132 (44.0)	318 (53.0)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
Patients may have more than one chronic medical condition.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-chronmed.sas
Output: t14-02-004-001-base-chronmed-l.rtf (Date Generated: 13AUG2015:23:59:35) Source Data: adam.amh, adam.aslinfo

Table 14-2.5.1. History of Significant Comorbidities or Conditions (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting a history of at least 1 comorbidity[a]	290 (96.7)	272 (90.7)	562 (93.7)
Chronic back pain	173 (57.7)	160 (53.3)	333 (55.5)
Hypertension	153 (51.0)	158 (52.7)	311 (51.8)
Historical spine-hip-leg fracture	130 (43.3)	45 (15.0)	175 (29.2)
Gastrointestinal disorders	107 (35.7)	57 (19.0)	164 (27.3)
Osteoarthritis	74 (24.7)	89 (29.7)	163 (27.2)
Endocrine disease	71 (23.7)	68 (22.7)	139 (23.2)
Obesity	44 (14.7)	58 (19.3)	102 (17.0)
Heart disease	56 (18.7)	45 (15.0)	101 (16.8)
Peripheral vascular disease	62 (20.7)	33 (11.0)	95 (15.8)
Lung disease	40 (13.3)	25 (8.3)	65 (10.8)
Liver disease	31 (10.3)	26 (8.7)	57 (9.5)
Diabetes - type 1 or 2	27 (9.0)	27 (9.0)	54 (9.0)
Depression	26 (8.7)	23 (7.7)	49 (8.2)
Genito-urinary disease	26 (8.7)	21 (7.0)	47 (7.8)
Visual impairment	31 (10.3)	14 (4.7)	45 (7.5)
Rheumatologic diseases (excluding osteoarthritism degenerative arthritis and rheumatoid arthritis)	19 (6.3)	21 (7.0)	40 (6.7)
Kidney disease	19 (6.3)	20 (6.7)	39 (6.5)
Anemia or other blood disease	19 (6.3)	13 (4.3)	32 (5.3)
Cancer	22 (7.3)	7 (2.3)	29 (4.8)
Neurological disease	18 (6.0)	8 (2.7)	26 (4.3)
Rheumatoid arthritis	19 (6.3)	5 (1.7)	24 (4.0)
Hearing impairment	7 (2.3)	9 (3.0)	16 (2.7)
Stroke	8 (2.7)	5 (1.7)	13 (2.2)
Myocardial infarction	7 (2.3)	5 (1.7)	12 (2.0)
Mental illness (excluding depression)	2 (0.7)	4 (1.3)	6 (1.0)
Alcohol or drug problem	1 (0.3)	3 (1.0)	4 (0.7)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
Patients may have more than one comorbidity.
[a] Protocol specified comorbidities or conditions reported within 12 months before baseline.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-comorb.sas Output: t14-02-005-001-base-comorb-p.rtf (Date Generated: 13AUG15:23:59:59) Source Data: adam.amh, adam.aslinfo

Table 14-2.6.1. Summary of Prior Osteoporosis Medications (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Was the patient ever exposed to prior PMO therapy?			
Yes	255 (85.0)	146 (48.7)	401 (66.8)
No	45 (15.0)	154 (51.3)	199 (33.2)
Did the patient receive any PMO therapy during the 12 months prior to enrollment?			
Yes	240 (80.0)	119 (39.7)	359 (59.8)
No	60 (20.0)	181 (60.3)	241 (40.2)
All PMO medication			
Ibandronate	121 (40.3)	54 (18.0)	175 (29.2)
Vitamin D supplements	148 (49.3)	12 (4.0)	160 (26.7)
Calcium supplements	144 (48.0)	15 (5.0)	159 (26.5)
Alendronate	114 (38.0)	15 (5.0)	129 (21.5)
Risedronate	40 (13.3)	45 (15.0)	85 (14.2)
Strontium ranelate	54 (18.0)	31 (10.3)	85 (14.2)
SERMs	36 (12.0)	10 (3.3)	46 (7.7)
Zoledronate	10 (3.3)	30 (10.0)	40 (6.7)
Calcitonin	16 (5.3)	7 (2.3)	23 (3.8)
PTH/Teriparatide	7 (2.3)	4 (1.3)	11 (1.8)
Hormone replacement therapy	3 (1.0)	3 (1.0)	6 (1.0)
Other (non-bisphosphonate)	5 (1.7)	1 (0.3)	6 (1.0)
Other bisphosphonate	2 (0.7)	0 (0.0)	2 (0.3)
Etidronate	0 (0.0)	1 (0.3)	1 (0.2)
Did the patient receive any prior calcium and/or vitamin D supplement?			
Yes	151 (50.3)	19 (6.3)	170 (28.3)
No	149 (49.7)	281 (93.7)	430 (71.7)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
Patients may have been prescribed to more than one PMO medication.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-pr-expos.sas
Output: t14-02-006-001-base-pr-expos-p.rtf (Date Generated: 14AUG2015: 0:04:18) Source Data: adam.acm, adam.aslbase, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Ibandronate	121	54	175
Type			
Branded	116 (95.9)	48 (88.9)	164 (93.7)
Generic	5 (4.1)	6 (11.1)	11 (6.3)
Route			
Intravenous	11 (9.1)	5 (9.3)	16 (9.1)
Oral	112 (92.6)	47 (87.0)	159 (90.9)
Other	0 (0.0)	2 (3.7)	2 (1.1)
Frequency			
Daily	0 (0.0)	1 (1.9)	1 (0.6)
Monthly	112 (92.6)	48 (88.9)	160 (91.4)
Every 3 months	11 (9.1)	5 (9.3)	16 (9.1)

N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Vitamin D supplements	148	12	160
Type			
Branded	135 (91.2)	10 (83.3)	145 (90.6)
Generic	14 (9.5)	2 (16.7)	16 (10.0)
Route			
Oral	148 (100.0)	12 (100.0)	160 (100.0)
Frequency			
Daily	108 (73.0)	12 (100.0)	120 (75.0)
Weekly	45 (30.4)	1 (8.3)	46 (28.8)
Monthly	1 (0.7)	0 (0.0)	1 (0.6)
Every 3 months	1 (0.7)	0 (0.0)	1 (0.6)
Other	1 (0.7)	0 (0.0)	1 (0.6)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Calcium supplements	144	15	159
Type			
Branded	133 (92.4)	13 (86.7)	146 (91.8)
Generic	14 (9.7)	2 (13.3)	16 (10.1)
Route			
Intravenous	1 (0.7)	0 (0.0)	1 (0.6)
Oral	143 (99.3)	15 (100.0)	158 (99.4)
Frequency			
Daily	143 (99.3)	15 (100.0)	158 (99.4)
Monthly	1 (0.7)	0 (0.0)	1 (0.6)
Other	1 (0.7)	0 (0.0)	1 (0.6)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Alendronate	114	15	129
Type			
Branded	84 (73.7)	9 (60.0)	93 (72.1)
Generic	33 (28.9)	6 (40.0)	39 (30.2)
Route			
Oral	114 (100.0)	15 (100.0)	129 (100.0)
Frequency			
Daily	4 (3.5)	5 (33.3)	9 (7.0)
Weekly	111 (97.4)	9 (60.0)	120 (93.0)
Monthly	0 (0.0)	1 (6.7)	1 (0.8)
Other	1 (0.9)	0 (0.0)	1 (0.8)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Risedronate	40	45	85
Type			
Branded	23 (57.5)	25 (55.6)	48 (56.5)
Generic	19 (47.5)	22 (48.9)	41 (48.2)
Route			
Oral	40 (100.0)	44 (97.8)	84 (98.8)
Unknown	0 (0.0)	1 (2.2)	1 (1.2)
Frequency			
Weekly	40 (100.0)	32 (71.1)	72 (84.7)
Monthly	0 (0.0)	10 (22.2)	10 (11.8)
Other	0 (0.0)	3 (6.7)	3 (3.5)
Unknown	0 (0.0)	1 (2.2)	1 (1.2)

N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Strontium ranelate	54	31	85
Type			
Branded	52 (96.3)	31 (100.0)	83 (97.6)
Generic	2 (3.7)	0 (0.0)	2 (2.4)
Route			
Oral	54 (100.0)	31 (100.0)	85 (100.0)
Frequency			
Daily	53 (98.1)	31 (100.0)	84 (98.8)
Unknown	1 (1.9)	0 (0.0)	1 (1.2)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
SERMs	36	10	46
Type			
Branded	34 (94.4)	10 (100.0)	44 (95.7)
Generic	2 (5.6)	0 (0.0)	2 (4.3)
Route			
Oral	36 (100.0)	10 (100.0)	46 (100.0)
Frequency			
Daily	35 (97.2)	9 (90.0)	44 (95.7)
Weekly	1 (2.8)	0 (0.0)	1 (2.2)
Unknown	1 (2.8)	1 (10.0)	2 (4.3)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Zoledronate	10	30	40
Type			
Branded	10 (100.0)	30 (100.0)	40 (100.0)
Route			
Intravenous	10 (100.0)	30 (100.0)	40 (100.0)
Frequency			
Yearly	9 (90.0)	30 (100.0)	39 (97.5)
Other	1 (10.0)	0 (0.0)	1 (2.5)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Calcitonin	16	7	23
Type			
Branded	12 (75.0)	1 (14.3)	13 (56.5)
Generic	5 (31.3)	6 (85.7)	11 (47.8)
Route			
Oral	3 (18.8)	1 (14.3)	4 (17.4)
Other	13 (81.3)	6 (85.7)	19 (82.6)
Frequency			
Daily	16 (100.0)	7 (100.0)	23 (100.0)
Unknown	1 (6.3)	0 (0.0)	1 (4.3)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
PTH/Teriparatide	7	4	11
Type			
Branded	6 (85.7)	4 (100.0)	10 (90.9)
Generic	1 (14.3)	0 (0.0)	1 (9.1)
Route			
Other	7 (100.0)	4 (100.0)	11 (100.0)
Frequency			
Daily	7 (100.0)	4 (100.0)	11 (100.0)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Hormone replacement therapy	3	3	6
Type			
Branded	3 (100.0)	2 (66.7)	5 (83.3)
Generic	0 (0.0)	1 (33.3)	1 (16.7)
Route			
Oral	3 (100.0)	2 (66.7)	5 (83.3)
Unknown	0 (0.0)	1 (33.3)	1 (16.7)
Frequency			
Daily	3 (100.0)	2 (66.7)	5 (83.3)
Unknown	0 (0.0)	1 (33.3)	1 (16.7)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Other (non-bisphosphonate)	5	1	6
Type			
Branded	5 (100.0)	0 (0.0)	5 (83.3)
Generic	0 (0.0)	1 (100.0)	1 (16.7)
Route			
Oral	5 (100.0)	0 (0.0)	5 (83.3)
Other	0 (0.0)	1 (100.0)	1 (16.7)
Frequency			
Daily	5 (100.0)	0 (0.0)	5 (83.3)
Other	0 (0.0)	1 (100.0)	1 (16.7)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Other bisphosphonate	2	0	2
Type			
Branded	2 (100.0)	0 (0.0)	2 (100.0)
Route			
Oral	2 (100.0)	0 (0.0)	2 (100.0)
Frequency			
Daily	1 (50.0)	0 (0.0)	1 (50.0)
Weekly	1 (50.0)	0 (0.0)	1 (50.0)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.7.1. Prior Osteoporosis Medications by Type, Route and Frequency (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Etidronate	0	1	1
Type			
Branded	0 (0.0)	1 (100.0)	1 (100.0)
Route			
Oral	0 (0.0)	1 (100.0)	1 (100.0)
Frequency			
Daily	0 (0.0)	1 (100.0)	1 (100.0)

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N = Number of patients in the full analysis set
Percentages based on number of patients who took the medication
Patients may be counted in more than one medication, type, route or frequency, but patients are only counted once within each row.
PTH = Parathyroid hormone; SERM = Selective estrogen receptor modulator.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-osteo.sas
Output: t14-02-007-001-base-osteo-p.rtf (Date Generated: 14AUG2015: 0:03:38) Source Data: adam.acm, adam.aslinfo

Table 14-2.8.1. Baseline Body Composition (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Height (cm)[a]			
n	296	268	564
Mean	158.5	159.4	159.0
SD	6.7	6.3	6.5
Median	158.0	160.0	159.0
Q1, Q3	154.0, 163.0	155.0, 164.0	155.0, 164.0
Min, Max	130, 182	141, 176	130, 182
Weight (kg)[a]			
n	296	268	564
Mean	63.7	68.1	65.8
SD	10.8	12.6	11.9
Median	62.8	66.6	64.0
Q1, Q3	57.0, 70.5	59.8, 75.0	58.0, 73.0
Min, Max	39, 96	38, 128	38, 128
Body mass index (kg/m^2)[a]			
n	296	268	564
Mean	25.39	26.78	26.05
SD	4.30	4.74	4.57
Median	24.97	25.85	25.48
Q1, Q3	22.49, 28.05	23.35, 29.55	22.84, 28.71
Min, Max	14.2, 39.4	17.6, 43.3	14.2, 43.3
Body mass index - n (%)[a]			
≤ 25 kg/m^2	151 (50.3)	104 (34.7)	255 (42.5)
> 25 kg/m^2	145 (48.3)	164 (54.7)	309 (51.5)
Missing	4 (1.3)	32 (10.7)	36 (6.0)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
[a]Includes the closest height, weight and BMI data up to 1 year prior to or at baseline Prolia® injection. If there is no pre-injection data the earliest post injection data up to study day 91 is included.
One subject in Czech Republic had reported height loss since maximal height but did not enter their loss value.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-bodycomp.sas
Output: t14-02-008-001-base-bodycomp-p.rtf (Date Generated: 17AUG15:04:04:35) Source Data: adam.aslbase

Table 14-2.8.1. Baseline Body Composition (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Height loss since self-reported maximal height - n (%)			
Yes	237 (79.0)	111 (37.0)	348 (58.0)
No	63 (21.0)	189 (63.0)	252 (42.0)
Height loss since self-reported maximal height (cm)			
n	236	111	347
Mean	4.71	4.36	4.59
SD	3.12	2.96	3.07
Median	4.00	3.50	4.00
Q1, Q3	2.00, 7.00	2.00, 6.00	2.00, 6.00
Min, Max	0.5, 14.0	0.5, 15.0	0.5, 15.0
Height loss since self-reported maximal height (cm) - n (%)			
≤ Median	125 (41.7)	56 (18.7)	191 (31.8)
> Median	111 (37.0)	55 (18.3)	156 (26.0)
Missing	64 (21.3)	189 (63.0)	253 (42.2)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
[a]Includes the closest height, weight and BMI data up to 1 year prior to or at baseline Prolia® injection. If there is no pre-injection data the earliest post injection data up to study day 91 is included.
One subject in Czech Republic had reported height loss since maximal height but did not enter their loss value.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-bodycomp.sas
Output: t14-02-008-001-base-bodycomp-p.rtf (Date Generated: 17AUG15:04:04:35) Source Data: adam.aslbase

Table 14-2.9.1. Fracture History (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Any historical fracture - n (%)	221 (73.7)	100 (33.3)	321 (53.5)
Osteoporotic[a]	203 (67.7)	90 (30.0)	293 (48.8)
Vertebral	93 (31.0)	21 (7.0)	114 (19.0)
Nonvertebral	153 (51.0)	74 (24.7)	227 (37.8)
Major nonvertebral[b]	119 (39.7)	62 (20.7)	181 (30.2)
Hip	18 (6.0)	5 (1.7)	23 (3.8)
More than one	97 (32.3)	21 (7.0)	118 (19.7)
Time since most recent fracture (years)			
n	221	92	313
Mean	5.5	6.7	5.8
SD	7.9	9.6	8.4
Median	2.0	3.0	2.0
Q1, Q3	0.0, 8.0	0.0, 10.0	0.0, 8.0
Min, Max	0, 57	0, 44	0, 57
Time since most recent fracture - n (%)			
< 12 Months	63 (21.0)	29 (9.7)	92 (15.3)
≥ 12 Months	158 (52.7)	63 (21.0)	221 (36.8)
Missing	0 (0.0)	8 (2.7)	8 (1.3)
Not applicable	79 (26.3)	200 (66.7)	279 (46.5)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
Table displays self-reported data captured on the historical fracture CRF page since adulthood.
Patients may have more than one fracture
[a] Any fracture recorded on the CRF not including skull, facial bones, fingers, and toes and not associated with known high trauma severity or pathological fractures.
[b] A subset of nonvertebral fractures including the following locations: pelvis, hip, upper leg (not hip), lower leg (not knee or ankle), ribs, shoulder, forearm, and wrist and not associated with known high trauma severity or pathological fractures.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-fxhx.sas
Output: t14-02-009-001-base-fxhx-p.rtf (Date Generated: 14AUG15:00:03:08) Source Data: adam.aslbase

Table 14-2.9.2. Fracture History at 50 Years or Older (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Patients at 50 years or older	296 (98.7)	294 (98.0)	590 (98.3)
Any historical fracture at 50 years or older	204 (68.9)	76 (25.9)	280 (47.5)
Osteoporotic[a]	186 (62.8)	67 (22.8)	253 (42.9)
Vertebral	86 (29.1)	14 (4.8)	100 (16.9)
Nonvertebral	136 (45.9)	55 (18.7)	191 (32.4)
Major nonvertebral[b]	103 (34.8)	44 (15.0)	147 (24.9)
Hip	16 (5.4)	4 (1.4)	20 (3.4)
More than one	85 (28.7)	12 (4.1)	97 (16.4)

N = Number of patients in the full analysis set
Percentages based on number of patients over 50 years
Table displays self-reported data captured on the historical fracture CRF page.
Patients may have more than one fracture
[a] Any fracture recorded on the CRF which happened when patient was 50 years or older, not including skull, facial bones, fingers, and toes and not associated with known high trauma severity or pathological fractures.
[b] A subset of nonvertebral fractures including the following locations: pelvis, hip, upper leg (not hip), lower leg (not knee or ankle), ribs, shoulder, forearm, and wrist and not associated with known high trauma severity or pathological fractures.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-fxhx-agege50.sas
Output: t14-02-009-002-base-fxhx-agege50-p.rtf (Date Generated: 14AUG2015: 0:02:32) Source Data: adam.aslbase

Table 14-2.10.1. Prescribing Prolia®
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Reason for prescribing Prolia® to post-menopausal patient with osteoporosis[a]			
This patient has a history of osteoporotic fracture	136 (45.3)	55 (18.3)	191 (31.8)
This patient has multiple risk factors for fracture	126 (42.0)	60 (20.0)	186 (31.0)
The patient failed other available osteoporosis therapy	109 (36.3)	47 (15.7)	156 (26.0)
Patient is intolerant to other osteoporosis therapy	160 (53.3)	39 (13.0)	199 (33.2)
Low BMD T-score	138 (46.0)	178 (59.3)	316 (52.7)
Other	10 (3.3)	17 (5.7)	27 (4.5)
Injection administered at the prescribing physician's site			
Yes	300 (100.0)	298 (99.3)	598 (99.7)
No	0 (0.0)	2 (0.7)	2 (0.3)

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N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
[a] A patient may have 1 or more reasons for being prescribed Prolia®
[b]. Derives from free text provided when chosen Other health care professional.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-presc-prolia.sas
Output: t14-02-010-001-base-presc-prolia-l.rtf (Date Generated: 14AUG2015: 0:04:32) Source Data: adam.apresc, adam.aslinfo

Table 14-2.10.1. Prescribing Prolia®
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Individual administrating injection			
Physician other than prescribing physician	19 (6.3)	21 (7.0)	40 (6.7)
Prescribing physician	54 (18.0)	84 (28.0)	138 (23.0)
Other health care professional	227 (75.7)	195 (65.0)	422 (70.3)
Nurse[b]	227 (75.7)	195 (65.0)	422 (70.3)
Appointment at which Prolia® was administered			
Same appointment (in which the prescription/order for Prolia® was written)	262 (87.3)	290 (96.7)	552 (92.0)
Separate appointment	38 (12.7)	10 (3.3)	48 (8.0)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
[a] A patient may have 1 or more reasons for being prescribed Prolia®
[b]. Derives from free text provided when chosen Other health care professional.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-presc-prolia.sas
Output: t14-02-010-001-base-presc-prolia-l.rtf (Date Generated: 14AUG2015: 0:04:32) Source Data: adam.apresc, adam.aslinfo

Table 14-2.11.1. Timing of Baseline DXA Assessment (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
At least one baseline DXA assessment[a]			
Yes	272 (90.7)	275 (91.7)	547 (91.2)
No	28 (9.3)	25 (8.3)	53 (8.8)
DXA assessment time since first dose			
6-12 months before first dose	46 (15.3)	28 (9.3)	74 (12.3)
3-6 months before first dose	29 (9.7)	40 (13.3)	69 (11.5)
Up to 3 months before first dose	122 (40.7)	140 (46.7)	262 (43.7)
Same day as first dose	74 (24.7)	66 (22.0)	140 (23.3)
Post first dose (up to 91 days)	1 (0.3)	1 (0.3)	2 (0.3)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set
DXA = dual energy X-ray absorptiometry
[a] Includes the closest DXA data up to 1 year prior to or at baseline Prolia® injection. If there is no pre-injection DXA data the earliest post injection DXA up to study day 91 is included.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-timesince-bmd.sas
Output: t14-02-011-001-base-timesince-bmd-p.rtf (Date Generated: 14AUG15:02:29:30) Source Data: adam.aslbase

Table 14-2.12.1. Baseline Bone Mineral Density by DXA (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Patients with baseline BMD T-score ≤ -2.5 on any site[a] - n (%)	245 (81.7)	230 (76.7)	475 (79.2)
Lumbar spine BMD (g/cm^2)			
n	268	273	541
Mean	0.8023	0.7824	0.7923
SD	0.1247	0.1048	0.1154
Median	0.7835	0.7730	0.7790
Q1, Q3	0.7260, 0.8630	0.7180, 0.8330	0.7190, 0.8480
Min, Max	0.523, 1.398	0.484, 1.293	0.484, 1.398
Lumbar spine BMD T-score			
n	268	273	541
Mean	-2.74	-2.57	-2.66
SD	1.03	0.85	0.95
Median	-2.80	-2.70	-2.70
Q1, Q3	-3.40, -2.40	-3.00, -2.20	-3.20, -2.30
Min, Max	-5.0, 3.2	-5.0, 1.7	-5.0, 3.2
Lumbar spine BMD T-score - n (%)			
≤ -2.5	198 (66.0)	188 (62.7)	386 (64.3)
> -2.5	70 (23.3)	85 (28.3)	155 (25.8)
Missing	32 (10.7)	27 (9.0)	59 (9.8)

N = Number of patients in the full analysis set
DXA = dual energy X-ray absorptiometry
Includes the closest DXA data up to 1 year prior to or at baseline Prolia® injection. If there is no pre-injection DXA data the earliest post injection DXA up to study day 91 is included.
[a] Only BMD T-scores with non-missing body locations are counted.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-bmd.sas
Output: t14-02-012-001-base-bmd-p.rtf (Date Generated: 13AUG15:23:59:04) Source Data: adam.aslbase

Table 14-2.12.1. Baseline Bone Mineral Density by DXA (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Total hip BMD (g/cm^2)			
n	263	246	509
Mean	0.7337	0.7908	0.7613
SD	0.1051	0.1196	0.1158
Median	0.7300	0.7910	0.7580
Q1, Q3	0.6680, 0.7950	0.7290, 0.8600	0.6850, 0.8430
Min, Max	0.416, 1.050	0.456, 1.207	0.416, 1.207
Total hip BMD T-score			
n	263	246	509
Mean	-1.98	-1.28	-1.64
SD	0.84	0.92	0.94
Median	-2.00	-1.30	-1.70
Q1, Q3	-2.60, -1.40	-1.80, -0.70	-2.30, -1.00
Min, Max	-4.3, 0.6	-3.7, 2.2	-4.3, 2.2
Total hip BMD T-score - n (%)			
≤ -2.5	84 (28.0)	26 (8.7)	110 (18.3)
> -2.5	179 (59.7)	220 (73.3)	399 (66.5)
Missing	37 (12.3)	54 (18.0)	91 (15.2)

N = Number of patients in the full analysis set
DXA = dual energy X-ray absorptiometry
Includes the closest DXA data up to 1 year prior to or at baseline Prolia® injection. If there is no pre-injection DXA data the earliest post injection DXA up to study day 91 is included.
[a] Only BMD T-scores with non-missing body locations are counted.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-bmd.sas Output: t14-02-012-001-base-bmd-p.rtf (Date Generated: 13AUG15:23:59:04) Source Data: adam.aslbase

Table 14-2.12.1. Baseline Bone Mineral Density by DXA (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)	Slovakia (N = 300)	Overall (N = 600)
Femoral neck BMD (g/cm^2)			
n	262	273	535
Mean	0.6707	0.6643	0.6675
SD	0.1102	0.1086	0.1093
Median	0.6710	0.6530	0.6650
Q1, Q3	0.6000, 0.7410	0.5880, 0.7390	0.5910, 0.7390
Min, Max	0.332, 0.974	0.316, 1.006	0.316, 1.006
Femoral neck BMD T-score			
n	262	273	535
Mean	-2.16	-1.87	-2.02
SD	0.77	0.82	0.81
Median	-2.20	-1.90	-2.00
Q1, Q3	-2.70, -1.60	-2.50, -1.40	-2.60, -1.50
Min, Max	-4.7, 0.0	-4.8, 0.6	-4.8, 0.6
Femoral neck BMD T-score - n (%)			
≤ -2.5	103 (34.3)	73 (24.3)	176 (29.3)
> -2.5	159 (53.0)	200 (66.7)	359 (59.8)
Missing	38 (12.7)	27 (9.0)	65 (10.8)

N = Number of patients in the full analysis set
DXA = dual energy X-ray absorptiometry
Includes the closest DXA data up to 1 year prior to or at baseline Prolia® injection. If there is no pre-injection DXA data the earliest post injection DXA up to study day 91 is included.
[a] Only BMD T-scores with non-missing body locations are counted.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-bmd.sas Output: t14-02-012-001-base-bmd-p.rtf (Date Generated: 13AUG15:23:59:04) Source Data: adam.aslbase

Table 14-2.13.1. Physician and Site Characteristics (24-month Final Analysis)

	Czech Republic (N = 15) n (%)	Slovakia (N = 17) n (%)	Overall (N = 32) n (%)
Physician specialty			
Rheumatologist	6 (40.0)	8 (47.1)	14 (43.8)
Internist	7 (46.7)	3 (17.6)	10 (31.3)
Endocrinologist	1 (6.7)	3 (17.6)	4 (12.5)
Orthopedist	0 (0.0)	3 (17.6)	3 (9.4)
Other	1 (6.7)	0 (0.0)	1 (3.1)
Physician gender			
Female	4 (26.7)	8 (47.1)	12 (37.5)
Male	11 (73.3)	9 (52.9)	20 (62.5)
Physician years of practice			
5 to 9 years	1 (6.7)	2 (11.8)	3 (9.4)
≥ 10 years	14 (93.3)	15 (88.2)	29 (90.6)
Sole physician			
Sole	6 (40.0)	13 (76.5)	19 (59.4)
Group	9 (60.0)	4 (23.5)	13 (40.6)
Group size			
2 - 3	6 (40.0)	2 (11.8)	8 (25.0)
4 - 5	2 (13.3)	1 (5.9)	3 (9.4)
6 - 10	1 (6.7)	0 (0.0)	1 (3.1)
> 10	0 (0.0)	1 (5.9)	1 (3.1)
Centre type			
Hospital	5 (33.3)	7 (41.2)	12 (37.5)
Non-hospital	10 (66.7)	10 (58.8)	20 (62.5)

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N = Number of sites
Percentages based on the number of sites
[a] Site may have more than one service.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-sitechar.sas
Output: t14-02-013-001-base-sitechar-p.rtf (Date Generated: 14AUG15:01:50:53) Source Data: adam.aslbase

Table 14-2.13.1. Physician and Site Characteristics (24-month Final Analysis)

	Czech Republic (N = 15) n (%)	Slovakia (N = 17) n (%)	Overall (N = 32) n (%)
Academic centre			
Academic	1 (6.7)	4 (23.5)	5 (15.6)
Non-academic	14 (93.3)	10 (58.8)	24 (75.0)
Both	0 (0.0)	2 (11.8)	2 (6.3)
Not available	0 (0.0)	1 (5.9)	1 (3.1)
Region			
Urban	14 (93.3)	17 (100.0)	31 (96.9)
Rural	1 (6.7)	0 (0.0)	1 (3.1)
Active reminder service for next Prolia® administration			
Yes	8 (53.3)	14 (82.4)	22 (68.8)
No	7 (46.7)	3 (17.6)	10 (31.3)
Type of reminder service[a]			
Telephone call	4 (26.7)	7 (41.2)	11 (34.4)
Appointment card	4 (26.7)	5 (29.4)	9 (28.1)
Mailing	2 (13.3)	4 (23.5)	6 (18.8)
Sticker from drug package	0 (0.0)	2 (11.8)	2 (6.3)
Email/SMS	0 (0.0)	1 (5.9)	1 (3.1)

N = Number of sites
Percentages based on the number of sites
[a] Site may have more than one service.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-sitechar.sas
Output: t14-02-013-001-base-sitechar-p.rtf (Date Generated: 14AUG15:01:50:53) Source Data: adam.aslbase

Table 14-2.14.1. Patient Reported Outcome at Baseline - Patient Questionnaire (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Living situation			
At home with spouse/family	210 (70.0)	237 (79.0)	447 (74.5)
At home with care/support	5 (1.7)	1 (0.3)	6 (1.0)
At home alone	80 (26.7)	32 (10.7)	112 (18.7)
Nursing home	0 (0.0)	2 (0.7)	2 (0.3)
Not available	5 (1.7)	28 (9.3)	33 (5.5)
Highest education level			
University	29 (9.7)	39 (13.0)	68 (11.3)
Secondary education	185 (61.7)	167 (55.7)	352 (58.7)
Elementary education	86 (28.7)	74 (24.7)	160 (26.7)
Not applicable	0 (0.0)	20 (6.7)	20 (3.3)
Employment status			
Retired	265 (88.3)	202 (67.3)	467 (77.8)
Employed	25 (8.3)	81 (27.0)	106 (17.7)
Self Employed	6 (2.0)	5 (1.7)	11 (1.8)
Unemployed	4 (1.3)	7 (2.3)	11 (1.8)
Missing	0 (0.0)	5 (1.7)	5 (0.8)
Stopped taking osteoporosis medications (other than calcium and vitamin D)			
Yes	32 (10.7)	29 (9.7)	61 (10.2)
No	241 (80.3)	255 (85.0)	496 (82.7)
Not applicable	27 (9.0)	16 (5.3)	43 (7.2)

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N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-patient-pro.sas
Output: t14-02-014-001-base-patient-pro-p.rtf (Date Generated: 14AUG15:00:04:04) Source Data: adam.aqspq, adam.aslinfo

Table 14-2.15.1. Patients Satisfying Czech Republic Reimbursement Criteria - Czech Republic (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)
Patients with BMD T-score ≤ -2.5 on either femoral neck, lumbar spine or total hip	269 (89.7)
Historical osteoporotic fracture[a]	189 (63.0)
Intolerant to other osteoporosis therapy	185 (61.7)
Failed other available osteoporosis therapy	97 (32.3)
Patients satisfying Czech Republic reimbursement criteria[b]	267 (89.0)

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N = Number of patients in the full analysis set
Percentage are based on the number of patient in the full analysis set.
Patients may fulfill more than one criteria
[a]Data comes from both patient reported outcome and physician prescribing questionnaire.
[b]Patient must have a baseline BMD T-score less than or equal to -2.5 on either lumbar spine, total hip or femoral neck and also have at least one of historical osteoporotic fractures or intolerant or failed to other osteoporosis therapy to satisfy Czech Republic reimbursement criteria.
The definition of the baseline assessment here is the DXA assessment taken closest to the baseline injection.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-osteo-reimb.sas
Output: t14-02-015-001-osteo-reimb-p.rtf (Date Generated: 09DEC15:00:58:32) Source Data: adam.aslbase, adam.amh, adam.apresc

Table 14-2.16.1. Patients Not Satisfying Czech Republic Reimbursement Criteria - Czech Republic (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)
Patients fulfilling Czech Republic reimbursement criteria[a]	267 (89.0)
Patients not fulfilling Czech Republic reimbursement criteria[a]	33 (11.0)
Missing baseline T-score	3 (1.0)
Baseline T-score = - 2.4	13 (4.3)
Historical OP fracture only[b]	1 (0.3)
Intolerance or failure to OP drugs only	4 (1.3)
Both historical OP fracture and intolerance or failure to OP drugs	8 (2.7)
Neither historical OP fracture nor intolerance or failure to OP drugs	0 (0.0)
Baseline T-score > - 2.4	17 (5.7)
Historical OP fracture only[b]	1 (0.3)
Intolerance or failure to OP drugs only	2 (0.7)
Both historical OP fracture and intolerance or failure to OP drugs	12 (4.0)
Neither historical OP fracture nor intolerance or failure to OP drugs	2 (0.7)

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N = Number of patients in the full analysis set
Percentage are based on the number of patient in the full analysis set.
OP = Osteoporosis
[a]Patient must have a baseline BMD T-score less than or equal to -2.5 on either lumbar spine, total hip or femoral neck and also have at least one of historical osteoporotic fractures or intolerant or failed to other osteoporosis therapy to satisfy Czech Republic reimbursement criteria.
[b]Data comes from both patient reported outcome and physician prescribing questionnaire.
The definition of the baseline assessment here is the DXA assessment taken closest to the baseline injection.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-osteo-reimb-notsat.sas
Output: t14-02-016-001-osteo-reimb-notsat-p.rtf (Date Generated: 09DEC15:00:53:12) Source Data: adam.aslbase, adam.amh, adam.apresc

Table 14-2.16.2. Patients Not Satisfying Czech Republic Reimbursement Criteria With Alternative Denominators - Czech Republic (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)
Patients fulfilling Czech Republic reimbursement criteria[a]	267 (89.0)
Patients not fulfilling Czech Republic reimbursement criteria[a]	33 (11.0)
Missing baseline T-score	3 (1.0)
Baseline T-score = - 2.4	13 (4.3)
Historical OP fracture only[b]	1 (7.7)[c]
Intolerance or failure to OP drugs only	4 (30.8)[c]
Both historical OP fracture and intolerance or failure to OP drugs	8 (61.5)[c]
Neither historical OP fracture nor intolerance or failure to OP drugs	0 (0.0)[c]
Baseline T-score > - 2.4	17 (5.7)
Historical OP fracture only[b]	1 (5.9)[c]
Intolerance or failure to OP drugs only	2 (11.8)[c]
Both historical OP fracture and intolerance or failure to OP drugs	12 (70.6)[c]
Neither historical OP fracture nor intolerance or failure to OP drugs	2 (11.8)[c]

N = Number of patients in the full analysis set
Percentages are based on the number of patients in the full analysis set unless otherwise specified.
OP = Osteoporosis
[a]Patient must have a baseline BMD t-score less than or equal to -2.5 on either lumbar spine, total hip or femoral neck and also have at least one of historical osteoporotic fractures or intolerant or failed to other osteoporotic therapy to satisfy Czech Republic reimbursement criteria.
[b]Data comes from both patient reported outcome and physician prescribing questionnaire.
[c]Percentages are calculated based on the number of patients in the respective T-score subgroup
The definition of the baseline assessment here is the DXA assessment taken closest to the baseline injection.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-osteo-reimb-notsat.sas
Output: t14-02-016-002-osteo-reimb-notsat-sen-p.rtf (Date Generated: 09DEC2015: 0:52:55) Source Data: adam.aslbase, adam.amh, adam.apresc

Table 14-4.1.1. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N	% (95% CI)	n/N	% (95% CI)	n/N	% (95% CI)
Patient receiving all prescriptions and injections of Prolia® from the inital site						
Yes	295/300	98.3 (96.2, 99.5)	296/300	98.7 (96.6, 99.6)	591/600	98.5 (97.2, 99.3)
No	5/300	1.7 (0.5, 3.8)	4/300	1.3 (0.4, 3.4)	9/600	1.5 (0.7, 2.8)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl.sas
Output: t14-04-001-001-fi-injapafl-l.rtf (Date Generated: 14AUG2015: 0:09:39) Source Data: adam.aslinfo

Table 14-4.1.2. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Living situation						
At home with spouse/family	207/210	98.6 (95.9, 99.7)	234/237	98.7 (96.3, 99.7)	441/447	98.7 (97.1, 99.5)
At home with care/support	5/5	100.0 (47.8, 100.0)	1/1	100.0 (2.5, 100.0)	6/6	100.0 (54.1, 100.0)
At home alone	78/80	97.5 (91.3, 99.7)	31/32	96.9 (83.8, 99.9)	109/112	97.3 (92.4, 99.4)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	28/28	100.0 (87.7, 100.0)	33/33	100.0 (89.4, 100.0)
Highest educational level						
University	29/29	100.0 (88.1, 100.0)	38/39	97.4 (86.5, 99.9)	67/68	98.5 (92.1, 100.0)
Secondary education	183/185	98.9 (96.1, 99.9)	165/167	98.8 (95.7, 99.9)	348/352	98.9 (97.1, 99.7)
Elementary education	83/86	96.5 (90.1, 99.3)	73/74	98.6 (92.7, 100.0)	156/160	97.5 (93.7, 99.3)
Not applicable	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)	20/20	100.0 (83.2, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-002-fi-injapafl-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aqspq

Table 14-4.1.2. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Employment status						
Retired	260/265	98.1 (95.7, 99.4)	198/202	98.0 (95.0, 99.5)	458/467	98.1 (96.4, 99.1)
Employed	25/25	100.0 (86.3, 100.0)	81/81	100.0 (95.5, 100.0)	106/106	100.0 (96.6, 100.0)
Self employed	6/6	100.0 (54.1, 100.0)	5/5	100.0 (47.8, 100.0)	11/11	100.0 (71.5, 100.0)
Unemployed	4/4	100.0 (39.8, 100.0)	7/7	100.0 (59.0, 100.0)	11/11	100.0 (71.5, 100.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-002-fi-injapafl-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aqspq

Table 14-4.1.3. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Body mass index						
≤ 25 kg/m^2	148/151	98.0 (94.3, 99.6)	103/104	99.0 (94.8, 100.0)	251/255	98.4 (96.0, 99.6)
> 25 kg/m^2	143/145	98.6 (95.1, 99.8)	162/164	98.8 (95.7, 99.9)	305/309	98.7 (96.7, 99.6)
Missing	4/4	100.0 (39.8, 100.0)	31/32	96.9 (83.8, 99.9)	35/36	97.2 (85.5, 99.9)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	206/210	98.1 (95.2, 99.5)	196/199	98.5 (95.7, 99.7)	402/409	98.3 (96.5, 99.3)
> Median	89/90	98.9 (94.0, 100.0)	100/101	99.0 (94.6, 100.0)	189/191	99.0 (96.3, 99.9)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	159/163	97.5 (93.8, 99.3)	160/160	100.0 (97.7, 100.0)	301/305	98.7 (96.7, 99.6)
> Median	136/137	99.3 (96.0, 100.0)	136/140	97.1 (92.8, 99.2)	290/295	98.3 (96.1, 99.4)

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n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-003-fi-injapafl-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase

Table 14-4.1.3. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Cause of menopause						
Natural onset	244/248	98.4 (95.9, 99.6)	240/244	98.4 (95.9, 99.6)	484/492	98.4 (96.8, 99.3)
Clinically/surgically induced	50/51	98.0 (89.6, 100.0)	53/53	100.0 (93.3, 100.0)	103/104	99.0 (94.8, 100.0)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	36/36	100.0 (90.3, 100.0)	20/20	100.0 (83.2, 100.0)	56/56	100.0 (93.6, 100.0)
No	215/219	98.2 (95.4, 99.5)	220/222	99.1 (96.8, 99.9)	435/441	98.6 (97.1, 99.5)
Unknown	44/45	97.8 (88.2, 99.9)	56/58	96.6 (88.1, 99.6)	100/103	97.1 (91.7, 99.4)
Hospitalized for osteoporotic fracture						
Yes	62/63	98.4 (91.5, 100.0)	10/11	90.9 (58.7, 99.8)	72/74	97.3 (90.6, 99.7)
No	233/237	98.3 (95.7, 99.5)	286/289	99.0 (97.0, 99.8)	519/526	98.7 (97.3, 99.5)

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n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-003-fi-injapafl-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase

Table 14-4.1.3. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
≥ 1 Fall in the last 12 months						
Yes	60/61	98.4 (91.2, 100.0)	22/24	91.7 (73.0, 99.0)	82/85	96.5 (90.0, 99.3)
No	235/239	98.3 (95.8, 99.5)	274/276	99.3 (97.4, 99.9)	509/515	98.8 (97.5, 99.6)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	19/19	100.0 (82.4, 100.0)	5/6	83.3 (35.9, 99.6)	24/25	96.0 (79.6, 99.9)
No	276/281	98.2 (95.9, 99.4)	291/294	99.0 (97.0, 99.8)	567/575	98.6 (97.3, 99.4)
Glucocorticoid use						
Yes	32/33	97.0 (84.2, 99.9)	11/12	91.7 (61.5, 99.8)	43/45	95.6 (84.9, 99.5)
No	263/267	98.5 (96.2, 99.6)	285/288	99.0 (97.0, 99.8)	548/555	98.7 (97.4, 99.5)
Secondary osteoporosis						
Yes	43/45	95.6 (84.9, 99.5)	23/23	100.0 (85.2, 100.0)	66/68	97.1 (89.8, 99.6)
No	252/255	98.8 (96.6, 99.8)	273/277	98.6 (96.3, 99.6)	525/532	98.7 (97.3, 99.5)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-003-fi-injapafl-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase

Table 14-4.1.3. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	295/300	98.3 (96.2, 99.5)	295/299	98.7 (96.6, 99.6)	590/599	98.5 (97.2, 99.3)
Former smoker						
Yes	33/35	94.3 (80.8, 99.3)	23/23	100.0 (85.2, 100.0)	56/58	96.6 (88.1, 99.6)
No	262/265	98.9 (96.7, 99.8)	273/277	98.6 (96.3, 99.6)	535/542	98.7 (97.4, 99.5)
Current smoker						
Yes	39/39	100.0 (91.0, 100.0)	29/29	100.0 (88.1, 100.0)	68/68	100.0 (94.7, 100.0)
No	256/261	98.1 (95.6, 99.4)	267/271	98.5 (96.3, 99.6)	523/532	98.3 (96.8, 99.2)
Height loss since self-reported maximal height						
Yes	232/237	97.9 (95.1, 99.3)	107/111	96.4 (91.0, 99.0)	339/348	97.4 (95.1, 98.8)
No	63/63	100.0 (94.3, 100.0)	189/189	100.0 (98.1, 100.0)	252/252	100.0 (98.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-003-fi-injapafl-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase

Table 14-4.1.3. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	122/125	97.6 (93.1, 99.5)	55/56	98.2 (90.4, 100.0)	187/191	97.9 (94.7, 99.4)
> Median	109/111	98.2 (93.6, 99.8)	52/55	94.5 (84.9, 98.9)	151/156	96.8 (92.7, 99.0)
Missing	64/64	100.0 (94.4, 100.0)	189/189	100.0 (98.1, 100.0)	253/253	100.0 (98.6, 100.0)
Previous fracture						
Yes	218/221	98.6 (96.1, 99.7)	99/100	99.0 (94.6, 100.0)	317/321	98.8 (96.8, 99.7)
No	77/79	97.5 (91.2, 99.7)	197/200	98.5 (95.7, 99.7)	274/279	98.2 (95.9, 99.4)
Previous hip fracture						
Yes	18/18	100.0 (81.5, 100.0)	5/5	100.0 (47.8, 100.0)	23/23	100.0 (85.2, 100.0)
No	277/282	98.2 (95.9, 99.4)	291/295	98.6 (96.6, 99.6)	568/577	98.4 (97.1, 99.3)

N = Number of patients in the full analysis set
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N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-003-fi-injapafl-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase

Table 14-4.1.3. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Previous vertebral fracture						
Yes	90/93	96.8 (90.9, 99.3)	21/21	100.0 (83.9, 100.0)	111/114	97.4 (92.5, 99.5)
No	205/207	99.0 (96.6, 99.9)	275/279	98.6 (96.4, 99.6)	480/486	98.8 (97.3, 99.5)
Time since most recent historical fracture to first injection						
< 12 months	62/63	98.4 (91.5, 100.0)	28/29	96.6 (82.2, 99.9)	90/92	97.8 (92.4, 99.7)
≥ 12 months	156/158	98.7 (95.5, 99.8)	63/63	100.0 (94.3, 100.0)	219/221	99.1 (96.8, 99.9)
Baseline lumbar spine DXA BMD T-score						
> -2.5	70/70	100.0 (94.9, 100.0)	84/85	98.8 (93.6, 100.0)	154/155	99.4 (96.5, 100.0)
≤ -2.5	193/198	97.5 (94.2, 99.2)	185/188	98.4 (95.4, 99.7)	378/386	97.9 (96.0, 99.1)
Missing	32/32	100.0 (89.1, 100.0)	27/27	100.0 (87.2, 100.0)	59/59	100.0 (93.9, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-003-fi-injapafl-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase

Table 14-4.1.3. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline total hip DXA BMD T-score						
> -2.5	175/179	97.8 (94.4, 99.4)	218/220	99.1 (96.8, 99.9)	393/399	98.5 (96.8, 99.4)
≤ -2.5	83/84	98.8 (93.5, 100.0)	25/26	96.2 (80.4, 99.9)	108/110	98.2 (93.6, 99.8)
Missing	37/37	100.0 (90.5, 100.0)	53/54	98.1 (90.1, 100.0)	90/91	98.9 (94.0, 100.0)
Baseline femoral neck DXA BMD T-score						
> -2.5	155/159	97.5 (93.7, 99.3)	199/200	99.5 (97.2, 100.0)	354/359	98.6 (96.8, 99.5)
≤ -2.5	102/103	99.0 (94.7, 100.0)	71/73	97.3 (90.5, 99.7)	173/176	98.3 (95.1, 99.6)
Missing	38/38	100.0 (90.7, 100.0)	26/27	96.3 (81.0, 99.9)	64/65	98.5 (91.7, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-003-fi-injapafl-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase

Table 14-4.1.4. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	153/157	97.5 (93.6, 99.3)	151/151	100.0 (97.6, 100.0)	311/315	98.7 (96.8, 99.7)
> Median	142/143	99.3 (96.2, 100.0)	145/149	97.3 (93.3, 99.3)	280/285	98.2 (96.0, 99.4)
Age group						
< 65 years	87/90	96.7 (90.6, 99.3)	164/164	100.0 (97.8, 100.0)	251/254	98.8 (96.6, 99.8)
≥ 65 - < 75 years	120/121	99.2 (95.5, 100.0)	97/98	99.0 (94.4, 100.0)	217/219	99.1 (96.7, 99.9)
≥ 75 years	88/89	98.9 (93.9, 100.0)	35/38	92.1 (78.6, 98.3)	123/127	96.9 (92.1, 99.1)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	148/151	98.0 (94.3, 99.6)	149/151	98.7 (95.3, 99.8)	297/301	98.7 (96.6, 99.6)
> Median	147/149	98.7 (95.2, 99.8)	147/149	98.7 (95.2, 99.8)	294/299	98.3 (96.1, 99.5)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-004-fi-injapafl-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.1.4. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	156/158	98.7 (95.5, 99.8)	191/194	98.5 (95.5, 99.7)	364/369	98.6 (96.9, 99.6)
> Median	139/142	97.9 (94.0, 99.6)	105/106	99.1 (94.9, 100.0)	227/231	98.3 (95.6, 99.5)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	184/186	98.9 (96.2, 99.9)	186/187	99.5 (97.1, 100.0)	325/328	99.1 (97.4, 99.8)
> Median	111/114	97.4 (92.5, 99.5)	110/113	97.3 (92.4, 99.4)	266/272	97.8 (95.3, 99.2)
Any chronic medical condition						
Yes	273/278	98.2 (95.9, 99.4)	238/242	98.3 (95.8, 99.5)	511/520	98.3 (96.7, 99.2)
No	22/22	100.0 (84.6, 100.0)	58/58	100.0 (93.8, 100.0)	80/80	100.0 (95.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-004-fi-injapafl-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.1.4. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Type of chronic medical condition						
Diabetes	20/20	100.0 (83.2, 100.0)	23/23	100.0 (85.2, 100.0)	43/43	100.0 (91.8, 100.0)
Osteoporosis	248/253	98.0 (95.4, 99.4)	84/86	97.7 (91.9, 99.7)	332/339	97.9 (95.8, 99.2)
Hypertension	147/149	98.7 (95.2, 99.8)	155/159	97.5 (93.7, 99.3)	302/308	98.1 (95.8, 99.3)
Other	182/186	97.8 (94.6, 99.4)	130/132	98.5 (94.6, 99.8)	312/318	98.1 (95.9, 99.3)
Any prior PMO therapy						
Yes	251/255	98.4 (96.0, 99.6)	144/146	98.6 (95.1, 99.8)	395/401	98.5 (96.8, 99.4)
No	44/45	97.8 (88.2, 99.9)	152/154	98.7 (95.4, 99.8)	196/199	98.5 (95.7, 99.7)
Any PMO therapy within the 12 months prior to enrollment						
Yes	236/240	98.3 (95.8, 99.5)	117/119	98.3 (94.1, 99.8)	353/359	98.3 (96.4, 99.4)
No	59/60	98.3 (91.1, 100.0)	179/181	98.9 (96.1, 99.9)	238/241	98.8 (96.4, 99.7)

N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-004-fi-injapafl-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.1.4. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Prior calcium and/or vitamin D supplement						
Yes	149/151	98.7 (95.3, 99.8)	19/19	100.0 (82.4, 100.0)	168/170	98.8 (95.8, 99.9)
No	146/149	98.0 (94.2, 99.6)	277/281	98.6 (96.4, 99.6)	423/430	98.4 (96.7, 99.3)

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N = Number of patients in the full analysis set
n = Number of patients who received all injection(s), including baseline injection, from the initial prescribing site irrespective of total number of injections received on study
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-004-fi-injapafl-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.1.5. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Physician specialty						
Rheumatologist	112/113	99.1 (95.2, 100.0)	133/136	97.8 (93.7, 99.5)	245/249	98.4 (95.9, 99.6)
Internist	153/154	99.4 (96.4, 100.0)	54/54	100.0 (93.4, 100.0)	207/208	99.5 (97.4, 100.0)
Endocrinologist	12/13	92.3 (64.0, 99.8)	51/51	100.0 (93.0, 100.0)	63/64	98.4 (91.6, 100.0)
Orthopedist	0/0	- (-, -)	58/59	98.3 (90.9, 100.0)	58/59	98.3 (90.9, 100.0)
Other	18/20	90.0 (68.3, 98.8)	0/0	- (-, -)	18/20	90.0 (68.3, 98.8)
Physician years of practice						
5 to 9 years	20/20	100.0 (83.2, 100.0)	32/32	100.0 (89.1, 100.0)	52/52	100.0 (93.2, 100.0)
≥ 10 years	275/280	98.2 (95.9, 99.4)	264/268	98.5 (96.2, 99.6)	539/548	98.4 (96.9, 99.2)

N = Number of patients in the full analysis set
N1 = Number of patients in the full analysis set with non-missing covariate;
n = Number of patients who received all injection(s) from the initial prescribing site with non-missing covariate data.
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-005-fi-injapafl-covar-sr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.1.5. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Sole physician						
Sole	124/124	100.0 (97.1, 100.0)	233/235	99.1 (97.0, 99.9)	357/359	99.4 (98.0, 99.9)
Group	171/176	97.2 (93.5, 99.1)	63/65	96.9 (89.3, 99.6)	234/241	97.1 (94.1, 98.8)
Group size						
2 - 3	104/106	98.1 (93.4, 99.8)	24/26	92.3 (74.9, 99.1)	128/132	97.0 (92.4, 99.2)
4 - 5	47/50	94.0 (83.5, 98.7)	25/25	100.0 (86.3, 100.0)	72/75	96.0 (88.8, 99.2)
6 - 10	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
> 10	0/0	- (-, -)	14/14	100.0 (76.8, 100.0)	14/14	100.0 (76.8, 100.0)
Center type						
Hospital	86/90	95.6 (89.0, 98.8)	114/117	97.4 (92.7, 99.5)	200/207	96.6 (93.2, 98.6)
Non-hospital	209/210	99.5 (97.4, 100.0)	182/183	99.5 (97.0, 100.0)	391/393	99.5 (98.2, 99.9)

N = Number of patients in the full analysis set
N1 = Number of patients in the full analysis set with non-missing covariate;
n = Number of patients who received all injection(s) from the initial prescribing site with non-missing covariate data.
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-005-fi-injapafl-covar-sr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.1.5. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Academic centre						
Academic	16/17	94.1 (71.3, 99.9)	61/63	96.8 (89.0, 99.6)	77/80	96.3 (89.4, 99.2)
Non-academic	279/283	98.6 (96.4, 99.6)	175/177	98.9 (96.0, 99.9)	454/460	98.7 (97.2, 99.5)
Both	0/0	- (-, -)	39/39	100.0 (91.0, 100.0)	39/39	100.0 (91.0, 100.0)
Not available	0/0	- (-, -)	21/21	100.0 (83.9, 100.0)	21/21	100.0 (83.9, 100.0)
Region						
Urban	275/280	98.2 (95.9, 99.4)	296/300	98.7 (96.6, 99.6)	571/580	98.4 (97.1, 99.3)
Rural	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician active reminder service for next Prolia® administration						
Yes	157/160	98.1 (94.6, 99.6)	253/256	98.8 (96.6, 99.8)	410/416	98.6 (96.9, 99.5)
No	138/140	98.6 (94.9, 99.8)	43/44	97.7 (88.0, 99.9)	181/184	98.4 (95.3, 99.7)

N = Number of patients in the full analysis set
N1 = Number of patients in the full analysis set with non-missing covariate;
n = Number of patients who received all injection(s) from the initial prescribing site with non-missing covariate data.
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-005-fi-injapafl-covar-sr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.1.5. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Types of reminders[a]						
Telephone call	85/87	97.7 (91.9, 99.7)	122/124	98.4 (94.3, 99.8)	207/211	98.1 (95.2, 99.5)
Appointment card	72/73	98.6 (92.6, 100.0)	90/91	98.9 (94.0, 100.0)	162/164	98.8 (95.7, 99.9)
Mailing	40/40	100.0 (91.2, 100.0)	74/74	100.0 (95.1, 100.0)	114/114	100.0 (96.8, 100.0)
Sticker from drug package	0/0	- (-, -)	30/30	100.0 (88.4, 100.0)	30/30	100.0 (88.4, 100.0)
Email/SMS	0/0	- (-, -)	25/25	100.0 (86.3, 100.0)	25/25	100.0 (86.3, 100.0)

N = Number of patients in the full analysis set
N1 = Number of patients in the full analysis set with non-missing covariate;
n = Number of patients who received all injection(s) from the initial prescribing site with non-missing covariate data.
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-005-fi-injapafl-covar-sr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.1.5. Summary of Patients Receiving All Prolia® Injections from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	135/138	97.8 (93.8, 99.5)	176/178	98.9 (96.0, 99.9)	311/316	98.4 (96.3, 99.5)
History of osteoporotic fracture	134/136	98.5 (94.8, 99.8)	54/55	98.2 (90.3, 100.0)	188/191	98.4 (95.5, 99.7)
Multiple risk factors for fracture	123/126	97.6 (93.2, 99.5)	59/60	98.3 (91.1, 100.0)	182/186	97.8 (94.6, 99.4)
Failed other available osteoporosis therapy	107/109	98.2 (93.5, 99.8)	45/47	95.7 (85.5, 99.5)	152/156	97.4 (93.6, 99.3)
Intolerant to other osteoporosis therapy	157/160	98.1 (94.6, 99.6)	39/39	100.0 (91.0, 100.0)	196/199	98.5 (95.7, 99.7)
Other	9/10	90.0 (55.5, 99.7)	17/17	100.0 (80.5, 100.0)	26/27	96.3 (81.0, 99.9)

N = Number of patients in the full analysis set
N1 = Number of patients in the full analysis set with non-missing covariate;
n = Number of patients who received all injection(s) from the initial prescribing site with non-missing covariate data.
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injapafl-covar.sas
Output: t14-04-001-005-fi-injapafl-covar-sr-l.rtf (Date Generated: 14AUG2015: 1:22:33) Source Data: adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.2.1. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Yes	300/300	100.0 (98.8, 100.0)	298/300	99.3 (97.6, 99.9)	598/600	99.7 (98.8, 100.0)
No	0/300	- (-, -)	2/300	0.7 (0.1, 2.4)	2/600	0.3 (0.0, 1.2)
1st post-baseline injection						
Yes	282/283	99.6 (98.0, 100.0)	291/293	99.3 (97.6, 99.9)	573/576	99.5 (98.5, 99.9)
No	1/283	0.4 (0.0, 2.0)	2/293	0.7 (0.1, 2.4)	3/576	0.5 (0.1, 1.5)
2nd post-baseline injection						
Yes	275/276	99.6 (98.0, 100.0)	282/283	99.6 (98.0, 100.0)	557/559	99.6 (98.7, 100.0)
No	1/276	0.4 (0.0, 2.0)	1/283	0.4 (0.0, 2.0)	2/559	0.4 (0.0, 1.3)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site
N1 = Number of patients who received the corresponding injection
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl.sas
Output: t14-04-002-001-fi-injappfl-l.rtf (Date Generated: 20NOV2015: 1:19:31) Source Data: adam.apresc, adam.aslinfo

Table 14-4.2.1. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection						
Yes	260/262	99.2 (97.3, 99.9)	274/276	99.3 (97.4, 99.9)	534/538	99.3 (98.1, 99.8)
No	2/262	0.8 (0.1, 2.7)	2/276	0.7 (0.1, 2.6)	4/538	0.7 (0.2, 1.9)
4th post-baseline injection						
Yes	245/246	99.6 (97.8, 100.0)	240/243	98.8 (96.4, 99.7)	485/489	99.2 (97.9, 99.8)
No	1/246	0.4 (0.0, 2.2)	3/243	1.2 (0.3, 3.6)	4/489	0.8 (0.2, 2.1)

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N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site
N1 = Number of patients who received the corresponding injection
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl.sas
Output: t14-04-002-001-fi-injappfl-l.rtf (Date Generated: 20NOV2015: 1:19:31) Source Data: adam.apresc, adam.aslinfo

Table 14-4.2.2. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Living situation						
At home with spouse/family	210/210	100.0 (98.3, 100.0)	235/237	99.2 (97.0, 99.9)	445/447	99.6 (98.4, 99.9)
At home with care/support	5/5	100.0 (47.8, 100.0)	1/1	100.0 (2.5, 100.0)	6/6	100.0 (54.1, 100.0)
At home alone	80/80	100.0 (95.5, 100.0)	32/32	100.0 (89.1, 100.0)	112/112	100.0 (96.8, 100.0)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	28/28	100.0 (87.7, 100.0)	33/33	100.0 (89.4, 100.0)
Highest educational level						
University	29/29	100.0 (88.1, 100.0)	38/39	97.4 (86.5, 99.9)	67/68	98.5 (92.1, 100.0)
Secondary education	185/185	100.0 (98.0, 100.0)	167/167	100.0 (97.8, 100.0)	352/352	100.0 (99.0, 100.0)
Elementary education	86/86	100.0 (95.8, 100.0)	73/74	98.6 (92.7, 100.0)	159/160	99.4 (96.6, 100.0)
Not applicable	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)	20/20	100.0 (83.2, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-002-fi-injappfl-covar-sd-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aqspq, adam.aslinfo

Table 14-4.2.2. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Employment status						
Retired	265/265	100.0 (98.6, 100.0)	200/202	99.0 (96.5, 99.9)	465/467	99.6 (98.5, 99.9)
Employed	25/25	100.0 (86.3, 100.0)	81/81	100.0 (95.5, 100.0)	106/106	100.0 (96.6, 100.0)
Self employed	6/6	100.0 (54.1, 100.0)	5/5	100.0 (47.8, 100.0)	11/11	100.0 (71.5, 100.0)
Unemployed	4/4	100.0 (39.8, 100.0)	7/7	100.0 (59.0, 100.0)	11/11	100.0 (71.5, 100.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)
1st post-baseline injection						
Living situation						
At home with spouse/family	201/201	100.0 (98.2, 100.0)	229/231	99.1 (96.9, 99.9)	430/432	99.5 (98.3, 99.9)
At home with care/support	5/5	100.0 (47.8, 100.0)	1/1	100.0 (2.5, 100.0)	6/6	100.0 (54.1, 100.0)
At home alone	71/72	98.6 (92.5, 100.0)	31/31	100.0 (88.8, 100.0)	102/103	99.0 (94.7, 100.0)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	28/28	100.0 (87.7, 100.0)	33/33	100.0 (89.4, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-002-fi-injappfl-covar-sd-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aqspq, adam.aslinfo

Table 14-4.2.2. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Highest educational level						
University	26/26	100.0 (86.8, 100.0)	37/38	97.4 (86.2, 99.9)	63/64	98.4 (91.6, 100.0)
Secondary education	174/175	99.4 (96.9, 100.0)	165/165	100.0 (97.8, 100.0)	339/340	99.7 (98.4, 100.0)
Elementary education	82/82	100.0 (95.6, 100.0)	70/71	98.6 (92.4, 100.0)	152/153	99.3 (96.4, 100.0)
Not applicable	0/0	- (-, -)	19/19	100.0 (82.4, 100.0)	19/19	100.0 (82.4, 100.0)
Employment status						
Retired	248/249	99.6 (97.8, 100.0)	194/196	99.0 (96.4, 99.9)	442/445	99.3 (98.0, 99.9)
Employed	24/24	100.0 (85.8, 100.0)	81/81	100.0 (95.5, 100.0)	105/105	100.0 (96.5, 100.0)
Self employed	6/6	100.0 (54.1, 100.0)	4/4	100.0 (39.8, 100.0)	10/10	100.0 (69.2, 100.0)
Unemployed	4/4	100.0 (39.8, 100.0)	7/7	100.0 (59.0, 100.0)	11/11	100.0 (71.5, 100.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-002-fi-injappfl-covar-sd-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aqspq, adam.aslinfo

Table 14-4.2.2. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection						
Living situation						
At home with spouse/family	195/196	99.5 (97.2, 100.0)	223/224	99.6 (97.5, 100.0)	418/420	99.5 (98.3, 99.9)
At home with care/support	5/5	100.0 (47.8, 100.0)	1/1	100.0 (2.5, 100.0)	6/6	100.0 (54.1, 100.0)
At home alone	70/70	100.0 (94.9, 100.0)	30/30	100.0 (88.4, 100.0)	100/100	100.0 (96.4, 100.0)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	26/26	100.0 (86.8, 100.0)	31/31	100.0 (88.8, 100.0)
Highest educational level						
University	26/26	100.0 (86.8, 100.0)	35/36	97.2 (85.5, 99.9)	61/62	98.4 (91.3, 100.0)
Secondary education	170/170	100.0 (97.9, 100.0)	160/160	100.0 (97.7, 100.0)	330/330	100.0 (98.9, 100.0)
Elementary education	79/80	98.8 (93.2, 100.0)	69/69	100.0 (94.8, 100.0)	148/149	99.3 (96.3, 100.0)
Not applicable	0/0	- (-, -)	18/18	100.0 (81.5, 100.0)	18/18	100.0 (81.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-002-fi-injappfl-covar-sd-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aqspq, adam.aslinfo

Table 14-4.2.2. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Employment status						
Retired	241/242	99.6 (97.7, 100.0)	190/191	99.5 (97.1, 100.0)	431/433	99.5 (98.3, 99.9)
Employed	24/24	100.0 (85.8, 100.0)	76/76	100.0 (95.3, 100.0)	100/100	100.0 (96.4, 100.0)
Self employed	6/6	100.0 (54.1, 100.0)	4/4	100.0 (39.8, 100.0)	10/10	100.0 (69.2, 100.0)
Unemployed	4/4	100.0 (39.8, 100.0)	7/7	100.0 (59.0, 100.0)	11/11	100.0 (71.5, 100.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)
3rd post-baseline injection						
Living situation						
At home with spouse/family	186/187	99.5 (97.1, 100.0)	216/218	99.1 (96.7, 99.9)	402/405	99.3 (97.9, 99.8)
At home with care/support	5/5	100.0 (47.8, 100.0)	1/1	100.0 (2.5, 100.0)	6/6	100.0 (54.1, 100.0)
At home alone	64/65	98.5 (91.7, 100.0)	30/30	100.0 (88.4, 100.0)	94/95	98.9 (94.3, 100.0)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	25/25	100.0 (86.3, 100.0)	30/30	100.0 (88.4, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
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Table 14-4.2.2. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Highest educational level						
University	25/25	100.0 (86.3, 100.0)	33/34	97.1 (84.7, 99.9)	58/59	98.3 (90.9, 100.0)
Secondary education	161/162	99.4 (96.6, 100.0)	155/156	99.4 (96.5, 100.0)	316/318	99.4 (97.7, 99.9)
Elementary education	74/75	98.7 (92.8, 100.0)	68/68	100.0 (94.7, 100.0)	142/143	99.3 (96.2, 100.0)
Not applicable	0/0	- (-, -)	18/18	100.0 (81.5, 100.0)	18/18	100.0 (81.5, 100.0)
Employment status						
Retired	228/230	99.1 (96.9, 99.9)	184/186	98.9 (96.2, 99.9)	412/416	99.0 (97.6, 99.7)
Employed	23/23	100.0 (85.2, 100.0)	74/74	100.0 (95.1, 100.0)	97/97	100.0 (96.3, 100.0)
Self employed	6/6	100.0 (54.1, 100.0)	4/4	100.0 (39.8, 100.0)	10/10	100.0 (69.2, 100.0)
Unemployed	3/3	100.0 (29.2, 100.0)	7/7	100.0 (59.0, 100.0)	10/10	100.0 (69.2, 100.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
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Table 14-4.2.2. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection						
Living situation						
At home with spouse/family	177/178	99.4 (96.9, 100.0)	188/190	98.9 (96.2, 99.9)	365/368	99.2 (97.6, 99.8)
At home with care/support	5/5	100.0 (47.8, 100.0)	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)
At home alone	58/58	100.0 (93.8, 100.0)	26/27	96.3 (81.0, 99.9)	84/85	98.8 (93.6, 100.0)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	24/24	100.0 (85.8, 100.0)	29/29	100.0 (88.1, 100.0)
Highest educational level						
University	23/23	100.0 (85.2, 100.0)	32/33	97.0 (84.2, 99.9)	55/56	98.2 (90.4, 100.0)
Secondary education	153/153	100.0 (97.6, 100.0)	132/134	98.5 (94.7, 99.8)	285/287	99.3 (97.5, 99.9)
Elementary education	69/70	98.6 (92.3, 100.0)	59/59	100.0 (93.9, 100.0)	128/129	99.2 (95.8, 100.0)
Not applicable	0/0	- (-, -)	17/17	100.0 (80.5, 100.0)	17/17	100.0 (80.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-002-fi-injappfl-covar-sd-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aqspq, adam.aslinfo

Table 14-4.2.2. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Employment status						
Retired	216/217	99.5 (97.5, 100.0)	164/167	98.2 (94.8, 99.6)	380/384	99.0 (97.4, 99.7)
Employed	22/22	100.0 (84.6, 100.0)	62/62	100.0 (94.2, 100.0)	84/84	100.0 (95.7, 100.0)
Self employed	4/4	100.0 (39.8, 100.0)	3/3	100.0 (29.2, 100.0)	7/7	100.0 (59.0, 100.0)
Unemployed	3/3	100.0 (29.2, 100.0)	6/6	100.0 (54.1, 100.0)	9/9	100.0 (66.4, 100.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-002-fi-injappfl-covar-sd-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aqspq, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Body mass index						
≤ 25 kg/m^2	151/151	100.0 (97.6, 100.0)	103/104	99.0 (94.8, 100.0)	254/255	99.6 (97.8, 100.0)
> 25 kg/m^2	145/145	100.0 (97.5, 100.0)	163/164	99.4 (96.6, 100.0)	308/309	99.7 (98.2, 100.0)
Missing	4/4	100.0 (39.8, 100.0)	32/32	100.0 (89.1, 100.0)	36/36	100.0 (90.3, 100.0)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	210/210	100.0 (98.3, 100.0)	197/199	99.0 (96.4, 99.9)	407/409	99.5 (98.2, 99.9)
> Median	90/90	100.0 (96.0, 100.0)	101/101	100.0 (96.4, 100.0)	191/191	100.0 (98.1, 100.0)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	163/163	100.0 (97.8, 100.0)	160/160	100.0 (97.7, 100.0)	305/305	100.0 (98.8, 100.0)
> Median	137/137	100.0 (97.3, 100.0)	138/140	98.6 (94.9, 99.8)	293/295	99.3 (97.6, 99.9)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Cause of menopause						
Natural onset	248/248	100.0 (98.5, 100.0)	242/244	99.2 (97.1, 99.9)	490/492	99.6 (98.5, 100.0)
Clinically/surgically induced	51/51	100.0 (93.0, 100.0)	53/53	100.0 (93.3, 100.0)	104/104	100.0 (96.5, 100.0)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	36/36	100.0 (90.3, 100.0)	20/20	100.0 (83.2, 100.0)	56/56	100.0 (93.6, 100.0)
No	219/219	100.0 (98.3, 100.0)	220/222	99.1 (96.8, 99.9)	439/441	99.5 (98.4, 99.9)
Unknown	45/45	100.0 (92.1, 100.0)	58/58	100.0 (93.8, 100.0)	103/103	100.0 (96.5, 100.0)
Hospitalized for osteoporotic fracture						
Yes	63/63	100.0 (94.3, 100.0)	11/11	100.0 (71.5, 100.0)	74/74	100.0 (95.1, 100.0)
No	237/237	100.0 (98.5, 100.0)	287/289	99.3 (97.5, 99.9)	524/526	99.6 (98.6, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
≥ 1 Fall in the last 12 months						
Yes	61/61	100.0 (94.1, 100.0)	23/24	95.8 (78.9, 99.9)	84/85	98.8 (93.6, 100.0)
No	239/239	100.0 (98.5, 100.0)	275/276	99.6 (98.0, 100.0)	514/515	99.8 (98.9, 100.0)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	19/19	100.0 (82.4, 100.0)	5/6	83.3 (35.9, 99.6)	24/25	96.0 (79.6, 99.9)
No	281/281	100.0 (98.7, 100.0)	293/294	99.7 (98.1, 100.0)	574/575	99.8 (99.0, 100.0)
Glucocorticoid use						
Yes	33/33	100.0 (89.4, 100.0)	12/12	100.0 (73.5, 100.0)	45/45	100.0 (92.1, 100.0)
No	267/267	100.0 (98.6, 100.0)	286/288	99.3 (97.5, 99.9)	553/555	99.6 (98.7, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Secondary osteoporosis						
Yes	45/45	100.0 (92.1, 100.0)	23/23	100.0 (85.2, 100.0)	68/68	100.0 (94.7, 100.0)
No	255/255	100.0 (98.6, 100.0)	275/277	99.3 (97.4, 99.9)	530/532	99.6 (98.6, 100.0)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	300/300	100.0 (98.8, 100.0)	297/299	99.3 (97.6, 99.9)	597/599	99.7 (98.8, 100.0)
Former smoker						
Yes	35/35	100.0 (90.0, 100.0)	23/23	100.0 (85.2, 100.0)	58/58	100.0 (93.8, 100.0)
No	265/265	100.0 (98.6, 100.0)	275/277	99.3 (97.4, 99.9)	540/542	99.6 (98.7, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Current smoker						
Yes	39/39	100.0 (91.0, 100.0)	29/29	100.0 (88.1, 100.0)	68/68	100.0 (94.7, 100.0)
No	261/261	100.0 (98.6, 100.0)	269/271	99.3 (97.4, 99.9)	530/532	99.6 (98.6, 100.0)
Height loss since self-reported maximal height						
Yes	237/237	100.0 (98.5, 100.0)	109/111	98.2 (93.6, 99.8)	346/348	99.4 (97.9, 99.9)
No	63/63	100.0 (94.3, 100.0)	189/189	100.0 (98.1, 100.0)	252/252	100.0 (98.5, 100.0)
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	125/125	100.0 (97.1, 100.0)	56/56	100.0 (93.6, 100.0)	191/191	100.0 (98.1, 100.0)
> Median	111/111	100.0 (96.7, 100.0)	53/55	96.4 (87.5, 99.6)	154/156	98.7 (95.4, 99.8)
Missing	64/64	100.0 (94.4, 100.0)	189/189	100.0 (98.1, 100.0)	253/253	100.0 (98.6, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Previous fracture						
Yes	221/221	100.0 (98.3, 100.0)	100/100	100.0 (96.4, 100.0)	321/321	100.0 (98.9, 100.0)
No	79/79	100.0 (95.4, 100.0)	198/200	99.0 (96.4, 99.9)	277/279	99.3 (97.4, 99.9)
Previous hip fracture						
Yes	18/18	100.0 (81.5, 100.0)	5/5	100.0 (47.8, 100.0)	23/23	100.0 (85.2, 100.0)
No	282/282	100.0 (98.7, 100.0)	293/295	99.3 (97.6, 99.9)	575/577	99.7 (98.8, 100.0)
Previous vertebral fracture						
Yes	93/93	100.0 (96.1, 100.0)	21/21	100.0 (83.9, 100.0)	114/114	100.0 (96.8, 100.0)
No	207/207	100.0 (98.2, 100.0)	277/279	99.3 (97.4, 99.9)	484/486	99.6 (98.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Time since most recent historical fracture to first injection						
< 12 months	63/63	100.0 (94.3, 100.0)	29/29	100.0 (88.1, 100.0)	92/92	100.0 (96.1, 100.0)
≥ 12 months	158/158	100.0 (97.7, 100.0)	63/63	100.0 (94.3, 100.0)	221/221	100.0 (98.3, 100.0)
Baseline lumbar spine DXA BMD T-score						
> -2.5	70/70	100.0 (94.9, 100.0)	85/85	100.0 (95.8, 100.0)	155/155	100.0 (97.6, 100.0)
≤ -2.5	198/198	100.0 (98.2, 100.0)	186/188	98.9 (96.2, 99.9)	384/386	99.5 (98.1, 99.9)
Missing	32/32	100.0 (89.1, 100.0)	27/27	100.0 (87.2, 100.0)	59/59	100.0 (93.9, 100.0)
Baseline total hip DXA BMD T-score						
> -2.5	179/179	100.0 (98.0, 100.0)	219/220	99.5 (97.5, 100.0)	398/399	99.7 (98.6, 100.0)
≤ -2.5	84/84	100.0 (95.7, 100.0)	26/26	100.0 (86.8, 100.0)	110/110	100.0 (96.7, 100.0)
Missing	37/37	100.0 (90.5, 100.0)	53/54	98.1 (90.1, 100.0)	90/91	98.9 (94.0, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Baseline femoral neck DXA BMD T-score						
> -2.5	159/159	100.0 (97.7, 100.0)	200/200	100.0 (98.2, 100.0)	359/359	100.0 (99.0, 100.0)
≤ -2.5	103/103	100.0 (96.5, 100.0)	72/73	98.6 (92.6, 100.0)	175/176	99.4 (96.9, 100.0)
Missing	38/38	100.0 (90.7, 100.0)	26/27	96.3 (81.0, 99.9)	64/65	98.5 (91.7, 100.0)
1st post-baseline injection						
Body mass index						
≤ 25 kg/m^2	139/139	100.0 (97.4, 100.0)	102/103	99.0 (94.7, 100.0)	241/242	99.6 (97.7, 100.0)
> 25 kg/m^2	139/140	99.3 (96.1, 100.0)	158/159	99.4 (96.5, 100.0)	297/299	99.3 (97.6, 99.9)
Missing	4/4	100.0 (39.8, 100.0)	31/31	100.0 (88.8, 100.0)	35/35	100.0 (90.0, 100.0)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	196/196	100.0 (98.1, 100.0)	191/193	99.0 (96.3, 99.9)	387/389	99.5 (98.2, 99.9)
> Median	86/87	98.9 (93.8, 100.0)	100/100	100.0 (96.4, 100.0)	186/187	99.5 (97.1, 100.0)

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	152/153	99.3 (96.4, 100.0)	158/158	100.0 (97.7, 100.0)	299/300	99.7 (98.2, 100.0)
> Median	130/130	100.0 (97.2, 100.0)	133/135	98.5 (94.8, 99.8)	274/276	99.3 (97.4, 99.9)
Cause of menopause						
Natural onset	235/235	100.0 (98.4, 100.0)	236/238	99.2 (97.0, 99.9)	471/473	99.6 (98.5, 99.9)
Clinically/surgically induced	46/47	97.9 (88.7, 99.9)	52/52	100.0 (93.2, 100.0)	98/99	99.0 (94.5, 100.0)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	33/33	100.0 (89.4, 100.0)	19/19	100.0 (82.4, 100.0)	52/52	100.0 (93.2, 100.0)
No	205/206	99.5 (97.3, 100.0)	216/218	99.1 (96.7, 99.9)	421/424	99.3 (97.9, 99.9)
Unknown	44/44	100.0 (92.0, 100.0)	56/56	100.0 (93.6, 100.0)	100/100	100.0 (96.4, 100.0)

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	60/60	100.0 (94.0, 100.0)	11/11	100.0 (71.5, 100.0)	71/71	100.0 (94.9, 100.0)
No	222/223	99.6 (97.5, 100.0)	280/282	99.3 (97.5, 99.9)	502/505	99.4 (98.3, 99.9)
≥ 1 Fall in the last 12 months						
Yes	56/57	98.2 (90.6, 100.0)	22/23	95.7 (78.1, 99.9)	78/80	97.5 (91.3, 99.7)
No	226/226	100.0 (98.4, 100.0)	269/270	99.6 (98.0, 100.0)	495/496	99.8 (98.9, 100.0)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	17/17	100.0 (80.5, 100.0)	5/6	83.3 (35.9, 99.6)	22/23	95.7 (78.1, 99.9)
No	265/266	99.6 (97.9, 100.0)	286/287	99.7 (98.1, 100.0)	551/553	99.6 (98.7, 100.0)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Glucocorticoid use						
Yes	33/33	100.0 (89.4, 100.0)	12/12	100.0 (73.5, 100.0)	45/45	100.0 (92.1, 100.0)
No	249/250	99.6 (97.8, 100.0)	279/281	99.3 (97.5, 99.9)	528/531	99.4 (98.4, 99.9)
Secondary osteoporosis						
Yes	41/42	97.6 (87.4, 99.9)	22/22	100.0 (84.6, 100.0)	63/64	98.4 (91.6, 100.0)
No	241/241	100.0 (98.5, 100.0)	269/271	99.3 (97.4, 99.9)	510/512	99.6 (98.6, 100.0)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	282/283	99.6 (98.0, 100.0)	290/292	99.3 (97.5, 99.9)	572/575	99.5 (98.5, 99.9)

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Former smoker						
Yes	32/32	100.0 (89.1, 100.0)	22/22	100.0 (84.6, 100.0)	54/54	100.0 (93.4, 100.0)
No	250/251	99.6 (97.8, 100.0)	269/271	99.3 (97.4, 99.9)	519/522	99.4 (98.3, 99.9)
Current smoker						
Yes	37/37	100.0 (90.5, 100.0)	29/29	100.0 (88.1, 100.0)	66/66	100.0 (94.6, 100.0)
No	245/246	99.6 (97.8, 100.0)	262/264	99.2 (97.3, 99.9)	507/510	99.4 (98.3, 99.9)
Height loss since self-reported maximal height						
Yes	222/223	99.6 (97.5, 100.0)	106/108	98.1 (93.5, 99.8)	328/331	99.1 (97.4, 99.8)
No	60/60	100.0 (94.0, 100.0)	185/185	100.0 (98.0, 100.0)	245/245	100.0 (98.5, 100.0)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	119/119	100.0 (96.9, 100.0)	56/56	100.0 (93.6, 100.0)	185/185	100.0 (98.0, 100.0)
> Median	102/103	99.0 (94.7, 100.0)	50/52	96.2 (86.8, 99.5)	142/145	97.9 (94.1, 99.6)
Missing	61/61	100.0 (94.1, 100.0)	185/185	100.0 (98.0, 100.0)	246/246	100.0 (98.5, 100.0)
Previous fracture						
Yes	209/210	99.5 (97.4, 100.0)	98/98	100.0 (96.3, 100.0)	307/308	99.7 (98.2, 100.0)
No	73/73	100.0 (95.1, 100.0)	193/195	99.0 (96.3, 99.9)	266/268	99.3 (97.3, 99.9)
Previous hip fracture						
Yes	17/17	100.0 (80.5, 100.0)	5/5	100.0 (47.8, 100.0)	22/22	100.0 (84.6, 100.0)
No	265/266	99.6 (97.9, 100.0)	286/288	99.3 (97.5, 99.9)	551/554	99.5 (98.4, 99.9)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Previous vertebral fracture						
Yes	88/89	98.9 (93.9, 100.0)	21/21	100.0 (83.9, 100.0)	109/110	99.1 (95.0, 100.0)
No	194/194	100.0 (98.1, 100.0)	270/272	99.3 (97.4, 99.9)	464/466	99.6 (98.5, 99.9)
Time since most recent historical fracture to first injection						
< 12 months	59/60	98.3 (91.1, 100.0)	28/28	100.0 (87.7, 100.0)	87/88	98.9 (93.8, 100.0)
≥ 12 months	150/150	100.0 (97.6, 100.0)	63/63	100.0 (94.3, 100.0)	213/213	100.0 (98.3, 100.0)
Baseline lumbar spine DXA BMD T-score						
> -2.5	65/65	100.0 (94.5, 100.0)	83/83	100.0 (95.7, 100.0)	148/148	100.0 (97.5, 100.0)
≤ -2.5	185/186	99.5 (97.0, 100.0)	181/183	98.9 (96.1, 99.9)	366/369	99.2 (97.6, 99.8)
Missing	32/32	100.0 (89.1, 100.0)	27/27	100.0 (87.2, 100.0)	59/59	100.0 (93.9, 100.0)

N = Number of patients in the full analysis set
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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	164/165	99.4 (96.7, 100.0)	212/213	99.5 (97.4, 100.0)	376/378	99.5 (98.1, 99.9)
≤ -2.5	81/81	100.0 (95.5, 100.0)	26/26	100.0 (86.8, 100.0)	107/107	100.0 (96.6, 100.0)
Missing	37/37	100.0 (90.5, 100.0)	53/54	98.1 (90.1, 100.0)	90/91	98.9 (94.0, 100.0)
Baseline femoral neck DXA BMD T-score						
> -2.5	146/147	99.3 (96.3, 100.0)	194/194	100.0 (98.1, 100.0)	340/341	99.7 (98.4, 100.0)
≤ -2.5	98/98	100.0 (96.3, 100.0)	71/72	98.6 (92.5, 100.0)	169/170	99.4 (96.8, 100.0)
Missing	38/38	100.0 (90.7, 100.0)	26/27	96.3 (81.0, 99.9)	64/65	98.5 (91.7, 100.0)

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(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection						
Body mass index						
≤ 25 kg/m^2	135/136	99.3 (96.0, 100.0)	100/100	100.0 (96.4, 100.0)	235/236	99.6 (97.7, 100.0)
> 25 kg/m^2	136/136	100.0 (97.3, 100.0)	154/155	99.4 (96.5, 100.0)	290/291	99.7 (98.1, 100.0)
Missing	4/4	100.0 (39.8, 100.0)	28/28	100.0 (87.7, 100.0)	32/32	100.0 (89.1, 100.0)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	188/189	99.5 (97.1, 100.0)	186/187	99.5 (97.1, 100.0)	374/376	99.5 (98.1, 99.9)
> Median	87/87	100.0 (95.8, 100.0)	96/96	100.0 (96.2, 100.0)	183/183	100.0 (98.0, 100.0)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	148/149	99.3 (96.3, 100.0)	151/151	100.0 (97.6, 100.0)	289/290	99.7 (98.1, 100.0)
> Median	127/127	100.0 (97.1, 100.0)	131/132	99.2 (95.9, 100.0)	268/269	99.6 (97.9, 100.0)

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Cause of menopause						
Natural onset	231/232	99.6 (97.6, 100.0)	229/230	99.6 (97.6, 100.0)	460/462	99.6 (98.4, 99.9)
Clinically/surgically induced	43/43	100.0 (91.8, 100.0)	50/50	100.0 (92.9, 100.0)	93/93	100.0 (96.1, 100.0)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	32/32	100.0 (89.1, 100.0)	18/18	100.0 (81.5, 100.0)	50/50	100.0 (92.9, 100.0)
No	199/200	99.5 (97.2, 100.0)	209/210	99.5 (97.4, 100.0)	408/410	99.5 (98.2, 99.9)
Unknown	44/44	100.0 (92.0, 100.0)	55/55	100.0 (93.5, 100.0)	99/99	100.0 (96.3, 100.0)
Hospitalized for osteoporotic fracture						
Yes	58/58	100.0 (93.8, 100.0)	11/11	100.0 (71.5, 100.0)	69/69	100.0 (94.8, 100.0)
No	217/218	99.5 (97.5, 100.0)	271/272	99.6 (98.0, 100.0)	488/490	99.6 (98.5, 100.0)

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n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
≥ 1 Fall in the last 12 months						
Yes	54/54	100.0 (93.4, 100.0)	22/22	100.0 (84.6, 100.0)	76/76	100.0 (95.3, 100.0)
No	221/222	99.5 (97.5, 100.0)	260/261	99.6 (97.9, 100.0)	481/483	99.6 (98.5, 99.9)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	16/16	100.0 (79.4, 100.0)	5/5	100.0 (47.8, 100.0)	21/21	100.0 (83.9, 100.0)
No	259/260	99.6 (97.9, 100.0)	277/278	99.6 (98.0, 100.0)	536/538	99.6 (98.7, 100.0)
Glucocorticoid use						
Yes	31/31	100.0 (88.8, 100.0)	11/11	100.0 (71.5, 100.0)	42/42	100.0 (91.6, 100.0)
No	244/245	99.6 (97.7, 100.0)	271/272	99.6 (98.0, 100.0)	515/517	99.6 (98.6, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Secondary osteoporosis						
Yes	41/41	100.0 (91.4, 100.0)	22/22	100.0 (84.6, 100.0)	63/63	100.0 (94.3, 100.0)
No	234/235	99.6 (97.7, 100.0)	260/261	99.6 (97.9, 100.0)	494/496	99.6 (98.6, 100.0)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	275/276	99.6 (98.0, 100.0)	281/282	99.6 (98.0, 100.0)	556/558	99.6 (98.7, 100.0)
Former smoker						
Yes	31/32	96.9 (83.8, 99.9)	20/20	100.0 (83.2, 100.0)	51/52	98.1 (89.7, 100.0)
No	244/244	100.0 (98.5, 100.0)	262/263	99.6 (97.9, 100.0)	506/507	99.8 (98.9, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Current smoker						
Yes	35/35	100.0 (90.0, 100.0)	29/29	100.0 (88.1, 100.0)	64/64	100.0 (94.4, 100.0)
No	240/241	99.6 (97.7, 100.0)	253/254	99.6 (97.8, 100.0)	493/495	99.6 (98.5, 100.0)
Height loss since self-reported maximal height						
Yes	215/216	99.5 (97.4, 100.0)	103/104	99.0 (94.8, 100.0)	318/320	99.4 (97.8, 99.9)
No	60/60	100.0 (94.0, 100.0)	179/179	100.0 (98.0, 100.0)	239/239	100.0 (98.5, 100.0)
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	114/115	99.1 (95.3, 100.0)	53/53	100.0 (93.3, 100.0)	177/178	99.4 (96.9, 100.0)
> Median	100/100	100.0 (96.4, 100.0)	50/51	98.0 (89.6, 100.0)	140/141	99.3 (96.1, 100.0)
Missing	61/61	100.0 (94.1, 100.0)	179/179	100.0 (98.0, 100.0)	240/240	100.0 (98.5, 100.0)

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Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Previous fracture						
Yes	205/205	100.0 (98.2, 100.0)	95/95	100.0 (96.2, 100.0)	300/300	100.0 (98.8, 100.0)
No	70/71	98.6 (92.4, 100.0)	187/188	99.5 (97.1, 100.0)	257/259	99.2 (97.2, 99.9)
Previous hip fracture						
Yes	17/17	100.0 (80.5, 100.0)	5/5	100.0 (47.8, 100.0)	22/22	100.0 (84.6, 100.0)
No	258/259	99.6 (97.9, 100.0)	277/278	99.6 (98.0, 100.0)	535/537	99.6 (98.7, 100.0)
Previous vertebral fracture						
Yes	86/86	100.0 (95.8, 100.0)	21/21	100.0 (83.9, 100.0)	107/107	100.0 (96.6, 100.0)
No	189/190	99.5 (97.1, 100.0)	261/262	99.6 (97.9, 100.0)	450/452	99.6 (98.4, 99.9)

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Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Time since most recent historical fracture to first injection						
< 12 months	57/57	100.0 (93.7, 100.0)	28/28	100.0 (87.7, 100.0)	85/85	100.0 (95.8, 100.0)
≥ 12 months	148/148	100.0 (97.5, 100.0)	60/60	100.0 (94.0, 100.0)	208/208	100.0 (98.2, 100.0)
Baseline lumbar spine DXA BMD T-score						
> -2.5	63/63	100.0 (94.3, 100.0)	79/79	100.0 (95.4, 100.0)	142/142	100.0 (97.4, 100.0)
≤ -2.5	181/182	99.5 (97.0, 100.0)	177/178	99.4 (96.9, 100.0)	358/360	99.4 (98.0, 99.9)
Missing	31/31	100.0 (88.8, 100.0)	26/26	100.0 (86.8, 100.0)	57/57	100.0 (93.7, 100.0)
Baseline total hip DXA BMD T-score						
> -2.5	159/160	99.4 (96.6, 100.0)	204/204	100.0 (98.2, 100.0)	363/364	99.7 (98.5, 100.0)
≤ -2.5	80/80	100.0 (95.5, 100.0)	26/26	100.0 (86.8, 100.0)	106/106	100.0 (96.6, 100.0)
Missing	36/36	100.0 (90.3, 100.0)	52/53	98.1 (89.9, 100.0)	88/89	98.9 (93.9, 100.0)

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Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Baseline femoral neck DXA BMD T-score						
> -2.5	144/144	100.0 (97.5, 100.0)	188/188	100.0 (98.1, 100.0)	332/332	100.0 (98.9, 100.0)
≤ -2.5	94/95	98.9 (94.3, 100.0)	69/69	100.0 (94.8, 100.0)	163/164	99.4 (96.6, 100.0)
Missing	37/37	100.0 (90.5, 100.0)	25/26	96.2 (80.4, 99.9)	62/63	98.4 (91.5, 100.0)
3rd post-baseline injection						
Body mass index						
≤ 25 kg/m^2	129/130	99.2 (95.8, 100.0)	100/100	100.0 (96.4, 100.0)	229/230	99.6 (97.6, 100.0)
> 25 kg/m^2	127/128	99.2 (95.7, 100.0)	149/151	98.7 (95.3, 99.8)	276/279	98.9 (96.9, 99.8)
Missing	4/4	100.0 (39.8, 100.0)	25/25	100.0 (86.3, 100.0)	29/29	100.0 (88.1, 100.0)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	175/177	98.9 (96.0, 99.9)	182/183	99.5 (97.0, 100.0)	357/360	99.2 (97.6, 99.8)
> Median	85/85	100.0 (95.8, 100.0)	92/93	98.9 (94.2, 100.0)	177/178	99.4 (96.9, 100.0)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	143/144	99.3 (96.2, 100.0)	148/148	100.0 (97.5, 100.0)	282/283	99.6 (98.0, 100.0)
> Median	117/118	99.2 (95.4, 100.0)	126/128	98.4 (94.5, 99.8)	252/255	98.8 (96.6, 99.8)
Cause of menopause						
Natural onset	221/223	99.1 (96.8, 99.9)	224/226	99.1 (96.8, 99.9)	445/449	99.1 (97.7, 99.8)
Clinically/surgically induced	38/38	100.0 (90.7, 100.0)	48/48	100.0 (92.6, 100.0)	86/86	100.0 (95.8, 100.0)
Not available	1/1	100.0 (2.5, 100.0)	2/2	100.0 (15.8, 100.0)	3/3	100.0 (29.2, 100.0)
Parental hip fracture						
Yes	30/30	100.0 (88.4, 100.0)	18/18	100.0 (81.5, 100.0)	48/48	100.0 (92.6, 100.0)
No	187/189	98.9 (96.2, 99.9)	205/206	99.5 (97.3, 100.0)	392/395	99.2 (97.8, 99.8)
Unknown	43/43	100.0 (91.8, 100.0)	51/52	98.1 (89.7, 100.0)	94/95	98.9 (94.3, 100.0)

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Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	53/54	98.1 (90.1, 100.0)	10/11	90.9 (58.7, 99.8)	63/65	96.9 (89.3, 99.6)
No	207/208	99.5 (97.4, 100.0)	264/265	99.6 (97.9, 100.0)	471/473	99.6 (98.5, 99.9)
≥ 1 Fall in the last 12 months						
Yes	50/50	100.0 (92.9, 100.0)	22/22	100.0 (84.6, 100.0)	72/72	100.0 (95.0, 100.0)
No	210/212	99.1 (96.6, 99.9)	252/254	99.2 (97.2, 99.9)	462/466	99.1 (97.8, 99.8)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	15/15	100.0 (78.2, 100.0)	5/5	100.0 (47.8, 100.0)	20/20	100.0 (83.2, 100.0)
No	245/247	99.2 (97.1, 99.9)	269/271	99.3 (97.4, 99.9)	514/518	99.2 (98.0, 99.8)

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Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Glucocorticoid use						
Yes	29/29	100.0 (88.1, 100.0)	11/11	100.0 (71.5, 100.0)	40/40	100.0 (91.2, 100.0)
No	231/233	99.1 (96.9, 99.9)	263/265	99.2 (97.3, 99.9)	494/498	99.2 (98.0, 99.8)
Secondary osteoporosis						
Yes	38/38	100.0 (90.7, 100.0)	22/22	100.0 (84.6, 100.0)	60/60	100.0 (94.0, 100.0)
No	222/224	99.1 (96.8, 99.9)	252/254	99.2 (97.2, 99.9)	474/478	99.2 (97.9, 99.8)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	260/262	99.2 (97.3, 99.9)	273/275	99.3 (97.4, 99.9)	533/537	99.3 (98.1, 99.8)

N = Number of patients in the full analysis set
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Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Former smoker						
Yes	29/30	96.7 (82.8, 99.9)	19/19	100.0 (82.4, 100.0)	48/49	98.0 (89.1, 99.9)
No	231/232	99.6 (97.6, 100.0)	255/257	99.2 (97.2, 99.9)	486/489	99.4 (98.2, 99.9)
Current smoker						
Yes	34/34	100.0 (89.7, 100.0)	29/29	100.0 (88.1, 100.0)	63/63	100.0 (94.3, 100.0)
No	226/228	99.1 (96.9, 99.9)	245/247	99.2 (97.1, 99.9)	471/475	99.2 (97.9, 99.8)
Height loss since self-reported maximal height						
Yes	204/206	99.0 (96.5, 99.9)	98/100	98.0 (93.0, 99.8)	302/306	98.7 (96.7, 99.6)
No	56/56	100.0 (93.6, 100.0)	176/176	100.0 (97.9, 100.0)	232/232	100.0 (98.4, 100.0)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	111/112	99.1 (95.1, 100.0)	50/50	100.0 (92.9, 100.0)	171/172	99.4 (96.8, 100.0)
> Median	92/93	98.9 (94.2, 100.0)	48/50	96.0 (86.3, 99.5)	130/133	97.7 (93.5, 99.5)
Missing	57/57	100.0 (93.7, 100.0)	176/176	100.0 (97.9, 100.0)	233/233	100.0 (98.4, 100.0)
Previous fracture						
Yes	192/193	99.5 (97.1, 100.0)	93/94	98.9 (94.2, 100.0)	285/287	99.3 (97.5, 99.9)
No	68/69	98.6 (92.2, 100.0)	181/182	99.5 (97.0, 100.0)	249/251	99.2 (97.2, 99.9)
Previous hip fracture						
Yes	16/16	100.0 (79.4, 100.0)	5/5	100.0 (47.8, 100.0)	21/21	100.0 (83.9, 100.0)
No	244/246	99.2 (97.1, 99.9)	269/271	99.3 (97.4, 99.9)	513/517	99.2 (98.0, 99.8)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Previous vertebral fracture						
Yes	79/80	98.8 (93.2, 100.0)	20/20	100.0 (83.2, 100.0)	99/100	99.0 (94.6, 100.0)
No	181/182	99.5 (97.0, 100.0)	254/256	99.2 (97.2, 99.9)	435/438	99.3 (98.0, 99.9)
Time since most recent historical fracture to first injection						
< 12 months	54/54	100.0 (93.4, 100.0)	26/27	96.3 (81.0, 99.9)	80/81	98.8 (93.3, 100.0)
≥ 12 months	138/139	99.3 (96.1, 100.0)	60/60	100.0 (94.0, 100.0)	198/199	99.5 (97.2, 100.0)
Baseline lumbar spine DXA BMD T-score						
> -2.5	58/58	100.0 (93.8, 100.0)	76/77	98.7 (93.0, 100.0)	134/135	99.3 (95.9, 100.0)
≤ -2.5	172/174	98.9 (95.9, 99.9)	173/174	99.4 (96.8, 100.0)	345/348	99.1 (97.5, 99.8)
Missing	30/30	100.0 (88.4, 100.0)	25/25	100.0 (86.3, 100.0)	55/55	100.0 (93.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	152/153	99.3 (96.4, 100.0)	198/198	100.0 (98.2, 100.0)	350/351	99.7 (98.4, 100.0)
≤ -2.5	73/74	98.6 (92.7, 100.0)	25/26	96.2 (80.4, 99.9)	98/100	98.0 (93.0, 99.8)
Missing	35/35	100.0 (90.0, 100.0)	51/52	98.1 (89.7, 100.0)	86/87	98.9 (93.8, 100.0)
Baseline femoral neck DXA BMD T-score						
> -2.5	133/135	98.5 (94.8, 99.8)	183/183	100.0 (98.0, 100.0)	316/318	99.4 (97.7, 99.9)
≤ -2.5	91/91	100.0 (96.0, 100.0)	67/68	98.5 (92.1, 100.0)	158/159	99.4 (96.5, 100.0)
Missing	36/36	100.0 (90.3, 100.0)	24/25	96.0 (79.6, 99.9)	60/61	98.4 (91.2, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection						
Body mass index						
≤ 25 kg/m^2	121/122	99.2 (95.5, 100.0)	92/92	100.0 (96.1, 100.0)	213/214	99.5 (97.4, 100.0)
> 25 kg/m^2	120/120	100.0 (97.0, 100.0)	135/137	98.5 (94.8, 99.8)	255/257	99.2 (97.2, 99.9)
Missing	4/4	100.0 (39.8, 100.0)	13/14	92.9 (66.1, 99.8)	17/18	94.4 (72.7, 99.9)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	163/164	99.4 (96.6, 100.0)	159/161	98.8 (95.6, 99.8)	322/325	99.1 (97.3, 99.8)
> Median	82/82	100.0 (95.6, 100.0)	81/82	98.8 (93.4, 100.0)	163/164	99.4 (96.6, 100.0)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	138/139	99.3 (96.1, 100.0)	130/130	100.0 (97.2, 100.0)	257/258	99.6 (97.9, 100.0)
> Median	107/107	100.0 (96.6, 100.0)	110/113	97.3 (92.4, 99.4)	228/231	98.7 (96.3, 99.7)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Cause of menopause						
Natural onset	208/209	99.5 (97.4, 100.0)	194/197	98.5 (95.6, 99.7)	402/406	99.0 (97.5, 99.7)
Clinically/surgically induced	36/36	100.0 (90.3, 100.0)	44/44	100.0 (92.0, 100.0)	80/80	100.0 (95.5, 100.0)
Not available	1/1	100.0 (2.5, 100.0)	2/2	100.0 (15.8, 100.0)	3/3	100.0 (29.2, 100.0)
Parental hip fracture						
Yes	28/28	100.0 (87.7, 100.0)	17/17	100.0 (80.5, 100.0)	45/45	100.0 (92.1, 100.0)
No	175/175	100.0 (97.9, 100.0)	182/183	99.5 (97.0, 100.0)	357/358	99.7 (98.5, 100.0)
Unknown	42/43	97.7 (87.7, 99.9)	41/43	95.3 (84.2, 99.4)	83/86	96.5 (90.1, 99.3)
Hospitalized for osteoporotic fracture						
Yes	53/53	100.0 (93.3, 100.0)	10/11	90.9 (58.7, 99.8)	63/64	98.4 (91.6, 100.0)
No	192/193	99.5 (97.1, 100.0)	230/232	99.1 (96.9, 99.9)	422/425	99.3 (98.0, 99.9)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
≥ 1 Fall in the last 12 months						
Yes	46/46	100.0 (92.3, 100.0)	16/17	94.1 (71.3, 99.9)	62/63	98.4 (91.5, 100.0)
No	199/200	99.5 (97.2, 100.0)	224/226	99.1 (96.8, 99.9)	423/426	99.3 (98.0, 99.9)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	15/15	100.0 (78.2, 100.0)	4/4	100.0 (39.8, 100.0)	19/19	100.0 (82.4, 100.0)
No	230/231	99.6 (97.6, 100.0)	236/239	98.7 (96.4, 99.7)	466/470	99.1 (97.8, 99.8)
Glucocorticoid use						
Yes	27/28	96.4 (81.7, 99.9)	10/11	90.9 (58.7, 99.8)	37/39	94.9 (82.7, 99.4)
No	218/218	100.0 (98.3, 100.0)	230/232	99.1 (96.9, 99.9)	448/450	99.6 (98.4, 99.9)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Secondary osteoporosis						
Yes	36/37	97.3 (85.8, 99.9)	21/21	100.0 (83.9, 100.0)	57/58	98.3 (90.8, 100.0)
No	209/209	100.0 (98.3, 100.0)	219/222	98.6 (96.1, 99.7)	428/431	99.3 (98.0, 99.9)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	245/246	99.6 (97.8, 100.0)	239/242	98.8 (96.4, 99.7)	484/488	99.2 (97.9, 99.8)
Former smoker						
Yes	26/26	100.0 (86.8, 100.0)	16/16	100.0 (79.4, 100.0)	42/42	100.0 (91.6, 100.0)
No	219/220	99.5 (97.5, 100.0)	224/227	98.7 (96.2, 99.7)	443/447	99.1 (97.7, 99.8)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Current smoker						
Yes	33/33	100.0 (89.4, 100.0)	28/28	100.0 (87.7, 100.0)	61/61	100.0 (94.1, 100.0)
No	212/213	99.5 (97.4, 100.0)	212/215	98.6 (96.0, 99.7)	424/428	99.1 (97.6, 99.7)
Height loss since self-reported maximal height						
Yes	193/194	99.5 (97.2, 100.0)	84/87	96.6 (90.3, 99.3)	277/281	98.6 (96.4, 99.6)
No	52/52	100.0 (93.2, 100.0)	156/156	100.0 (97.7, 100.0)	208/208	100.0 (98.2, 100.0)
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	108/109	99.1 (95.0, 100.0)	46/47	97.9 (88.7, 99.9)	161/163	98.8 (95.6, 99.9)
> Median	84/84	100.0 (95.7, 100.0)	38/40	95.0 (83.1, 99.4)	115/117	98.3 (94.0, 99.8)
Missing	53/53	100.0 (93.3, 100.0)	156/156	100.0 (97.7, 100.0)	209/209	100.0 (98.3, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Previous fracture						
Yes	179/180	99.4 (96.9, 100.0)	80/81	98.8 (93.3, 100.0)	259/261	99.2 (97.3, 99.9)
No	66/66	100.0 (94.6, 100.0)	160/162	98.8 (95.6, 99.9)	226/228	99.1 (96.9, 99.9)
Previous hip fracture						
Yes	16/16	100.0 (79.4, 100.0)	5/5	100.0 (47.8, 100.0)	21/21	100.0 (83.9, 100.0)
No	229/230	99.6 (97.6, 100.0)	235/238	98.7 (96.4, 99.7)	464/468	99.1 (97.8, 99.8)
Previous vertebral fracture						
Yes	72/73	98.6 (92.6, 100.0)	19/19	100.0 (82.4, 100.0)	91/92	98.9 (94.1, 100.0)
No	173/173	100.0 (97.9, 100.0)	221/224	98.7 (96.1, 99.7)	394/397	99.2 (97.8, 99.8)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Time since most recent historical fracture to first injection						
< 12 months	53/53	100.0 (93.3, 100.0)	24/25	96.0 (79.6, 99.9)	77/78	98.7 (93.1, 100.0)
≥ 12 months	126/127	99.2 (95.7, 100.0)	51/51	100.0 (93.0, 100.0)	177/178	99.4 (96.9, 100.0)
Baseline lumbar spine DXA BMD T-score						
> -2.5	54/54	100.0 (93.4, 100.0)	72/73	98.6 (92.6, 100.0)	126/127	99.2 (95.7, 100.0)
≤ -2.5	162/163	99.4 (96.6, 100.0)	145/147	98.6 (95.2, 99.8)	307/310	99.0 (97.2, 99.8)
Missing	29/29	100.0 (88.1, 100.0)	23/23	100.0 (85.2, 100.0)	52/52	100.0 (93.2, 100.0)
Baseline total hip DXA BMD T-score						
> -2.5	142/143	99.3 (96.2, 100.0)	170/171	99.4 (96.8, 100.0)	312/314	99.4 (97.7, 99.9)
≤ -2.5	69/69	100.0 (94.8, 100.0)	22/23	95.7 (78.1, 99.9)	91/92	98.9 (94.1, 100.0)
Missing	34/34	100.0 (89.7, 100.0)	48/49	98.0 (89.1, 99.9)	82/83	98.8 (93.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.3. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Baseline femoral neck DXA BMD T-score						
> -2.5	126/127	99.2 (95.7, 100.0)	155/156	99.4 (96.5, 100.0)	281/283	99.3 (97.5, 99.9)
≤ -2.5	84/84	100.0 (95.7, 100.0)	63/64	98.4 (91.6, 100.0)	147/148	99.3 (96.3, 100.0)
Missing	35/35	100.0 (90.0, 100.0)	22/23	95.7 (78.1, 99.9)	57/58	98.3 (90.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-003-fi-injappfl-covar-cr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.4. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	157/157	100.0 (97.7, 100.0)	151/151	100.0 (97.6, 100.0)	315/315	100.0 (98.8, 100.0)
> Median	143/143	100.0 (97.5, 100.0)	147/149	98.7 (95.2, 99.8)	283/285	99.3 (97.5, 99.9)
Age group						
< 65 years	90/90	100.0 (96.0, 100.0)	164/164	100.0 (97.8, 100.0)	254/254	100.0 (98.6, 100.0)
≥ 65 - < 75 years	121/121	100.0 (97.0, 100.0)	97/98	99.0 (94.4, 100.0)	218/219	99.5 (97.5, 100.0)
≥ 75 years	89/89	100.0 (95.9, 100.0)	37/38	97.4 (86.2, 99.9)	126/127	99.2 (95.7, 100.0)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	151/151	100.0 (97.6, 100.0)	149/151	98.7 (95.3, 99.8)	299/301	99.3 (97.6, 99.9)
> Median	149/149	100.0 (97.6, 100.0)	149/149	100.0 (97.6, 100.0)	299/299	100.0 (98.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-004-fi-injappfl-covar-pr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.amh, adam.aslbase, adam.aslinfo

Table 14-4.2.4. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	158/158	100.0 (97.7, 100.0)	193/194	99.5 (97.2, 100.0)	367/369	99.5 (98.1, 99.9)
> Median	142/142	100.0 (97.4, 100.0)	105/106	99.1 (94.9, 100.0)	231/231	100.0 (98.4, 100.0)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	186/186	100.0 (98.0, 100.0)	187/187	100.0 (98.0, 100.0)	328/328	100.0 (98.9, 100.0)
> Median	114/114	100.0 (96.8, 100.0)	111/113	98.2 (93.8, 99.8)	270/272	99.3 (97.4, 99.9)
Any chronic medical condition						
Yes	278/278	100.0 (98.7, 100.0)	240/242	99.2 (97.0, 99.9)	518/520	99.6 (98.6, 100.0)
No	22/22	100.0 (84.6, 100.0)	58/58	100.0 (93.8, 100.0)	80/80	100.0 (95.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-004-fi-injappfl-covar-pr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.amh, adam.aslbase, adam.aslinfo

Table 14-4.2.4. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Type of chronic medical condition						
Diabetes	20/20	100.0 (83.2, 100.0)	23/23	100.0 (85.2, 100.0)	43/43	100.0 (91.8, 100.0)
Osteoporosis	253/253	100.0 (98.6, 100.0)	85/86	98.8 (93.7, 100.0)	338/339	99.7 (98.4, 100.0)
Hypertension	149/149	100.0 (97.6, 100.0)	157/159	98.7 (95.5, 99.8)	306/308	99.4 (97.7, 99.9)
Other	186/186	100.0 (98.0, 100.0)	131/132	99.2 (95.9, 100.0)	317/318	99.7 (98.3, 100.0)
Any prior PMO therapy						
Yes	255/255	100.0 (98.6, 100.0)	146/146	100.0 (97.5, 100.0)	401/401	100.0 (99.1, 100.0)
No	45/45	100.0 (92.1, 100.0)	152/154	98.7 (95.4, 99.8)	197/199	99.0 (96.4, 99.9)
Any PMO therapy within the 12 months prior to enrollment						
Yes	240/240	100.0 (98.5, 100.0)	119/119	100.0 (96.9, 100.0)	359/359	100.0 (99.0, 100.0)
No	60/60	100.0 (94.0, 100.0)	179/181	98.9 (96.1, 99.9)	239/241	99.2 (97.0, 99.9)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.4. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Prior calcium and/or vitamin D supplement						
Yes	151/151	100.0 (97.6, 100.0)	19/19	100.0 (82.4, 100.0)	170/170	100.0 (97.9, 100.0)
No	149/149	100.0 (97.6, 100.0)	279/281	99.3 (97.5, 99.9)	428/430	99.5 (98.3, 99.9)
1st post-baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	146/147	99.3 (96.3, 100.0)	148/148	100.0 (97.5, 100.0)	305/306	99.7 (98.2, 100.0)
> Median	136/136	100.0 (97.3, 100.0)	143/145	98.6 (95.1, 99.8)	268/270	99.3 (97.3, 99.9)
Age group						
< 65 years	87/87	100.0 (95.8, 100.0)	161/161	100.0 (97.7, 100.0)	248/248	100.0 (98.5, 100.0)
≥ 65 - < 75 years	111/112	99.1 (95.1, 100.0)	95/96	99.0 (94.3, 100.0)	206/208	99.0 (96.6, 99.9)
≥ 75 years	84/84	100.0 (95.7, 100.0)	35/36	97.2 (85.5, 99.9)	119/120	99.2 (95.4, 100.0)

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Table 14-4.2.4. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	141/142	99.3 (96.1, 100.0)	145/147	98.6 (95.2, 99.8)	286/289	99.0 (97.0, 99.8)
> Median	141/141	100.0 (97.4, 100.0)	146/146	100.0 (97.5, 100.0)	287/287	100.0 (98.7, 100.0)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	151/151	100.0 (97.6, 100.0)	189/190	99.5 (97.1, 100.0)	354/356	99.4 (98.0, 99.9)
> Median	131/132	99.2 (95.9, 100.0)	102/103	99.0 (94.7, 100.0)	219/220	99.5 (97.5, 100.0)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	178/178	100.0 (97.9, 100.0)	184/184	100.0 (98.0, 100.0)	319/319	100.0 (98.9, 100.0)
> Median	104/105	99.0 (94.8, 100.0)	107/109	98.2 (93.5, 99.8)	254/257	98.8 (96.6, 99.8)

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Any chronic medical condition						
Yes	262/263	99.6 (97.9, 100.0)	234/236	99.2 (97.0, 99.9)	496/499	99.4 (98.3, 99.9)
No	20/20	100.0 (83.2, 100.0)	57/57	100.0 (93.7, 100.0)	77/77	100.0 (95.3, 100.0)
Type of chronic medical condition						
Diabetes	18/18	100.0 (81.5, 100.0)	21/21	100.0 (83.9, 100.0)	39/39	100.0 (91.0, 100.0)
Osteoporosis	237/238	99.6 (97.7, 100.0)	83/84	98.8 (93.5, 100.0)	320/322	99.4 (97.8, 99.9)
Hypertension	140/141	99.3 (96.1, 100.0)	153/155	98.7 (95.4, 99.8)	293/296	99.0 (97.1, 99.8)
Other	174/175	99.4 (96.9, 100.0)	127/128	99.2 (95.7, 100.0)	301/303	99.3 (97.6, 99.9)
Any prior PMO therapy						
Yes	238/239	99.6 (97.7, 100.0)	143/143	100.0 (97.5, 100.0)	381/382	99.7 (98.6, 100.0)
No	44/44	100.0 (92.0, 100.0)	148/150	98.7 (95.3, 99.8)	192/194	99.0 (96.3, 99.9)

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Percentages based on N1

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Table 14-4.2.4. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Any PMO therapy within the 12 months prior to enrollment						
Yes	223/224	99.6 (97.5, 100.0)	118/118	100.0 (96.9, 100.0)	341/342	99.7 (98.4, 100.0)
No	59/59	100.0 (93.9, 100.0)	173/175	98.9 (95.9, 99.9)	232/234	99.1 (96.9, 99.9)
Prior calcium and/or vitamin D supplement						
Yes	140/141	99.3 (96.1, 100.0)	19/19	100.0 (82.4, 100.0)	159/160	99.4 (96.6, 100.0)
No	142/142	100.0 (97.4, 100.0)	272/274	99.3 (97.4, 99.9)	414/416	99.5 (98.3, 99.9)
2nd post-baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	141/142	99.3 (96.1, 100.0)	142/142	100.0 (97.4, 100.0)	294/295	99.7 (98.1, 100.0)
> Median	134/134	100.0 (97.3, 100.0)	140/141	99.3 (96.1, 100.0)	263/264	99.6 (97.9, 100.0)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Age group						
< 65 years	84/85	98.8 (93.6, 100.0)	155/155	100.0 (97.6, 100.0)	239/240	99.6 (97.7, 100.0)
≥ 65 - < 75 years	108/108	100.0 (96.6, 100.0)	93/94	98.9 (94.2, 100.0)	201/202	99.5 (97.3, 100.0)
≥ 75 years	83/83	100.0 (95.7, 100.0)	34/34	100.0 (89.7, 100.0)	117/117	100.0 (96.9, 100.0)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	135/136	99.3 (96.0, 100.0)	142/143	99.3 (96.2, 100.0)	278/280	99.3 (97.4, 99.9)
> Median	140/140	100.0 (97.4, 100.0)	140/140	100.0 (97.4, 100.0)	279/279	100.0 (98.7, 100.0)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	149/149	100.0 (97.6, 100.0)	183/184	99.5 (97.0, 100.0)	346/347	99.7 (98.4, 100.0)
> Median	126/127	99.2 (95.7, 100.0)	99/99	100.0 (96.3, 100.0)	211/212	99.5 (97.4, 100.0)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	175/175	100.0 (97.9, 100.0)	178/178	100.0 (97.9, 100.0)	312/312	100.0 (98.8, 100.0)
> Median	100/101	99.0 (94.6, 100.0)	104/105	99.0 (94.8, 100.0)	245/247	99.2 (97.1, 99.9)
Any chronic medical condition						
Yes	255/256	99.6 (97.8, 100.0)	228/229	99.6 (97.6, 100.0)	483/485	99.6 (98.5, 100.0)
No	20/20	100.0 (83.2, 100.0)	54/54	100.0 (93.4, 100.0)	74/74	100.0 (95.1, 100.0)
Type of chronic medical condition						
Diabetes	18/18	100.0 (81.5, 100.0)	20/20	100.0 (83.2, 100.0)	38/38	100.0 (90.7, 100.0)
Osteoporosis	230/231	99.6 (97.6, 100.0)	83/83	100.0 (95.7, 100.0)	313/314	99.7 (98.2, 100.0)
Hypertension	134/135	99.3 (95.9, 100.0)	148/149	99.3 (96.3, 100.0)	282/284	99.3 (97.5, 99.9)
Other	169/170	99.4 (96.8, 100.0)	124/124	100.0 (97.1, 100.0)	293/294	99.7 (98.1, 100.0)

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Any prior PMO therapy						
Yes	234/234	100.0 (98.4, 100.0)	136/136	100.0 (97.3, 100.0)	370/370	100.0 (99.0, 100.0)
No	41/42	97.6 (87.4, 99.9)	146/147	99.3 (96.3, 100.0)	187/189	98.9 (96.2, 99.9)
Any PMO therapy within the 12 months prior to enrollment						
Yes	219/219	100.0 (98.3, 100.0)	112/112	100.0 (96.8, 100.0)	331/331	100.0 (98.9, 100.0)
No	56/57	98.2 (90.6, 100.0)	170/171	99.4 (96.8, 100.0)	226/228	99.1 (96.9, 99.9)
Prior calcium and/or vitamin D supplement						
Yes	138/138	100.0 (97.4, 100.0)	18/18	100.0 (81.5, 100.0)	156/156	100.0 (97.7, 100.0)
No	137/138	99.3 (96.0, 100.0)	264/265	99.6 (97.9, 100.0)	401/403	99.5 (98.2, 99.9)

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	135/136	99.3 (96.0, 100.0)	140/140	100.0 (97.4, 100.0)	286/287	99.7 (98.1, 100.0)
> Median	125/126	99.2 (95.7, 100.0)	134/136	98.5 (94.8, 99.8)	248/251	98.8 (96.5, 99.8)
Age group						
< 65 years	82/83	98.8 (93.5, 100.0)	153/153	100.0 (97.6, 100.0)	235/236	99.6 (97.7, 100.0)
≥ 65 - < 75 years	102/102	100.0 (96.4, 100.0)	88/89	98.9 (93.9, 100.0)	190/191	99.5 (97.1, 100.0)
≥ 75 years	76/77	98.7 (93.0, 100.0)	33/34	97.1 (84.7, 99.9)	109/111	98.2 (93.6, 99.8)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	131/131	100.0 (97.2, 100.0)	141/142	99.3 (96.1, 100.0)	272/273	99.6 (98.0, 100.0)
> Median	129/131	98.5 (94.6, 99.8)	133/134	99.3 (95.9, 100.0)	262/265	98.9 (96.7, 99.8)

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Percentages based on N1

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(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	141/143	98.6 (95.0, 99.8)	175/177	98.9 (96.0, 99.9)	335/338	99.1 (97.4, 99.8)
> Median	119/119	100.0 (96.9, 100.0)	99/99	100.0 (96.3, 100.0)	199/200	99.5 (97.2, 100.0)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	167/169	98.8 (95.8, 99.9)	172/173	99.4 (96.8, 100.0)	299/302	99.0 (97.1, 99.8)
> Median	93/93	100.0 (96.1, 100.0)	102/103	99.0 (94.7, 100.0)	235/236	99.6 (97.7, 100.0)
Any chronic medical condition						
Yes	241/243	99.2 (97.1, 99.9)	223/225	99.1 (96.8, 99.9)	464/468	99.1 (97.8, 99.8)
No	19/19	100.0 (82.4, 100.0)	51/51	100.0 (93.0, 100.0)	70/70	100.0 (94.9, 100.0)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Type of chronic medical condition						
Diabetes	16/16	100.0 (79.4, 100.0)	19/19	100.0 (82.4, 100.0)	35/35	100.0 (90.0, 100.0)
Osteoporosis	216/218	99.1 (96.7, 99.9)	81/81	100.0 (95.5, 100.0)	297/299	99.3 (97.6, 99.9)
Hypertension	123/123	100.0 (97.0, 100.0)	145/147	98.6 (95.2, 99.8)	268/270	99.3 (97.3, 99.9)
Other	161/162	99.4 (96.6, 100.0)	123/123	100.0 (97.0, 100.0)	284/285	99.6 (98.1, 100.0)
Any prior PMO therapy						
Yes	218/220	99.1 (96.8, 99.9)	130/131	99.2 (95.8, 100.0)	348/351	99.1 (97.5, 99.8)
No	42/42	100.0 (91.6, 100.0)	144/145	99.3 (96.2, 100.0)	186/187	99.5 (97.1, 100.0)
Any PMO therapy within the 12 months prior to enrollment						
Yes	203/205	99.0 (96.5, 99.9)	106/107	99.1 (94.9, 100.0)	309/312	99.0 (97.2, 99.8)
No	57/57	100.0 (93.7, 100.0)	168/169	99.4 (96.7, 100.0)	225/226	99.6 (97.6, 100.0)

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Percentages based on N1

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(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Prior calcium and/or vitamin D supplement						
Yes	126/127	99.2 (95.7, 100.0)	18/18	100.0 (81.5, 100.0)	144/145	99.3 (96.2, 100.0)
No	134/135	99.3 (95.9, 100.0)	256/258	99.2 (97.2, 99.9)	390/393	99.2 (97.8, 99.8)
4th post-baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	130/131	99.2 (95.8, 100.0)	123/123	100.0 (97.0, 100.0)	260/261	99.6 (97.9, 100.0)
> Median	115/115	100.0 (96.8, 100.0)	117/120	97.5 (92.9, 99.5)	225/228	98.7 (96.2, 99.7)
Age group						
< 65 years	80/81	98.8 (93.3, 100.0)	133/133	100.0 (97.3, 100.0)	213/214	99.5 (97.4, 100.0)
≥ 65 - < 75 years	94/94	100.0 (96.2, 100.0)	80/81	98.8 (93.3, 100.0)	174/175	99.4 (96.9, 100.0)
≥ 75 years	71/71	100.0 (94.9, 100.0)	27/29	93.1 (77.2, 99.2)	98/100	98.0 (93.0, 99.8)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-004-fi-injappfl-covar-pr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.amh, adam.aslbase, adam.aslinfo

Table 14-4.2.4. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	123/124	99.2 (95.6, 100.0)	123/124	99.2 (95.6, 100.0)	246/247	99.6 (97.8, 100.0)
> Median	122/122	100.0 (97.0, 100.0)	117/119	98.3 (94.1, 99.8)	239/242	98.8 (96.4, 99.7)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	135/135	100.0 (97.3, 100.0)	147/150	98.0 (94.3, 99.6)	297/300	99.0 (97.1, 99.8)
> Median	110/111	99.1 (95.1, 100.0)	93/93	100.0 (96.1, 100.0)	188/189	99.5 (97.1, 100.0)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	159/159	100.0 (97.7, 100.0)	153/154	99.4 (96.4, 100.0)	274/275	99.6 (98.0, 100.0)
> Median	86/87	98.9 (93.8, 100.0)	87/89	97.8 (92.1, 99.7)	211/214	98.6 (96.0, 99.7)

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n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.4. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Any chronic medical condition						
Yes	227/228	99.6 (97.6, 100.0)	198/201	98.5 (95.7, 99.7)	425/429	99.1 (97.6, 99.7)
No	18/18	100.0 (81.5, 100.0)	42/42	100.0 (91.6, 100.0)	60/60	100.0 (94.0, 100.0)
Type of chronic medical condition						
Diabetes	14/14	100.0 (76.8, 100.0)	13/13	100.0 (75.3, 100.0)	27/27	100.0 (87.2, 100.0)
Osteoporosis	205/206	99.5 (97.3, 100.0)	71/72	98.6 (92.5, 100.0)	276/278	99.3 (97.4, 99.9)
Hypertension	116/116	100.0 (96.9, 100.0)	126/129	97.7 (93.4, 99.5)	242/245	98.8 (96.5, 99.7)
Other	147/148	99.3 (96.3, 100.0)	112/113	99.1 (95.2, 100.0)	259/261	99.2 (97.3, 99.9)
Any prior PMO therapy						
Yes	206/207	99.5 (97.3, 100.0)	114/116	98.3 (93.9, 99.8)	320/323	99.1 (97.3, 99.8)
No	39/39	100.0 (91.0, 100.0)	126/127	99.2 (95.7, 100.0)	165/166	99.4 (96.7, 100.0)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.4. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Any PMO therapy within the 12 months prior to enrollment						
Yes	192/193	99.5 (97.1, 100.0)	92/94	97.9 (92.5, 99.7)	284/287	99.0 (97.0, 99.8)
No	53/53	100.0 (93.3, 100.0)	148/149	99.3 (96.3, 100.0)	201/202	99.5 (97.3, 100.0)
Prior calcium and/or vitamin D supplement						
Yes	118/118	100.0 (96.9, 100.0)	14/14	100.0 (76.8, 100.0)	132/132	100.0 (97.2, 100.0)
No	127/128	99.2 (95.7, 100.0)	226/229	98.7 (96.2, 99.7)	353/357	98.9 (97.2, 99.7)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Physician specialty						
Rheumatologist	113/113	100.0 (96.8, 100.0)	135/136	99.3 (96.0, 100.0)	248/249	99.6 (97.8, 100.0)
Internist	154/154	100.0 (97.6, 100.0)	54/54	100.0 (93.4, 100.0)	208/208	100.0 (98.2, 100.0)
Endocrinologist	13/13	100.0 (75.3, 100.0)	51/51	100.0 (93.0, 100.0)	64/64	100.0 (94.4, 100.0)
Orthopedist	0/0	- (-, -)	58/59	98.3 (90.9, 100.0)	58/59	98.3 (90.9, 100.0)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	20/20	100.0 (83.2, 100.0)	32/32	100.0 (89.1, 100.0)	52/52	100.0 (93.2, 100.0)
≥ 10 years	280/280	100.0 (98.7, 100.0)	266/268	99.3 (97.3, 99.9)	546/548	99.6 (98.7, 100.0)

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n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Sole physician						
Sole	124/124	100.0 (97.1, 100.0)	234/235	99.6 (97.7, 100.0)	358/359	99.7 (98.5, 100.0)
Group	176/176	100.0 (97.9, 100.0)	64/65	98.5 (91.7, 100.0)	240/241	99.6 (97.7, 100.0)
Group size						
2 - 3	106/106	100.0 (96.6, 100.0)	25/26	96.2 (80.4, 99.9)	131/132	99.2 (95.9, 100.0)
4 - 5	50/50	100.0 (92.9, 100.0)	25/25	100.0 (86.3, 100.0)	75/75	100.0 (95.2, 100.0)
6 - 10	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
> 10	0/0	- (-, -)	14/14	100.0 (76.8, 100.0)	14/14	100.0 (76.8, 100.0)

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n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Center type						
Hospital	90/90	100.0 (96.0, 100.0)	116/117	99.1 (95.3, 100.0)	206/207	99.5 (97.3, 100.0)
Non-hospital	210/210	100.0 (98.3, 100.0)	182/183	99.5 (97.0, 100.0)	392/393	99.7 (98.6, 100.0)
Academic centre						
Academic	17/17	100.0 (80.5, 100.0)	62/63	98.4 (91.5, 100.0)	79/80	98.8 (93.2, 100.0)
Non-academic	283/283	100.0 (98.7, 100.0)	176/177	99.4 (96.9, 100.0)	459/460	99.8 (98.8, 100.0)
Both	0/0	- (-, -)	39/39	100.0 (91.0, 100.0)	39/39	100.0 (91.0, 100.0)
Not available	0/0	- (-, -)	21/21	100.0 (83.9, 100.0)	21/21	100.0 (83.9, 100.0)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Region						
Urban	280/280	100.0 (98.7, 100.0)	298/300	99.3 (97.6, 99.9)	578/580	99.7 (98.8, 100.0)
Rural	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician active reminder service for next Prolia® administration						
Yes	160/160	100.0 (97.7, 100.0)	255/256	99.6 (97.8, 100.0)	415/416	99.8 (98.7, 100.0)
No	140/140	100.0 (97.4, 100.0)	43/44	97.7 (88.0, 99.9)	183/184	99.5 (97.0, 100.0)

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n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	87/87	100.0 (95.8, 100.0)	123/124	99.2 (95.6, 100.0)	210/211	99.5 (97.4, 100.0)
Appointment card	73/73	100.0 (95.1, 100.0)	91/91	100.0 (96.0, 100.0)	164/164	100.0 (97.8, 100.0)
Mailing	40/40	100.0 (91.2, 100.0)	74/74	100.0 (95.1, 100.0)	114/114	100.0 (96.8, 100.0)
Sticker from drug package	0/0	- (-, -)	30/30	100.0 (88.4, 100.0)	30/30	100.0 (88.4, 100.0)
Email/SMS	0/0	- (-, -)	25/25	100.0 (86.3, 100.0)	25/25	100.0 (86.3, 100.0)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	138/138	100.0 (97.4, 100.0)	177/178	99.4 (96.9, 100.0)	315/316	99.7 (98.2, 100.0)
History of osteoporotic fracture	136/136	100.0 (97.3, 100.0)	55/55	100.0 (93.5, 100.0)	191/191	100.0 (98.1, 100.0)
Multiple risk factors for fracture	126/126	100.0 (97.1, 100.0)	59/60	98.3 (91.1, 100.0)	185/186	99.5 (97.0, 100.0)
Failed other available osteoporosis therapy	109/109	100.0 (96.7, 100.0)	47/47	100.0 (92.5, 100.0)	156/156	100.0 (97.7, 100.0)
Intolerant to other osteoporosis therapy	160/160	100.0 (97.7, 100.0)	39/39	100.0 (91.0, 100.0)	199/199	100.0 (98.2, 100.0)
Other	10/10	100.0 (69.2, 100.0)	17/17	100.0 (80.5, 100.0)	27/27	100.0 (87.2, 100.0)

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n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection						
Physician specialty						
Rheumatologist	106/106	100.0 (96.6, 100.0)	131/132	99.2 (95.9, 100.0)	237/238	99.6 (97.7, 100.0)
Internist	143/144	99.3 (96.2, 100.0)	53/53	100.0 (93.3, 100.0)	196/197	99.5 (97.2, 100.0)
Endocrinologist	13/13	100.0 (75.3, 100.0)	49/49	100.0 (92.7, 100.0)	62/62	100.0 (94.2, 100.0)
Orthopedist	0/0	- (-, -)	58/59	98.3 (90.9, 100.0)	58/59	98.3 (90.9, 100.0)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	20/20	100.0 (83.2, 100.0)	31/31	100.0 (88.8, 100.0)	51/51	100.0 (93.0, 100.0)
≥ 10 years	262/263	99.6 (97.9, 100.0)	260/262	99.2 (97.3, 99.9)	522/525	99.4 (98.3, 99.9)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Sole physician						
Sole	119/119	100.0 (96.9, 100.0)	228/229	99.6 (97.6, 100.0)	347/348	99.7 (98.4, 100.0)
Group	163/164	99.4 (96.6, 100.0)	63/64	98.4 (91.6, 100.0)	226/228	99.1 (96.9, 99.9)
Group size						
2 - 3	98/98	100.0 (96.3, 100.0)	25/26	96.2 (80.4, 99.9)	123/124	99.2 (95.6, 100.0)
4 - 5	45/46	97.8 (88.5, 99.9)	25/25	100.0 (86.3, 100.0)	70/71	98.6 (92.4, 100.0)
6 - 10	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
> 10	0/0	- (-, -)	13/13	100.0 (75.3, 100.0)	13/13	100.0 (75.3, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Center type						
Hospital	88/88	100.0 (95.9, 100.0)	111/112	99.1 (95.1, 100.0)	199/200	99.5 (97.2, 100.0)
Non-hospital	194/195	99.5 (97.2, 100.0)	180/181	99.4 (97.0, 100.0)	374/376	99.5 (98.1, 99.9)
Academic centre						
Academic	15/15	100.0 (78.2, 100.0)	62/63	98.4 (91.5, 100.0)	77/78	98.7 (93.1, 100.0)
Non-academic	267/268	99.6 (97.9, 100.0)	170/171	99.4 (96.8, 100.0)	437/439	99.5 (98.4, 99.9)
Both	0/0	- (-, -)	38/38	100.0 (90.7, 100.0)	38/38	100.0 (90.7, 100.0)
Not available	0/0	- (-, -)	21/21	100.0 (83.9, 100.0)	21/21	100.0 (83.9, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Region						
Urban	263/264	99.6 (97.9, 100.0)	291/293	99.3 (97.6, 99.9)	554/557	99.5 (98.4, 99.9)
Rural	19/19	100.0 (82.4, 100.0)	0/0	- (-, -)	19/19	100.0 (82.4, 100.0)
Physician active reminder service for next Prolia® administration						
Yes	151/152	99.3 (96.4, 100.0)	250/251	99.6 (97.8, 100.0)	401/403	99.5 (98.2, 99.9)
No	131/131	100.0 (97.2, 100.0)	41/42	97.6 (87.4, 99.9)	172/173	99.4 (96.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	80/81	98.8 (93.3, 100.0)	122/123	99.2 (95.6, 100.0)	202/204	99.0 (96.5, 99.9)
Appointment card	71/71	100.0 (94.9, 100.0)	87/87	100.0 (95.8, 100.0)	158/158	100.0 (97.7, 100.0)
Mailing	40/40	100.0 (91.2, 100.0)	73/73	100.0 (95.1, 100.0)	113/113	100.0 (96.8, 100.0)
Sticker from drug package	0/0	- (-, -)	30/30	100.0 (88.4, 100.0)	30/30	100.0 (88.4, 100.0)
Email/SMS	0/0	- (-, -)	25/25	100.0 (86.3, 100.0)	25/25	100.0 (86.3, 100.0)

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N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	130/131	99.2 (95.8, 100.0)	174/175	99.4 (96.9, 100.0)	304/306	99.3 (97.7, 99.9)
History of osteoporotic fracture	131/132	99.2 (95.9, 100.0)	54/54	100.0 (93.4, 100.0)	185/186	99.5 (97.0, 100.0)
Multiple risk factors for fracture	117/118	99.2 (95.4, 100.0)	58/59	98.3 (90.9, 100.0)	175/177	98.9 (96.0, 99.9)
Failed other available osteoporosis therapy	102/103	99.0 (94.7, 100.0)	46/46	100.0 (92.3, 100.0)	148/149	99.3 (96.3, 100.0)
Intolerant to other osteoporosis therapy	149/149	100.0 (97.6, 100.0)	37/37	100.0 (90.5, 100.0)	186/186	100.0 (98.0, 100.0)
Other	9/9	100.0 (66.4, 100.0)	16/16	100.0 (79.4, 100.0)	25/25	100.0 (86.3, 100.0)

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n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection						
Physician specialty						
Rheumatologist	103/104	99.0 (94.8, 100.0)	128/128	100.0 (97.2, 100.0)	231/232	99.6 (97.6, 100.0)
Internist	139/139	100.0 (97.4, 100.0)	49/49	100.0 (92.7, 100.0)	188/188	100.0 (98.1, 100.0)
Endocrinologist	13/13	100.0 (75.3, 100.0)	47/47	100.0 (92.5, 100.0)	60/60	100.0 (94.0, 100.0)
Orthopedist	0/0	- (-, -)	58/59	98.3 (90.9, 100.0)	58/59	98.3 (90.9, 100.0)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	20/20	100.0 (83.2, 100.0)	30/30	100.0 (88.4, 100.0)	50/50	100.0 (92.9, 100.0)
≥ 10 years	255/256	99.6 (97.8, 100.0)	252/253	99.6 (97.8, 100.0)	507/509	99.6 (98.6, 100.0)

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n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Sole physician						
Sole	116/116	100.0 (96.9, 100.0)	222/223	99.6 (97.5, 100.0)	338/339	99.7 (98.4, 100.0)
Group	159/160	99.4 (96.6, 100.0)	60/60	100.0 (94.0, 100.0)	219/220	99.5 (97.5, 100.0)
Group size						
2 - 3	95/96	99.0 (94.3, 100.0)	25/25	100.0 (86.3, 100.0)	120/121	99.2 (95.5, 100.0)
4 - 5	44/44	100.0 (92.0, 100.0)	23/23	100.0 (85.2, 100.0)	67/67	100.0 (94.6, 100.0)
6 - 10	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
> 10	0/0	- (-, -)	12/12	100.0 (73.5, 100.0)	12/12	100.0 (73.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Center type						
Hospital	86/87	98.9 (93.8, 100.0)	108/108	100.0 (96.6, 100.0)	194/195	99.5 (97.2, 100.0)
Non-hospital	189/189	100.0 (98.1, 100.0)	174/175	99.4 (96.9, 100.0)	363/364	99.7 (98.5, 100.0)
Academic centre						
Academic	14/15	93.3 (68.1, 99.8)	62/62	100.0 (94.2, 100.0)	76/77	98.7 (93.0, 100.0)
Non-academic	261/261	100.0 (98.6, 100.0)	166/167	99.4 (96.7, 100.0)	427/428	99.8 (98.7, 100.0)
Both	0/0	- (-, -)	35/35	100.0 (90.0, 100.0)	35/35	100.0 (90.0, 100.0)
Not available	0/0	- (-, -)	19/19	100.0 (82.4, 100.0)	19/19	100.0 (82.4, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Region						
Urban	257/258	99.6 (97.9, 100.0)	282/283	99.6 (98.0, 100.0)	539/541	99.6 (98.7, 100.0)
Rural	18/18	100.0 (81.5, 100.0)	0/0	- (-, -)	18/18	100.0 (81.5, 100.0)
Physician active reminder service for next Prolia® administration						
Yes	146/147	99.3 (96.3, 100.0)	242/242	100.0 (98.5, 100.0)	388/389	99.7 (98.6, 100.0)
No	129/129	100.0 (97.2, 100.0)	40/41	97.6 (87.1, 99.9)	169/170	99.4 (96.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	77/78	98.7 (93.1, 100.0)	119/119	100.0 (96.9, 100.0)	196/197	99.5 (97.2, 100.0)
Appointment card	69/69	100.0 (94.8, 100.0)	82/82	100.0 (95.6, 100.0)	151/151	100.0 (97.6, 100.0)
Mailing	39/39	100.0 (91.0, 100.0)	70/70	100.0 (94.9, 100.0)	109/109	100.0 (96.7, 100.0)
Sticker from drug package	0/0	- (-, -)	30/30	100.0 (88.4, 100.0)	30/30	100.0 (88.4, 100.0)
Email/SMS	0/0	- (-, -)	23/23	100.0 (85.2, 100.0)	23/23	100.0 (85.2, 100.0)

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n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	128/129	99.2 (95.8, 100.0)	169/169	100.0 (97.8, 100.0)	297/298	99.7 (98.1, 100.0)
History of osteoporotic fracture	128/128	100.0 (97.2, 100.0)	52/52	100.0 (93.2, 100.0)	180/180	100.0 (98.0, 100.0)
Multiple risk factors for fracture	114/115	99.1 (95.3, 100.0)	57/58	98.3 (90.8, 100.0)	171/173	98.8 (95.9, 99.9)
Failed other available osteoporosis therapy	102/102	100.0 (96.4, 100.0)	44/44	100.0 (92.0, 100.0)	146/146	100.0 (97.5, 100.0)
Intolerant to other osteoporosis therapy	145/146	99.3 (96.2, 100.0)	36/36	100.0 (90.3, 100.0)	181/182	99.5 (97.0, 100.0)
Other	9/9	100.0 (66.4, 100.0)	14/14	100.0 (76.8, 100.0)	23/23	100.0 (85.2, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
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Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection						
Physician specialty						
Rheumatologist	99/99	100.0 (96.3, 100.0)	123/124	99.2 (95.6, 100.0)	222/223	99.6 (97.5, 100.0)
Internist	131/131	100.0 (97.2, 100.0)	47/47	100.0 (92.5, 100.0)	178/178	100.0 (97.9, 100.0)
Endocrinologist	11/12	91.7 (61.5, 99.8)	46/46	100.0 (92.3, 100.0)	57/58	98.3 (90.8, 100.0)
Orthopedist	0/0	- (-, -)	58/59	98.3 (90.9, 100.0)	58/59	98.3 (90.9, 100.0)
Other	19/20	95.0 (75.1, 99.9)	0/0	- (-, -)	19/20	95.0 (75.1, 99.9)
Physician years of practice						
5 to 9 years	19/19	100.0 (82.4, 100.0)	30/30	100.0 (88.4, 100.0)	49/49	100.0 (92.7, 100.0)
≥ 10 years	241/243	99.2 (97.1, 99.9)	244/246	99.2 (97.1, 99.9)	485/489	99.2 (97.9, 99.8)

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Percentages based on N1
[a]Site may have more than one service
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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Sole physician						
Sole	112/112	100.0 (96.8, 100.0)	215/217	99.1 (96.7, 99.9)	327/329	99.4 (97.8, 99.9)
Group	148/150	98.7 (95.3, 99.8)	59/59	100.0 (93.9, 100.0)	207/209	99.0 (96.6, 99.9)
Group size						
2 - 3	88/89	98.9 (93.9, 100.0)	25/25	100.0 (86.3, 100.0)	113/114	99.1 (95.2, 100.0)
4 - 5	41/42	97.6 (87.4, 99.9)	22/22	100.0 (84.6, 100.0)	63/64	98.4 (91.6, 100.0)
6 - 10	19/19	100.0 (82.4, 100.0)	0/0	- (-, -)	19/19	100.0 (82.4, 100.0)
> 10	0/0	- (-, -)	12/12	100.0 (73.5, 100.0)	12/12	100.0 (73.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Center type						
Hospital	79/81	97.5 (91.4, 99.7)	105/106	99.1 (94.9, 100.0)	184/187	98.4 (95.4, 99.7)
Non-hospital	181/181	100.0 (98.0, 100.0)	169/170	99.4 (96.8, 100.0)	350/351	99.7 (98.4, 100.0)
Academic centre						
Academic	12/12	100.0 (73.5, 100.0)	61/61	100.0 (94.1, 100.0)	73/73	100.0 (95.1, 100.0)
Non-academic	248/250	99.2 (97.1, 99.9)	160/162	98.8 (95.6, 99.9)	408/412	99.0 (97.5, 99.7)
Both	0/0	- (-, -)	34/34	100.0 (89.7, 100.0)	34/34	100.0 (89.7, 100.0)
Not available	0/0	- (-, -)	19/19	100.0 (82.4, 100.0)	19/19	100.0 (82.4, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Region						
Urban	243/245	99.2 (97.1, 99.9)	274/276	99.3 (97.4, 99.9)	517/521	99.2 (98.0, 99.8)
Rural	17/17	100.0 (80.5, 100.0)	0/0	- (-, -)	17/17	100.0 (80.5, 100.0)
Physician active reminder service for next Prolia® administration						
Yes	137/138	99.3 (96.0, 100.0)	236/237	99.6 (97.7, 100.0)	373/375	99.5 (98.1, 99.9)
No	123/124	99.2 (95.6, 100.0)	38/39	97.4 (86.5, 99.9)	161/163	98.8 (95.6, 99.9)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	71/71	100.0 (94.9, 100.0)	117/117	100.0 (96.9, 100.0)	188/188	100.0 (98.1, 100.0)
Appointment card	66/67	98.5 (92.0, 100.0)	78/79	98.7 (93.1, 100.0)	144/146	98.6 (95.1, 99.8)
Mailing	37/37	100.0 (90.5, 100.0)	68/68	100.0 (94.7, 100.0)	105/105	100.0 (96.5, 100.0)
Sticker from drug package	0/0	- (-, -)	29/29	100.0 (88.1, 100.0)	29/29	100.0 (88.1, 100.0)
Email/SMS	0/0	- (-, -)	22/22	100.0 (84.6, 100.0)	22/22	100.0 (84.6, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	122/123	99.2 (95.6, 100.0)	167/168	99.4 (96.7, 100.0)	289/291	99.3 (97.5, 99.9)
History of osteoporotic fracture	119/119	100.0 (96.9, 100.0)	50/51	98.0 (89.6, 100.0)	169/170	99.4 (96.8, 100.0)
Multiple risk factors for fracture	108/108	100.0 (96.6, 100.0)	54/55	98.2 (90.3, 100.0)	162/163	99.4 (96.6, 100.0)
Failed other available osteoporosis therapy	97/97	100.0 (96.3, 100.0)	42/43	97.7 (87.7, 99.9)	139/140	99.3 (96.1, 100.0)
Intolerant to other osteoporosis therapy	137/138	99.3 (96.0, 100.0)	32/32	100.0 (89.1, 100.0)	169/170	99.4 (96.8, 100.0)
Other	7/8	87.5 (47.3, 99.7)	14/14	100.0 (76.8, 100.0)	21/22	95.5 (77.2, 99.9)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection						
Physician specialty						
Rheumatologist	90/90	100.0 (96.0, 100.0)	107/109	98.2 (93.5, 99.8)	197/199	99.0 (96.4, 99.9)
Internist	125/125	100.0 (97.1, 100.0)	37/37	100.0 (90.5, 100.0)	162/162	100.0 (97.7, 100.0)
Endocrinologist	11/11	100.0 (71.5, 100.0)	40/40	100.0 (91.2, 100.0)	51/51	100.0 (93.0, 100.0)
Orthopedist	0/0	- (-, -)	56/57	98.2 (90.6, 100.0)	56/57	98.2 (90.6, 100.0)
Other	19/20	95.0 (75.1, 99.9)	0/0	- (-, -)	19/20	95.0 (75.1, 99.9)
Physician years of practice						
5 to 9 years	18/18	100.0 (81.5, 100.0)	26/26	100.0 (86.8, 100.0)	44/44	100.0 (92.0, 100.0)
≥ 10 years	227/228	99.6 (97.6, 100.0)	214/217	98.6 (96.0, 99.7)	441/445	99.1 (97.7, 99.8)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Sole physician						
Sole	106/106	100.0 (96.6, 100.0)	185/187	98.9 (96.2, 99.9)	291/293	99.3 (97.6, 99.9)
Group	139/140	99.3 (96.1, 100.0)	55/56	98.2 (90.4, 100.0)	194/196	99.0 (96.4, 99.9)
Group size						
2 - 3	81/81	100.0 (95.5, 100.0)	23/24	95.8 (78.9, 99.9)	104/105	99.0 (94.8, 100.0)
4 - 5	40/41	97.6 (87.1, 99.9)	21/21	100.0 (83.9, 100.0)	61/62	98.4 (91.3, 100.0)
6 - 10	18/18	100.0 (81.5, 100.0)	0/0	- (-, -)	18/18	100.0 (81.5, 100.0)
> 10	0/0	- (-, -)	11/11	100.0 (71.5, 100.0)	11/11	100.0 (71.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Center type						
Hospital	74/75	98.7 (92.8, 100.0)	90/92	97.8 (92.4, 99.7)	164/167	98.2 (94.8, 99.6)
Non-hospital	171/171	100.0 (97.9, 100.0)	150/151	99.3 (96.4, 100.0)	321/322	99.7 (98.3, 100.0)
Academic centre						
Academic	8/8	100.0 (63.1, 100.0)	57/58	98.3 (90.8, 100.0)	65/66	98.5 (91.8, 100.0)
Non-academic	237/238	99.6 (97.7, 100.0)	132/134	98.5 (94.7, 99.8)	369/372	99.2 (97.7, 99.8)
Both	0/0	- (-, -)	32/32	100.0 (89.1, 100.0)	32/32	100.0 (89.1, 100.0)
Not available	0/0	- (-, -)	19/19	100.0 (82.4, 100.0)	19/19	100.0 (82.4, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Region						
Urban	229/230	99.6 (97.6, 100.0)	240/243	98.8 (96.4, 99.7)	469/473	99.2 (97.8, 99.8)
Rural	16/16	100.0 (79.4, 100.0)	0/0	- (-, -)	16/16	100.0 (79.4, 100.0)
Physician active reminder service for next Prolia® administration						
Yes	131/131	100.0 (97.2, 100.0)	211/213	99.1 (96.6, 99.9)	342/344	99.4 (97.9, 99.9)
No	114/115	99.1 (95.3, 100.0)	29/30	96.7 (82.8, 99.9)	143/145	98.6 (95.1, 99.8)

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N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	66/66	100.0 (94.6, 100.0)	112/113	99.1 (95.2, 100.0)	178/179	99.4 (96.9, 100.0)
Appointment card	65/65	100.0 (94.5, 100.0)	62/63	98.4 (91.5, 100.0)	127/128	99.2 (95.7, 100.0)
Mailing	37/37	100.0 (90.5, 100.0)	64/64	100.0 (94.4, 100.0)	101/101	100.0 (96.4, 100.0)
Sticker from drug package	0/0	- (-, -)	25/25	100.0 (86.3, 100.0)	25/25	100.0 (86.3, 100.0)
Email/SMS	0/0	- (-, -)	21/21	100.0 (83.9, 100.0)	21/21	100.0 (83.9, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.2.5. Summary of Individual Prolia® Injections Received from the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	117/117	100.0 (96.9, 100.0)	147/148	99.3 (96.3, 100.0)	264/265	99.6 (97.9, 100.0)
History of osteoporotic fracture	113/114	99.1 (95.2, 100.0)	42/43	97.7 (87.7, 99.9)	155/157	98.7 (95.5, 99.8)
Multiple risk factors for fracture	99/100	99.0 (94.6, 100.0)	49/50	98.0 (89.4, 99.9)	148/150	98.7 (95.3, 99.8)
Failed other available osteoporosis therapy	94/95	98.9 (94.3, 100.0)	34/36	94.4 (81.3, 99.3)	128/131	97.7 (93.5, 99.5)
Intolerant to other osteoporosis therapy	130/131	99.2 (95.8, 100.0)	29/29	100.0 (88.1, 100.0)	159/160	99.4 (96.6, 100.0)
Other	7/7	100.0 (59.0, 100.0)	12/12	100.0 (73.5, 100.0)	19/19	100.0 (82.4, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection from the initial prescribing site with non-missing covariate data.
N1 = Number of patients who received the corresponding injection with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-injappfl-covar.sas
Output: t14-04-002-005-fi-injappfl-covar-sr-l.rtf (Date Generated: 20NOV2015: 1:23:11) Source Data: adam.apresc, adam.aslbase, adam.aslinfo

Table 14-4.3.1. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N	% (95% CI)	n/N	% (95% CI)	n/N	% (95% CI)
1 post-baseline injection	283/300	94.3 (91.1, 96.7)	293/300	97.7 (95.3, 99.1)	576/600	96.0 (94.1, 97.4)
2 post-baseline injections	276/300	92.0 (88.3, 94.8)	283/300	94.3 (91.1, 96.7)	559/600	93.2 (90.8, 95.1)
3 post-baseline injections	262/300	87.3 (83.0, 90.9)	276/300	92.0 (88.3, 94.8)	538/600	89.7 (86.9, 92.0)
4 post-baseline injections	246/300	82.0 (77.2, 86.2)	243/300	81.0 (76.1, 85.3)	489/600	81.5 (78.2, 84.5)

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N = Number of patients in the full analysis set
n = Number of patients who received the corresponding post-baseline injection(s)
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres.sas
Output: t14-04-003-001-fi-inj-prres-l.rtf (Date Generated: 14AUG2015: 0:08:53) Source Data: adam.apresc, adam.aslinfo

Table 14-4.3.2. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection						
Living situation						
At home with spouse/family	201/210	95.7 (92.0, 98.0)	231/237	97.5 (94.6, 99.1)	432/447	96.6 (94.5, 98.1)
At home with care/support	5/5	100.0 (47.8, 100.0)	1/1	100.0 (2.5, 100.0)	6/6	100.0 (54.1, 100.0)
At home alone	72/80	90.0 (81.2, 95.6)	31/32	96.9 (83.8, 99.9)	103/112	92.0 (85.3, 96.3)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	28/28	100.0 (87.7, 100.0)	33/33	100.0 (89.4, 100.0)
Highest educational level						
University	26/29	89.7 (72.6, 97.8)	38/39	97.4 (86.5, 99.9)	64/68	94.1 (85.6, 98.4)
Secondary education	175/185	94.6 (90.3, 97.4)	165/167	98.8 (95.7, 99.9)	340/352	96.6 (94.1, 98.2)
Elementary education	82/86	95.3 (88.5, 98.7)	71/74	95.9 (88.6, 99.2)	153/160	95.6 (91.2, 98.2)
Not applicable	0/0	- (-, -)	19/20	95.0 (75.1, 99.9)	19/20	95.0 (75.1, 99.9)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-002-fi-inj-prres-covar-sd-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aqspq

Table 14-4.3.2. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Employment status						
Retired	249/265	94.0 (90.4, 96.5)	196/202	97.0 (93.6, 98.9)	445/467	95.3 (93.0, 97.0)
Employed	24/25	96.0 (79.6, 99.9)	81/81	100.0 (95.5, 100.0)	105/106	99.1 (94.9, 100.0)
Self employed	6/6	100.0 (54.1, 100.0)	4/5	80.0 (28.4, 99.5)	10/11	90.9 (58.7, 99.8)
Unemployed	4/4	100.0 (39.8, 100.0)	7/7	100.0 (59.0, 100.0)	11/11	100.0 (71.5, 100.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)
2 post-baseline injections						
Living situation						
At home with spouse/family	196/210	93.3 (89.1, 96.3)	224/237	94.5 (90.8, 97.0)	420/447	94.0 (91.3, 96.0)
At home with care/support	5/5	100.0 (47.8, 100.0)	1/1	100.0 (2.5, 100.0)	6/6	100.0 (54.1, 100.0)
At home alone	70/80	87.5 (78.2, 93.8)	30/32	93.8 (79.2, 99.2)	100/112	89.3 (82.0, 94.3)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	26/28	92.9 (76.5, 99.1)	31/33	93.9 (79.8, 99.3)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-002-fi-inj-prres-covar-sd-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aqspq

Table 14-4.3.2. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Highest educational level						
University	26/29	89.7 (72.6, 97.8)	36/39	92.3 (79.1, 98.4)	62/68	91.2 (81.8, 96.7)
Secondary education	170/185	91.9 (87.0, 95.4)	160/167	95.8 (91.6, 98.3)	330/352	93.8 (90.7, 96.0)
Elementary education	80/86	93.0 (85.4, 97.4)	69/74	93.2 (84.9, 97.8)	149/160	93.1 (88.0, 96.5)
Not applicable	0/0	- (-, -)	18/20	90.0 (68.3, 98.8)	18/20	90.0 (68.3, 98.8)
Employment status						
Retired	242/265	91.3 (87.3, 94.4)	191/202	94.6 (90.5, 97.3)	433/467	92.7 (90.0, 94.9)
Employed	24/25	96.0 (79.6, 99.9)	76/81	93.8 (86.2, 98.0)	100/106	94.3 (88.1, 97.9)
Self employed	6/6	100.0 (54.1, 100.0)	4/5	80.0 (28.4, 99.5)	10/11	90.9 (58.7, 99.8)
Unemployed	4/4	100.0 (39.8, 100.0)	7/7	100.0 (59.0, 100.0)	11/11	100.0 (71.5, 100.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-002-fi-inj-prres-covar-sd-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aqspq

Table 14-4.3.2. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections						
Living situation						
At home with spouse/family	187/210	89.0 (84.0, 92.9)	218/237	92.0 (87.8, 95.1)	405/447	90.6 (87.5, 93.1)
At home with care/support	5/5	100.0 (47.8, 100.0)	1/1	100.0 (2.5, 100.0)	6/6	100.0 (54.1, 100.0)
At home alone	65/80	81.3 (71.0, 89.1)	30/32	93.8 (79.2, 99.2)	95/112	84.8 (76.8, 90.9)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	25/28	89.3 (71.8, 97.7)	30/33	90.9 (75.7, 98.1)
Highest educational level						
University	25/29	86.2 (68.3, 96.1)	34/39	87.2 (72.6, 95.7)	59/68	86.8 (76.4, 93.8)
Secondary education	162/185	87.6 (81.9, 92.0)	156/167	93.4 (88.5, 96.7)	318/352	90.3 (86.8, 93.2)
Elementary education	75/86	87.2 (78.3, 93.4)	68/74	91.9 (83.2, 97.0)	143/160	89.4 (83.5, 93.7)
Not applicable	0/0	- (-, -)	18/20	90.0 (68.3, 98.8)	18/20	90.0 (68.3, 98.8)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.2. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Employment status						
Retired	230/265	86.8 (82.1, 90.6)	186/202	92.1 (87.5, 95.4)	416/467	89.1 (85.9, 91.8)
Employed	23/25	92.0 (74.0, 99.0)	74/81	91.4 (83.0, 96.5)	97/106	91.5 (84.5, 96.0)
Self employed	6/6	100.0 (54.1, 100.0)	4/5	80.0 (28.4, 99.5)	10/11	90.9 (58.7, 99.8)
Unemployed	3/4	75.0 (19.4, 99.4)	7/7	100.0 (59.0, 100.0)	10/11	90.9 (58.7, 99.8)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)
4 post-baseline injections						
Living situation						
At home with spouse/family	178/210	84.8 (79.2, 89.3)	190/237	80.2 (74.5, 85.0)	368/447	82.3 (78.5, 85.8)
At home with care/support	5/5	100.0 (47.8, 100.0)	0/1	0.0 (0.0, 97.5)	5/6	83.3 (35.9, 99.6)
At home alone	58/80	72.5 (61.4, 81.9)	27/32	84.4 (67.2, 94.7)	85/112	75.9 (66.9, 83.5)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	24/28	85.7 (67.3, 96.0)	29/33	87.9 (71.8, 96.6)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.2. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Highest educational level						
University	23/29	79.3 (60.3, 92.0)	33/39	84.6 (69.5, 94.1)	56/68	82.4 (71.2, 90.5)
Secondary education	153/185	82.7 (76.5, 87.9)	134/167	80.2 (73.4, 86.0)	287/352	81.5 (77.1, 85.4)
Elementary education	70/86	81.4 (71.6, 89.0)	59/74	79.7 (68.8, 88.2)	129/160	80.6 (73.6, 86.4)
Not applicable	0/0	- (-, -)	17/20	85.0 (62.1, 96.8)	17/20	85.0 (62.1, 96.8)
Employment status						
Retired	217/265	81.9 (76.7, 86.3)	167/202	82.7 (76.7, 87.6)	384/467	82.2 (78.5, 85.6)
Employed	22/25	88.0 (68.8, 97.5)	62/81	76.5 (65.8, 85.2)	84/106	79.2 (70.3, 86.5)
Self employed	4/6	66.7 (22.3, 95.7)	3/5	60.0 (14.7, 94.7)	7/11	63.6 (30.8, 89.1)
Unemployed	3/4	75.0 (19.4, 99.4)	6/7	85.7 (42.1, 99.6)	9/11	81.8 (48.2, 97.7)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection						
Body mass index						
≤ 25 kg/m^2	139/151	92.1 (86.5, 95.8)	103/104	99.0 (94.8, 100.0)	242/255	94.9 (91.4, 97.3)
> 25 kg/m^2	140/145	96.6 (92.1, 98.9)	159/164	97.0 (93.0, 99.0)	299/309	96.8 (94.1, 98.4)
Missing	4/4	100.0 (39.8, 100.0)	31/32	96.9 (83.8, 99.9)	35/36	97.2 (85.5, 99.9)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	196/210	93.3 (89.1, 96.3)	193/199	97.0 (93.6, 98.9)	389/409	95.1 (92.5, 97.0)
> Median	87/90	96.7 (90.6, 99.3)	100/101	99.0 (94.6, 100.0)	187/191	97.9 (94.7, 99.4)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	153/163	93.9 (89.0, 97.0)	158/160	98.8 (95.6, 99.8)	300/305	98.4 (96.2, 99.5)
> Median	130/137	94.9 (89.8, 97.9)	135/140	96.4 (91.9, 98.8)	276/295	93.6 (90.1, 96.1)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Cause of menopause						
Natural onset	235/248	94.8 (91.2, 97.2)	238/244	97.5 (94.7, 99.1)	473/492	96.1 (94.0, 97.7)
Clinically/surgically induced	47/51	92.2 (81.1, 97.8)	52/53	98.1 (89.9, 100.0)	99/104	95.2 (89.1, 98.4)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	33/36	91.7 (77.5, 98.2)	19/20	95.0 (75.1, 99.9)	52/56	92.9 (82.7, 98.0)
No	206/219	94.1 (90.1, 96.8)	218/222	98.2 (95.5, 99.5)	424/441	96.1 (93.9, 97.7)
Unknown	44/45	97.8 (88.2, 99.9)	56/58	96.6 (88.1, 99.6)	100/103	97.1 (91.7, 99.4)
Hospitalized for osteoporotic fracture						
Yes	60/63	95.2 (86.7, 99.0)	11/11	100.0 (71.5, 100.0)	71/74	95.9 (88.6, 99.2)
No	223/237	94.1 (90.3, 96.7)	282/289	97.6 (95.1, 99.0)	505/526	96.0 (94.0, 97.5)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
≥ 1 Fall in the last 12 months						
Yes	57/61	93.4 (84.1, 98.2)	23/24	95.8 (78.9, 99.9)	80/85	94.1 (86.8, 98.1)
No	226/239	94.6 (90.9, 97.1)	270/276	97.8 (95.3, 99.2)	496/515	96.3 (94.3, 97.8)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	17/19	89.5 (66.9, 98.7)	6/6	100.0 (54.1, 100.0)	23/25	92.0 (74.0, 99.0)
No	266/281	94.7 (91.3, 97.0)	287/294	97.6 (95.2, 99.0)	553/575	96.2 (94.3, 97.6)
Glucocorticoid use						
Yes	33/33	100.0 (89.4, 100.0)	12/12	100.0 (73.5, 100.0)	45/45	100.0 (92.1, 100.0)
No	250/267	93.6 (90.0, 96.2)	281/288	97.6 (95.1, 99.0)	531/555	95.7 (93.6, 97.2)

N = Number of patients in the full analysis set
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N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Secondary osteoporosis						
Yes	42/45	93.3 (81.7, 98.6)	22/23	95.7 (78.1, 99.9)	64/68	94.1 (85.6, 98.4)
No	241/255	94.5 (91.0, 97.0)	271/277	97.8 (95.3, 99.2)	512/532	96.2 (94.3, 97.7)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	283/300	94.3 (91.1, 96.7)	292/299	97.7 (95.2, 99.1)	575/599	96.0 (94.1, 97.4)
Former smoker						
Yes	32/35	91.4 (76.9, 98.2)	22/23	95.7 (78.1, 99.9)	54/58	93.1 (83.3, 98.1)
No	251/265	94.7 (91.3, 97.1)	271/277	97.8 (95.3, 99.2)	522/542	96.3 (94.4, 97.7)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Current smoker						
Yes	37/39	94.9 (82.7, 99.4)	29/29	100.0 (88.1, 100.0)	66/68	97.1 (89.8, 99.6)
No	246/261	94.3 (90.7, 96.7)	264/271	97.4 (94.8, 99.0)	510/532	95.9 (93.8, 97.4)
Height loss since self-reported maximal height						
Yes	223/237	94.1 (90.3, 96.7)	108/111	97.3 (92.3, 99.4)	331/348	95.1 (92.3, 97.1)
No	60/63	95.2 (86.7, 99.0)	185/189	97.9 (94.7, 99.4)	245/252	97.2 (94.4, 98.9)
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	119/125	95.2 (89.8, 98.2)	56/56	100.0 (93.6, 100.0)	185/191	96.9 (93.3, 98.8)
> Median	103/111	92.8 (86.3, 96.8)	52/55	94.5 (84.9, 98.9)	145/156	92.9 (87.7, 96.4)
Missing	61/64	95.3 (86.9, 99.0)	185/189	97.9 (94.7, 99.4)	246/253	97.2 (94.4, 98.9)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Previous fracture						
Yes	210/221	95.0 (91.3, 97.5)	98/100	98.0 (93.0, 99.8)	308/321	96.0 (93.2, 97.8)
No	73/79	92.4 (84.2, 97.2)	195/200	97.5 (94.3, 99.2)	268/279	96.1 (93.1, 98.0)
Previous hip fracture						
Yes	17/18	94.4 (72.7, 99.9)	5/5	100.0 (47.8, 100.0)	22/23	95.7 (78.1, 99.9)
No	266/282	94.3 (90.9, 96.7)	288/295	97.6 (95.2, 99.0)	554/577	96.0 (94.1, 97.5)
Previous vertebral fracture						
Yes	89/93	95.7 (89.4, 98.8)	21/21	100.0 (83.9, 100.0)	110/114	96.5 (91.3, 99.0)
No	194/207	93.7 (89.5, 96.6)	272/279	97.5 (94.9, 99.0)	466/486	95.9 (93.7, 97.5)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Time since most recent historical fracture to first injection						
< 12 months	60/63	95.2 (86.7, 99.0)	28/29	96.6 (82.2, 99.9)	88/92	95.7 (89.2, 98.8)
≥ 12 months	150/158	94.9 (90.3, 97.8)	63/63	100.0 (94.3, 100.0)	213/221	96.4 (93.0, 98.4)
Baseline lumbar spine DXA BMD T-score						
> -2.5	65/70	92.9 (84.1, 97.6)	83/85	97.6 (91.8, 99.7)	148/155	95.5 (90.9, 98.2)
≤ -2.5	186/198	93.9 (89.7, 96.8)	183/188	97.3 (93.9, 99.1)	369/386	95.6 (93.0, 97.4)
Missing	32/32	100.0 (89.1, 100.0)	27/27	100.0 (87.2, 100.0)	59/59	100.0 (93.9, 100.0)
Baseline total hip DXA BMD T-score						
> -2.5	165/179	92.2 (87.2, 95.7)	213/220	96.8 (93.6, 98.7)	378/399	94.7 (92.1, 96.7)
≤ -2.5	81/84	96.4 (89.9, 99.3)	26/26	100.0 (86.8, 100.0)	107/110	97.3 (92.2, 99.4)
Missing	37/37	100.0 (90.5, 100.0)	54/54	100.0 (93.4, 100.0)	91/91	100.0 (96.0, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-003-fi-inj-prres-covar-cr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase

Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Baseline femoral neck DXA BMD T-score						
> -2.5	147/159	92.5 (87.2, 96.0)	194/200	97.0 (93.6, 98.9)	341/359	95.0 (92.2, 97.0)
≤ -2.5	98/103	95.1 (89.0, 98.4)	72/73	98.6 (92.6, 100.0)	170/176	96.6 (92.7, 98.7)
Missing	38/38	100.0 (90.7, 100.0)	27/27	100.0 (87.2, 100.0)	65/65	100.0 (94.5, 100.0)
2 post-baseline injections						
Body mass index						
≤ 25 kg/m^2	136/151	90.1 (84.1, 94.3)	100/104	96.2 (90.4, 98.9)	236/255	92.5 (88.6, 95.5)
> 25 kg/m^2	136/145	93.8 (88.5, 97.1)	155/164	94.5 (89.8, 97.5)	291/309	94.2 (90.9, 96.5)
Missing	4/4	100.0 (39.8, 100.0)	28/32	87.5 (71.0, 96.5)	32/36	88.9 (73.9, 96.9)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	189/210	90.0 (85.1, 93.7)	187/199	94.0 (89.7, 96.8)	376/409	91.9 (88.9, 94.4)
> Median	87/90	96.7 (90.6, 99.3)	96/101	95.0 (88.8, 98.4)	183/191	95.8 (91.9, 98.2)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	149/163	91.4 (86.0, 95.2)	151/160	94.4 (89.6, 97.4)	290/305	95.1 (92.0, 97.2)
> Median	127/137	92.7 (87.0, 96.4)	132/140	94.3 (89.1, 97.5)	269/295	91.2 (87.4, 94.2)
Cause of menopause						
Natural onset	232/248	93.5 (89.7, 96.3)	230/244	94.3 (90.6, 96.8)	462/492	93.9 (91.4, 95.8)
Clinically/surgically induced	43/51	84.3 (71.4, 93.0)	50/53	94.3 (84.3, 98.8)	93/104	89.4 (81.9, 94.6)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	32/36	88.9 (73.9, 96.9)	18/20	90.0 (68.3, 98.8)	50/56	89.3 (78.1, 96.0)
No	200/219	91.3 (86.8, 94.7)	210/222	94.6 (90.7, 97.2)	410/441	93.0 (90.2, 95.2)
Unknown	44/45	97.8 (88.2, 99.9)	55/58	94.8 (85.6, 98.9)	99/103	96.1 (90.4, 98.9)

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n = Number of patients who received the corresponding injection(s)
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Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	58/63	92.1 (82.4, 97.4)	11/11	100.0 (71.5, 100.0)	69/74	93.2 (84.9, 97.8)
No	218/237	92.0 (87.8, 95.1)	272/289	94.1 (90.7, 96.5)	490/526	93.2 (90.7, 95.2)
≥ 1 Fall in the last 12 months						
Yes	54/61	88.5 (77.8, 95.3)	22/24	91.7 (73.0, 99.0)	76/85	89.4 (80.8, 95.0)
No	222/239	92.9 (88.9, 95.8)	261/276	94.6 (91.2, 96.9)	483/515	93.8 (91.3, 95.7)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	16/19	84.2 (60.4, 96.6)	5/6	83.3 (35.9, 99.6)	21/25	84.0 (63.9, 95.5)
No	260/281	92.5 (88.8, 95.3)	278/294	94.6 (91.3, 96.9)	538/575	93.6 (91.2, 95.4)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Glucocorticoid use						
Yes	31/33	93.9 (79.8, 99.3)	11/12	91.7 (61.5, 99.8)	42/45	93.3 (81.7, 98.6)
No	245/267	91.8 (87.8, 94.8)	272/288	94.4 (91.1, 96.8)	517/555	93.2 (90.7, 95.1)
Secondary osteoporosis						
Yes	41/45	91.1 (78.8, 97.5)	22/23	95.7 (78.1, 99.9)	63/68	92.6 (83.7, 97.6)
No	235/255	92.2 (88.1, 95.1)	261/277	94.2 (90.8, 96.7)	496/532	93.2 (90.8, 95.2)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	276/300	92.0 (88.3, 94.8)	282/299	94.3 (91.1, 96.7)	558/599	93.2 (90.8, 95.0)

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Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Former smoker						
Yes	32/35	91.4 (76.9, 98.2)	20/23	87.0 (66.4, 97.2)	52/58	89.7 (78.8, 96.1)
No	244/265	92.1 (88.1, 95.0)	263/277	94.9 (91.7, 97.2)	507/542	93.5 (91.1, 95.5)
Current smoker						
Yes	35/39	89.7 (75.8, 97.1)	29/29	100.0 (88.1, 100.0)	64/68	94.1 (85.6, 98.4)
No	241/261	92.3 (88.4, 95.3)	254/271	93.7 (90.1, 96.3)	495/532	93.0 (90.5, 95.1)
Height loss since self-reported maximal height						
Yes	216/237	91.1 (86.8, 94.4)	104/111	93.7 (87.4, 97.4)	320/348	92.0 (88.6, 94.6)
No	60/63	95.2 (86.7, 99.0)	179/189	94.7 (90.5, 97.4)	239/252	94.8 (91.3, 97.2)

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n = Number of patients who received the corresponding injection(s)
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Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	115/125	92.0 (85.8, 96.1)	53/56	94.6 (85.1, 98.9)	178/191	93.2 (88.6, 96.3)
> Median	100/111	90.1 (83.0, 94.9)	51/55	92.7 (82.4, 98.0)	141/156	90.4 (84.6, 94.5)
Missing	61/64	95.3 (86.9, 99.0)	179/189	94.7 (90.5, 97.4)	240/253	94.9 (91.4, 97.2)
Previous fracture						
Yes	205/221	92.8 (88.5, 95.8)	95/100	95.0 (88.7, 98.4)	300/321	93.5 (90.2, 95.9)
No	71/79	89.9 (81.0, 95.5)	188/200	94.0 (89.8, 96.9)	259/279	92.8 (89.1, 95.6)
Previous hip fracture						
Yes	17/18	94.4 (72.7, 99.9)	5/5	100.0 (47.8, 100.0)	22/23	95.7 (78.1, 99.9)
No	259/282	91.8 (88.0, 94.8)	278/295	94.2 (90.9, 96.6)	537/577	93.1 (90.7, 95.0)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
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Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Previous vertebral fracture						
Yes	86/93	92.5 (85.1, 96.9)	21/21	100.0 (83.9, 100.0)	107/114	93.9 (87.8, 97.5)
No	190/207	91.8 (87.2, 95.1)	262/279	93.9 (90.4, 96.4)	452/486	93.0 (90.4, 95.1)
Time since most recent historical fracture to first injection						
< 12 months	57/63	90.5 (80.4, 96.4)	28/29	96.6 (82.2, 99.9)	85/92	92.4 (84.9, 96.9)
≥ 12 months	148/158	93.7 (88.7, 96.9)	60/63	95.2 (86.7, 99.0)	208/221	94.1 (90.2, 96.8)
Baseline lumbar spine DXA BMD T-score						
> -2.5	63/70	90.0 (80.5, 95.9)	79/85	92.9 (85.3, 97.4)	142/155	91.6 (86.1, 95.5)
≤ -2.5	182/198	91.9 (87.2, 95.3)	178/188	94.7 (90.4, 97.4)	360/386	93.3 (90.3, 95.6)
Missing	31/32	96.9 (83.8, 99.9)	26/27	96.3 (81.0, 99.9)	57/59	96.6 (88.3, 99.6)

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Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	160/179	89.4 (83.9, 93.5)	204/220	92.7 (88.5, 95.8)	364/399	91.2 (88.0, 93.8)
≤ -2.5	80/84	95.2 (88.3, 98.7)	26/26	100.0 (86.8, 100.0)	106/110	96.4 (91.0, 99.0)
Missing	36/37	97.3 (85.8, 99.9)	53/54	98.1 (90.1, 100.0)	89/91	97.8 (92.3, 99.7)
Baseline femoral neck DXA BMD T-score						
> -2.5	144/159	90.6 (84.9, 94.6)	188/200	94.0 (89.8, 96.9)	332/359	92.5 (89.2, 95.0)
≤ -2.5	95/103	92.2 (85.3, 96.6)	69/73	94.5 (86.6, 98.5)	164/176	93.2 (88.4, 96.4)
Missing	37/38	97.4 (86.2, 99.9)	26/27	96.3 (81.0, 99.9)	63/65	96.9 (89.3, 99.6)

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N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections						
Body mass index						
≤ 25 kg/m^2	130/151	86.1 (79.5, 91.2)	100/104	96.2 (90.4, 98.9)	230/255	90.2 (85.9, 93.6)
> 25 kg/m^2	128/145	88.3 (81.9, 93.0)	151/164	92.1 (86.8, 95.7)	279/309	90.3 (86.4, 93.4)
Missing	4/4	100.0 (39.8, 100.0)	25/32	78.1 (60.0, 90.7)	29/36	80.6 (64.0, 91.8)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	177/210	84.3 (78.6, 88.9)	183/199	92.0 (87.3, 95.3)	360/409	88.0 (84.5, 91.0)
> Median	85/90	94.4 (87.5, 98.2)	93/101	92.1 (85.0, 96.5)	178/191	93.2 (88.6, 96.3)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	144/163	88.3 (82.4, 92.8)	148/160	92.5 (87.3, 96.1)	283/305	92.8 (89.3, 95.4)
> Median	118/137	86.1 (79.2, 91.4)	128/140	91.4 (85.5, 95.5)	255/295	86.4 (82.0, 90.1)

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n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Cause of menopause						
Natural onset	223/248	89.9 (85.5, 93.4)	226/244	92.6 (88.6, 95.6)	449/492	91.3 (88.4, 93.6)
Clinically/surgically induced	38/51	74.5 (60.4, 85.7)	48/53	90.6 (79.3, 96.9)	86/104	82.7 (74.0, 89.4)
Not available	1/1	100.0 (2.5, 100.0)	2/3	66.7 (9.4, 99.2)	3/4	75.0 (19.4, 99.4)
Parental hip fracture						
Yes	30/36	83.3 (67.2, 93.6)	18/20	90.0 (68.3, 98.8)	48/56	85.7 (73.8, 93.6)
No	189/219	86.3 (81.0, 90.6)	206/222	92.8 (88.6, 95.8)	395/441	89.6 (86.3, 92.3)
Unknown	43/45	95.6 (84.9, 99.5)	52/58	89.7 (78.8, 96.1)	95/103	92.2 (85.3, 96.6)
Hospitalized for osteoporotic fracture						
Yes	54/63	85.7 (74.6, 93.3)	11/11	100.0 (71.5, 100.0)	65/74	87.8 (78.2, 94.3)
No	208/237	87.8 (82.9, 91.6)	265/289	91.7 (87.9, 94.6)	473/526	89.9 (87.0, 92.4)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
≥ 1 Fall in the last 12 months						
Yes	50/61	82.0 (70.0, 90.6)	22/24	91.7 (73.0, 99.0)	72/85	84.7 (75.3, 91.6)
No	212/239	88.7 (84.0, 92.4)	254/276	92.0 (88.2, 94.9)	466/515	90.5 (87.6, 92.9)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	15/19	78.9 (54.4, 93.9)	5/6	83.3 (35.9, 99.6)	20/25	80.0 (59.3, 93.2)
No	247/281	87.9 (83.5, 91.5)	271/294	92.2 (88.5, 95.0)	518/575	90.1 (87.3, 92.4)
Glucocorticoid use						
Yes	29/33	87.9 (71.8, 96.6)	11/12	91.7 (61.5, 99.8)	40/45	88.9 (75.9, 96.3)
No	233/267	87.3 (82.7, 91.0)	265/288	92.0 (88.3, 94.9)	498/555	89.7 (86.9, 92.1)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-003-fi-inj-prres-covar-cr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase

Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Secondary osteoporosis						
Yes	38/45	84.4 (70.5, 93.5)	22/23	95.7 (78.1, 99.9)	60/68	88.2 (78.1, 94.8)
No	224/255	87.8 (83.2, 91.6)	254/277	91.7 (87.8, 94.7)	478/532	89.8 (87.0, 92.3)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	262/300	87.3 (83.0, 90.9)	275/299	92.0 (88.3, 94.8)	537/599	89.6 (86.9, 92.0)
Former smoker						
Yes	30/35	85.7 (69.7, 95.2)	19/23	82.6 (61.2, 95.0)	49/58	84.5 (72.6, 92.7)
No	232/265	87.5 (83.0, 91.3)	257/277	92.8 (89.1, 95.5)	489/542	90.2 (87.4, 92.6)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Current smoker						
Yes	34/39	87.2 (72.6, 95.7)	29/29	100.0 (88.1, 100.0)	63/68	92.6 (83.7, 97.6)
No	228/261	87.4 (82.7, 91.1)	247/271	91.1 (87.1, 94.2)	475/532	89.3 (86.3, 91.8)
Height loss since self-reported maximal height						
Yes	206/237	86.9 (82.0, 90.9)	100/111	90.1 (83.0, 94.9)	306/348	87.9 (84.0, 91.2)
No	56/63	88.9 (78.4, 95.4)	176/189	93.1 (88.5, 96.3)	232/252	92.1 (88.0, 95.1)
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	112/125	89.6 (82.9, 94.3)	50/56	89.3 (78.1, 96.0)	172/191	90.1 (84.9, 93.9)
> Median	93/111	83.8 (75.6, 90.1)	50/55	90.9 (80.0, 97.0)	133/156	85.3 (78.7, 90.4)
Missing	57/64	89.1 (78.8, 95.5)	176/189	93.1 (88.5, 96.3)	233/253	92.1 (88.1, 95.1)

N = Number of patients in the full analysis set
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N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Previous fracture						
Yes	193/221	87.3 (82.2, 91.4)	94/100	94.0 (87.4, 97.8)	287/321	89.4 (85.5, 92.6)
No	69/79	87.3 (78.0, 93.8)	182/200	91.0 (86.1, 94.6)	251/279	90.0 (85.8, 93.2)
Previous hip fracture						
Yes	16/18	88.9 (65.3, 98.6)	5/5	100.0 (47.8, 100.0)	21/23	91.3 (72.0, 98.9)
No	246/282	87.2 (82.8, 90.9)	271/295	91.9 (88.1, 94.7)	517/577	89.6 (86.8, 92.0)
Previous vertebral fracture						
Yes	80/93	86.0 (77.3, 92.3)	20/21	95.2 (76.2, 99.9)	100/114	87.7 (80.3, 93.1)
No	182/207	87.9 (82.7, 92.0)	256/279	91.8 (87.9, 94.7)	438/486	90.1 (87.1, 92.6)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
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Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Time since most recent historical fracture to first injection						
< 12 months	54/63	85.7 (74.6, 93.3)	27/29	93.1 (77.2, 99.2)	81/92	88.0 (79.6, 93.9)
≥ 12 months	139/158	88.0 (81.9, 92.6)	60/63	95.2 (86.7, 99.0)	199/221	90.0 (85.3, 93.7)
Baseline lumbar spine DXA BMD T-score						
> -2.5	58/70	82.9 (72.0, 90.8)	77/85	90.6 (82.3, 95.8)	135/155	87.1 (80.8, 91.9)
≤ -2.5	174/198	87.9 (82.5, 92.1)	174/188	92.6 (87.8, 95.9)	348/386	90.2 (86.7, 92.9)
Missing	30/32	93.8 (79.2, 99.2)	25/27	92.6 (75.7, 99.1)	55/59	93.2 (83.5, 98.1)
Baseline total hip DXA BMD T-score						
> -2.5	153/179	85.5 (79.4, 90.3)	198/220	90.0 (85.3, 93.6)	351/399	88.0 (84.4, 91.0)
≤ -2.5	74/84	88.1 (79.2, 94.1)	26/26	100.0 (86.8, 100.0)	100/110	90.9 (83.9, 95.6)
Missing	35/37	94.6 (81.8, 99.3)	52/54	96.3 (87.3, 99.5)	87/91	95.6 (89.1, 98.8)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Baseline femoral neck DXA BMD T-score						
> -2.5	135/159	84.9 (78.4, 90.1)	183/200	91.5 (86.7, 95.0)	318/359	88.6 (84.8, 91.7)
≤ -2.5	91/103	88.3 (80.5, 93.8)	68/73	93.2 (84.7, 97.7)	159/176	90.3 (85.0, 94.3)
Missing	36/38	94.7 (82.3, 99.4)	25/27	92.6 (75.7, 99.1)	61/65	93.8 (85.0, 98.3)
4 post-baseline injections						
Body mass index						
≤ 25 kg/m^2	122/151	80.8 (73.6, 86.7)	92/104	88.5 (80.7, 93.9)	214/255	83.9 (78.8, 88.2)
> 25 kg/m^2	120/145	82.8 (75.6, 88.5)	137/164	83.5 (77.0, 88.9)	257/309	83.2 (78.5, 87.2)
Missing	4/4	100.0 (39.8, 100.0)	14/32	43.8 (26.4, 62.3)	18/36	50.0 (32.9, 67.1)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	164/210	78.1 (71.9, 83.5)	161/199	80.9 (74.7, 86.1)	325/409	79.5 (75.2, 83.3)
> Median	82/90	91.1 (83.2, 96.1)	82/101	81.2 (72.2, 88.3)	164/191	85.9 (80.1, 90.5)

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N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	139/163	85.3 (78.9, 90.3)	130/160	81.3 (74.3, 87.0)	258/305	84.6 (80.0, 88.5)
> Median	107/137	78.1 (70.2, 84.7)	113/140	80.7 (73.2, 86.9)	231/295	78.3 (73.2, 82.9)
Cause of menopause						
Natural onset	209/248	84.3 (79.1, 88.6)	197/244	80.7 (75.2, 85.5)	406/492	82.5 (78.9, 85.8)
Clinically/surgically induced	36/51	70.6 (56.2, 82.5)	44/53	83.0 (70.2, 91.9)	80/104	76.9 (67.6, 84.6)
Not available	1/1	100.0 (2.5, 100.0)	2/3	66.7 (9.4, 99.2)	3/4	75.0 (19.4, 99.4)
Parental hip fracture						
Yes	28/36	77.8 (60.8, 89.9)	17/20	85.0 (62.1, 96.8)	45/56	80.4 (67.6, 89.8)
No	175/219	79.9 (74.0, 85.0)	183/222	82.4 (76.8, 87.2)	358/441	81.2 (77.2, 84.7)
Unknown	43/45	95.6 (84.9, 99.5)	43/58	74.1 (61.0, 84.7)	86/103	83.5 (74.9, 90.1)

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Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	53/63	84.1 (72.7, 92.1)	11/11	100.0 (71.5, 100.0)	64/74	86.5 (76.5, 93.3)
No	193/237	81.4 (75.9, 86.2)	232/289	80.3 (75.2, 84.7)	425/526	80.8 (77.2, 84.1)
≥ 1 Fall in the last 12 months						
Yes	46/61	75.4 (62.7, 85.5)	17/24	70.8 (48.9, 87.4)	63/85	74.1 (63.5, 83.0)
No	200/239	83.7 (78.4, 88.1)	226/276	81.9 (76.8, 86.2)	426/515	82.7 (79.2, 85.9)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	15/19	78.9 (54.4, 93.9)	4/6	66.7 (22.3, 95.7)	19/25	76.0 (54.9, 90.6)
No	231/281	82.2 (77.2, 86.5)	239/294	81.3 (76.4, 85.6)	470/575	81.7 (78.3, 84.8)

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Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Glucocorticoid use						
Yes	28/33	84.8 (68.1, 94.9)	11/12	91.7 (61.5, 99.8)	39/45	86.7 (73.2, 94.9)
No	218/267	81.6 (76.5, 86.1)	232/288	80.6 (75.5, 85.0)	450/555	81.1 (77.6, 84.3)
Secondary osteoporosis						
Yes	37/45	82.2 (67.9, 92.0)	21/23	91.3 (72.0, 98.9)	58/68	85.3 (74.6, 92.7)
No	209/255	82.0 (76.7, 86.5)	222/277	80.1 (75.0, 84.7)	431/532	81.0 (77.4, 84.3)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	246/300	82.0 (77.2, 86.2)	242/299	80.9 (76.0, 85.2)	488/599	81.5 (78.1, 84.5)

N = Number of patients in the full analysis set
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Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Former smoker						
Yes	26/35	74.3 (56.7, 87.5)	16/23	69.6 (47.1, 86.8)	42/58	72.4 (59.1, 83.3)
No	220/265	83.0 (77.9, 87.3)	227/277	81.9 (76.9, 86.3)	447/542	82.5 (79.0, 85.6)
Current smoker						
Yes	33/39	84.6 (69.5, 94.1)	28/29	96.6 (82.2, 99.9)	61/68	89.7 (79.9, 95.8)
No	213/261	81.6 (76.4, 86.1)	215/271	79.3 (74.0, 84.0)	428/532	80.5 (76.8, 83.7)
Height loss since self-reported maximal height						
Yes	194/237	81.9 (76.3, 86.5)	87/111	78.4 (69.6, 85.6)	281/348	80.7 (76.2, 84.8)
No	52/63	82.5 (70.9, 90.9)	156/189	82.5 (76.4, 87.7)	208/252	82.5 (77.3, 87.0)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	109/125	87.2 (80.0, 92.5)	47/56	83.9 (71.7, 92.4)	163/191	85.3 (79.5, 90.0)
> Median	84/111	75.7 (66.6, 83.3)	40/55	72.7 (59.0, 83.9)	117/156	75.0 (67.4, 81.6)
Missing	53/64	82.8 (71.3, 91.1)	156/189	82.5 (76.4, 87.7)	209/253	82.6 (77.4, 87.1)
Previous fracture						
Yes	180/221	81.4 (75.7, 86.3)	81/100	81.0 (71.9, 88.2)	261/321	81.3 (76.6, 85.4)
No	66/79	83.5 (73.5, 90.9)	162/200	81.0 (74.9, 86.2)	228/279	81.7 (76.7, 86.1)
Previous hip fracture						
Yes	16/18	88.9 (65.3, 98.6)	5/5	100.0 (47.8, 100.0)	21/23	91.3 (72.0, 98.9)
No	230/282	81.6 (76.5, 85.9)	238/295	80.7 (75.7, 85.0)	468/577	81.1 (77.7, 84.2)

N = Number of patients in the full analysis set
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N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Previous vertebral fracture						
Yes	73/93	78.5 (68.8, 86.3)	19/21	90.5 (69.6, 98.8)	92/114	80.7 (72.3, 87.5)
No	173/207	83.6 (77.8, 88.3)	224/279	80.3 (75.1, 84.8)	397/486	81.7 (78.0, 85.0)
Time since most recent historical fracture to first injection						
< 12 months	53/63	84.1 (72.7, 92.1)	25/29	86.2 (68.3, 96.1)	78/92	84.8 (75.8, 91.4)
≥ 12 months	127/158	80.4 (73.3, 86.3)	51/63	81.0 (69.1, 89.8)	178/221	80.5 (74.7, 85.5)
Baseline lumbar spine DXA BMD T-score						
> -2.5	54/70	77.1 (65.6, 86.3)	73/85	85.9 (76.6, 92.5)	127/155	81.9 (75.0, 87.6)
≤ -2.5	163/198	82.3 (76.3, 87.4)	147/188	78.2 (71.6, 83.9)	310/386	80.3 (76.0, 84.2)
Missing	29/32	90.6 (75.0, 98.0)	23/27	85.2 (66.3, 95.8)	52/59	88.1 (77.1, 95.1)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

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Table 14-4.3.3. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	143/179	79.9 (73.3, 85.5)	171/220	77.7 (71.6, 83.0)	314/399	78.7 (74.3, 82.6)
≤ -2.5	69/84	82.1 (72.3, 89.6)	23/26	88.5 (69.8, 97.6)	92/110	83.6 (75.4, 90.0)
Missing	34/37	91.9 (78.1, 98.3)	49/54	90.7 (79.7, 96.9)	83/91	91.2 (83.4, 96.1)
Baseline femoral neck DXA BMD T-score						
> -2.5	127/159	79.9 (72.8, 85.8)	156/200	78.0 (71.6, 83.5)	283/359	78.8 (74.2, 82.9)
≤ -2.5	84/103	81.6 (72.7, 88.5)	64/73	87.7 (77.9, 94.2)	148/176	84.1 (77.8, 89.2)
Missing	35/38	92.1 (78.6, 98.3)	23/27	85.2 (66.3, 95.8)	58/65	89.2 (79.1, 95.6)

N = Number of patients in the full analysis set
n = Number of patients who received the corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-003-fi-inj-prres-covar-cr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	147/157	93.6 (88.6, 96.9)	148/151	98.0 (94.3, 99.6)	306/315	97.1 (94.6, 98.7)
> Median	136/143	95.1 (90.2, 98.0)	145/149	97.3 (93.3, 99.3)	270/285	94.7 (91.5, 97.0)
Age group						
< 65 years	87/90	96.7 (90.6, 99.3)	161/164	98.2 (94.7, 99.6)	248/254	97.6 (94.9, 99.1)
≥ 65 - < 75 years	112/121	92.6 (86.3, 96.5)	96/98	98.0 (92.8, 99.8)	208/219	95.0 (91.2, 97.5)
≥ 75 years	84/89	94.4 (87.4, 98.2)	36/38	94.7 (82.3, 99.4)	120/127	94.5 (89.0, 97.8)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	142/151	94.0 (89.0, 97.2)	147/151	97.4 (93.4, 99.3)	289/301	96.0 (93.1, 97.9)
> Median	141/149	94.6 (89.7, 97.7)	146/149	98.0 (94.2, 99.6)	287/299	96.0 (93.1, 97.9)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	151/158	95.6 (91.1, 98.2)	190/194	97.9 (94.8, 99.4)	356/369	96.5 (94.1, 98.1)
> Median	132/142	93.0 (87.4, 96.6)	103/106	97.2 (92.0, 99.4)	220/231	95.2 (91.6, 97.6)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	178/186	95.7 (91.7, 98.1)	184/187	98.4 (95.4, 99.7)	319/328	97.3 (94.9, 98.7)
> Median	105/114	92.1 (85.5, 96.3)	109/113	96.5 (91.2, 99.0)	257/272	94.5 (91.1, 96.9)
Any chronic medical condition						
Yes	263/278	94.6 (91.3, 96.9)	236/242	97.5 (94.7, 99.1)	499/520	96.0 (93.9, 97.5)
No	20/22	90.9 (70.8, 98.9)	57/58	98.3 (90.8, 100.0)	77/80	96.3 (89.4, 99.2)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Type of chronic medical condition						
Diabetes	18/20	90.0 (68.3, 98.8)	21/23	91.3 (72.0, 98.9)	39/43	90.7 (77.9, 97.4)
Osteoporosis	238/253	94.1 (90.4, 96.6)	84/86	97.7 (91.9, 99.7)	322/339	95.0 (92.1, 97.1)
Hypertension	141/149	94.6 (89.7, 97.7)	155/159	97.5 (93.7, 99.3)	296/308	96.1 (93.3, 98.0)
Other	175/186	94.1 (89.7, 97.0)	128/132	97.0 (92.4, 99.2)	303/318	95.3 (92.3, 97.3)
Any prior PMO therapy						
Yes	239/255	93.7 (90.0, 96.4)	143/146	97.9 (94.1, 99.6)	382/401	95.3 (92.7, 97.1)
No	44/45	97.8 (88.2, 99.9)	150/154	97.4 (93.5, 99.3)	194/199	97.5 (94.2, 99.2)
Any PMO therapy within the 12 months prior to enrollment						
Yes	224/240	93.3 (89.4, 96.1)	118/119	99.2 (95.4, 100.0)	342/359	95.3 (92.5, 97.2)
No	59/60	98.3 (91.1, 100.0)	175/181	96.7 (92.9, 98.8)	234/241	97.1 (94.1, 98.8)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Prior calcium and/or vitamin D supplement						
Yes	141/151	93.4 (88.2, 96.8)	19/19	100.0 (82.4, 100.0)	160/170	94.1 (89.4, 97.1)
No	142/149	95.3 (90.6, 98.1)	274/281	97.5 (94.9, 99.0)	416/430	96.7 (94.6, 98.2)
2 post-baseline injections						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	142/157	90.4 (84.7, 94.6)	142/151	94.0 (89.0, 97.2)	295/315	93.7 (90.4, 96.1)
> Median	134/143	93.7 (88.4, 97.1)	141/149	94.6 (89.7, 97.7)	264/285	92.6 (89.0, 95.4)
Age group						
< 65 years	85/90	94.4 (87.5, 98.2)	155/164	94.5 (89.8, 97.5)	240/254	94.5 (90.9, 97.0)
≥ 65 - < 75 years	108/121	89.3 (82.3, 94.2)	94/98	95.9 (89.9, 98.9)	202/219	92.2 (87.9, 95.4)
≥ 75 years	83/89	93.3 (85.9, 97.5)	34/38	89.5 (75.2, 97.1)	117/127	92.1 (86.0, 96.2)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	136/151	90.1 (84.1, 94.3)	143/151	94.7 (89.8, 97.7)	280/301	93.0 (89.5, 95.6)
> Median	140/149	94.0 (88.8, 97.2)	140/149	94.0 (88.8, 97.2)	279/299	93.3 (89.9, 95.9)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	149/158	94.3 (89.5, 97.4)	184/194	94.8 (90.7, 97.5)	347/369	94.0 (91.1, 96.2)
> Median	127/142	89.4 (83.2, 94.0)	99/106	93.4 (86.9, 97.3)	212/231	91.8 (87.5, 95.0)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	175/186	94.1 (89.7, 97.0)	178/187	95.2 (91.1, 97.8)	312/328	95.1 (92.2, 97.2)
> Median	101/114	88.6 (81.3, 93.8)	105/113	92.9 (86.5, 96.9)	247/272	90.8 (86.7, 94.0)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Any chronic medical condition						
Yes	256/278	92.1 (88.3, 95.0)	229/242	94.6 (91.0, 97.1)	485/520	93.3 (90.8, 95.3)
No	20/22	90.9 (70.8, 98.9)	54/58	93.1 (83.3, 98.1)	74/80	92.5 (84.4, 97.2)
Type of chronic medical condition						
Diabetes	18/20	90.0 (68.3, 98.8)	20/23	87.0 (66.4, 97.2)	38/43	88.4 (74.9, 96.1)
Osteoporosis	231/253	91.3 (87.1, 94.5)	83/86	96.5 (90.1, 99.3)	314/339	92.6 (89.3, 95.2)
Hypertension	135/149	90.6 (84.7, 94.8)	149/159	93.7 (88.7, 96.9)	284/308	92.2 (88.6, 94.9)
Other	170/186	91.4 (86.4, 95.0)	124/132	93.9 (88.4, 97.3)	294/318	92.5 (89.0, 95.1)
Any prior PMO therapy						
Yes	234/255	91.8 (87.7, 94.8)	136/146	93.2 (87.8, 96.7)	370/401	92.3 (89.2, 94.7)
No	42/45	93.3 (81.7, 98.6)	147/154	95.5 (90.9, 98.2)	189/199	95.0 (91.0, 97.6)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Any PMO therapy within the 12 months prior to enrollment						
Yes	219/240	91.3 (86.9, 94.5)	112/119	94.1 (88.3, 97.6)	331/359	92.2 (88.9, 94.8)
No	57/60	95.0 (86.1, 99.0)	171/181	94.5 (90.1, 97.3)	228/241	94.6 (91.0, 97.1)
Prior calcium and/or vitamin D supplement						
Yes	138/151	91.4 (85.7, 95.3)	18/19	94.7 (74.0, 99.9)	156/170	91.8 (86.6, 95.4)
No	138/149	92.6 (87.2, 96.3)	265/281	94.3 (90.9, 96.7)	403/430	93.7 (91.0, 95.8)
3 post-baseline injections						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	136/157	86.6 (80.3, 91.5)	140/151	92.7 (87.3, 96.3)	287/315	91.1 (87.4, 94.0)
> Median	126/143	88.1 (81.6, 92.9)	136/149	91.3 (85.5, 95.3)	251/285	88.1 (83.7, 91.6)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Age group						
< 65 years	83/90	92.2 (84.6, 96.8)	153/164	93.3 (88.3, 96.6)	236/254	92.9 (89.0, 95.7)
≥ 65 - < 75 years	102/121	84.3 (76.6, 90.3)	89/98	90.8 (83.3, 95.7)	191/219	87.2 (82.1, 91.3)
≥ 75 years	77/89	86.5 (77.6, 92.8)	34/38	89.5 (75.2, 97.1)	111/127	87.4 (80.3, 92.6)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	131/151	86.8 (80.3, 91.7)	142/151	94.0 (89.0, 97.2)	273/301	90.7 (86.8, 93.7)
> Median	131/149	87.9 (81.6, 92.7)	134/149	89.9 (83.9, 94.3)	265/299	88.6 (84.5, 92.0)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	143/158	90.5 (84.8, 94.6)	177/194	91.2 (86.3, 94.8)	338/369	91.6 (88.3, 94.2)
> Median	119/142	83.8 (76.7, 89.4)	99/106	93.4 (86.9, 97.3)	200/231	86.6 (81.5, 90.7)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	169/186	90.9 (85.8, 94.6)	173/187	92.5 (87.8, 95.8)	302/328	92.1 (88.6, 94.8)
> Median	93/114	81.6 (73.2, 88.2)	103/113	91.2 (84.3, 95.7)	236/272	86.8 (82.2, 90.6)
Any chronic medical condition						
Yes	243/278	87.4 (82.9, 91.1)	225/242	93.0 (89.0, 95.9)	468/520	90.0 (87.1, 92.4)
No	19/22	86.4 (65.1, 97.1)	51/58	87.9 (76.7, 95.0)	70/80	87.5 (78.2, 93.8)
Type of chronic medical condition						
Diabetes	16/20	80.0 (56.3, 94.3)	19/23	82.6 (61.2, 95.0)	35/43	81.4 (66.6, 91.6)
Osteoporosis	218/253	86.2 (81.3, 90.2)	81/86	94.2 (87.0, 98.1)	299/339	88.2 (84.3, 91.4)
Hypertension	123/149	82.6 (75.5, 88.3)	147/159	92.5 (87.2, 96.0)	270/308	87.7 (83.5, 91.1)
Other	162/186	87.1 (81.4, 91.6)	123/132	93.2 (87.5, 96.8)	285/318	89.6 (85.7, 92.7)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Any prior PMO therapy						
Yes	220/255	86.3 (81.4, 90.2)	131/146	89.7 (83.6, 94.1)	351/401	87.5 (83.9, 90.6)
No	42/45	93.3 (81.7, 98.6)	145/154	94.2 (89.2, 97.3)	187/199	94.0 (89.7, 96.8)
Any PMO therapy within the 12 months prior to enrollment						
Yes	205/240	85.4 (80.3, 89.6)	107/119	89.9 (83.0, 94.7)	312/359	86.9 (83.0, 90.2)
No	57/60	95.0 (86.1, 99.0)	169/181	93.4 (88.7, 96.5)	226/241	93.8 (89.9, 96.5)
Prior calcium and/or vitamin D supplement						
Yes	127/151	84.1 (77.3, 89.5)	18/19	94.7 (74.0, 99.9)	145/170	85.3 (79.1, 90.3)
No	135/149	90.6 (84.7, 94.8)	258/281	91.8 (88.0, 94.7)	393/430	91.4 (88.3, 93.9)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	131/157	83.4 (76.7, 88.9)	123/151	81.5 (74.3, 87.3)	261/315	82.9 (78.2, 86.9)
> Median	115/143	80.4 (73.0, 86.6)	120/149	80.5 (73.3, 86.6)	228/285	80.0 (74.9, 84.5)
Age group						
< 65 years	81/90	90.0 (81.9, 95.3)	133/164	81.1 (74.3, 86.8)	214/254	84.3 (79.2, 88.5)
≥ 65 - < 75 years	94/121	77.7 (69.2, 84.8)	81/98	82.7 (73.7, 89.6)	175/219	79.9 (74.0, 85.0)
≥ 75 years	71/89	79.8 (69.9, 87.6)	29/38	76.3 (59.8, 88.6)	100/127	78.7 (70.6, 85.5)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	124/151	82.1 (75.1, 87.9)	124/151	82.1 (75.1, 87.9)	247/301	82.1 (77.2, 86.2)
> Median	122/149	81.9 (74.7, 87.7)	119/149	79.9 (72.5, 86.0)	242/299	80.9 (76.0, 85.2)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-004-fi-inj-prres-covar-pr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.amh

Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	135/158	85.4 (79.0, 90.5)	150/194	77.3 (70.8, 83.0)	300/369	81.3 (76.9, 85.1)
> Median	111/142	78.2 (70.5, 84.7)	93/106	87.7 (79.9, 93.3)	189/231	81.8 (76.2, 86.6)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	159/186	85.5 (79.6, 90.2)	154/187	82.4 (76.1, 87.5)	275/328	83.8 (79.4, 87.7)
> Median	87/114	76.3 (67.4, 83.8)	89/113	78.8 (70.1, 85.9)	214/272	78.7 (73.3, 83.4)
Any chronic medical condition						
Yes	228/278	82.0 (77.0, 86.3)	201/242	83.1 (77.7, 87.6)	429/520	82.5 (79.0, 85.7)
No	18/22	81.8 (59.7, 94.8)	42/58	72.4 (59.1, 83.3)	60/80	75.0 (64.1, 84.0)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Type of chronic medical condition						
Diabetes	14/20	70.0 (45.7, 88.1)	13/23	56.5 (34.5, 76.8)	27/43	62.8 (46.7, 77.0)
Osteoporosis	206/253	81.4 (76.1, 86.0)	72/86	83.7 (74.2, 90.8)	278/339	82.0 (77.5, 85.9)
Hypertension	116/149	77.9 (70.3, 84.2)	129/159	81.1 (74.2, 86.9)	245/308	79.5 (74.6, 83.9)
Other	148/186	79.6 (73.1, 85.1)	113/132	85.6 (78.4, 91.1)	261/318	82.1 (77.4, 86.1)
Any prior PMO therapy						
Yes	207/255	81.2 (75.8, 85.8)	116/146	79.5 (72.0, 85.7)	323/401	80.5 (76.3, 84.3)
No	39/45	86.7 (73.2, 94.9)	127/154	82.5 (75.5, 88.1)	166/199	83.4 (77.5, 88.3)
Any PMO therapy within the 12 months prior to enrollment						
Yes	193/240	80.4 (74.8, 85.2)	94/119	79.0 (70.6, 85.9)	287/359	79.9 (75.4, 84.0)
No	53/60	88.3 (77.4, 95.2)	149/181	82.3 (76.0, 87.6)	202/241	83.8 (78.5, 88.2)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.4. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Patient Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Prior calcium and/or vitamin D supplement						
Yes	118/151	78.1 (70.7, 84.5)	14/19	73.7 (48.8, 90.9)	132/170	77.6 (70.6, 83.7)
No	128/149	85.9 (79.3, 91.1)	229/281	81.5 (76.5, 85.9)	357/430	83.0 (79.1, 86.5)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.5. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection						
Physician specialty						
Rheumatologist	106/113	93.8 (87.7, 97.5)	132/136	97.1 (92.6, 99.2)	238/249	95.6 (92.2, 97.8)
Internist	144/154	93.5 (88.4, 96.8)	53/54	98.1 (90.1, 100.0)	197/208	94.7 (90.7, 97.3)
Endocrinologist	13/13	100.0 (75.3, 100.0)	49/51	96.1 (86.5, 99.5)	62/64	96.9 (89.2, 99.6)
Orthopedist	0/0	- (-, -)	59/59	100.0 (93.9, 100.0)	59/59	100.0 (93.9, 100.0)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	20/20	100.0 (83.2, 100.0)	31/32	96.9 (83.8, 99.9)	51/52	98.1 (89.7, 100.0)
≥ 10 years	263/280	93.9 (90.5, 96.4)	262/268	97.8 (95.2, 99.2)	525/548	95.8 (93.8, 97.3)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-005-fi-inj-prres-covar-sr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.3.5. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Sole physician						
Sole	119/124	96.0 (90.8, 98.7)	229/235	97.4 (94.5, 99.1)	348/359	96.9 (94.6, 98.5)
Group	164/176	93.2 (88.4, 96.4)	64/65	98.5 (91.7, 100.0)	228/241	94.6 (91.0, 97.1)
Group size						
2 - 3	98/106	92.5 (85.7, 96.7)	26/26	100.0 (86.8, 100.0)	124/132	93.9 (88.4, 97.3)
4 - 5	46/50	92.0 (80.8, 97.8)	25/25	100.0 (86.3, 100.0)	71/75	94.7 (86.9, 98.5)
6 - 10	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
> 10	0/0	- (-, -)	13/14	92.9 (66.1, 99.8)	13/14	92.9 (66.1, 99.8)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Center type						
Hospital	88/90	97.8 (92.2, 99.7)	112/117	95.7 (90.3, 98.6)	200/207	96.6 (93.2, 98.6)
Non-hospital	195/210	92.9 (88.5, 95.9)	181/183	98.9 (96.1, 99.9)	376/393	95.7 (93.2, 97.5)
Academic centre						
Academic	15/17	88.2 (63.6, 98.5)	63/63	100.0 (94.3, 100.0)	78/80	97.5 (91.3, 99.7)
Non-academic	268/283	94.7 (91.4, 97.0)	171/177	96.6 (92.8, 98.7)	439/460	95.4 (93.1, 97.2)
Both	0/0	- (-, -)	38/39	97.4 (86.5, 99.9)	38/39	97.4 (86.5, 99.9)
Not available	0/0	- (-, -)	21/21	100.0 (83.9, 100.0)	21/21	100.0 (83.9, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Region						
Urban	264/280	94.3 (90.9, 96.7)	293/300	97.7 (95.3, 99.1)	557/580	96.0 (94.1, 97.5)
Rural	19/20	95.0 (75.1, 99.9)	0/0	- (-, -)	19/20	95.0 (75.1, 99.9)
Physician active reminder service for next Prolia® administration						
Yes	152/160	95.0 (90.4, 97.8)	251/256	98.0 (95.5, 99.4)	403/416	96.9 (94.7, 98.3)
No	131/140	93.6 (88.1, 97.0)	42/44	95.5 (84.5, 99.4)	173/184	94.0 (89.6, 97.0)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	81/87	93.1 (85.6, 97.4)	123/124	99.2 (95.6, 100.0)	204/211	96.7 (93.3, 98.7)
Appointment card	71/73	97.3 (90.5, 99.7)	87/91	95.6 (89.1, 98.8)	158/164	96.3 (92.2, 98.6)
Mailing	40/40	100.0 (91.2, 100.0)	73/74	98.6 (92.7, 100.0)	113/114	99.1 (95.2, 100.0)
Sticker from drug package	0/0	- (-, -)	30/30	100.0 (88.4, 100.0)	30/30	100.0 (88.4, 100.0)
Email/SMS	0/0	- (-, -)	25/25	100.0 (86.3, 100.0)	25/25	100.0 (86.3, 100.0)

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n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1 post-baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	131/138	94.9 (89.8, 97.9)	175/178	98.3 (95.2, 99.7)	306/316	96.8 (94.3, 98.5)
History of osteoporotic fracture	132/136	97.1 (92.6, 99.2)	54/55	98.2 (90.3, 100.0)	186/191	97.4 (94.0, 99.1)
Multiple risk factors for fracture	118/126	93.7 (87.9, 97.2)	59/60	98.3 (91.1, 100.0)	177/186	95.2 (91.0, 97.8)
Failed other available osteoporosis therapy	103/109	94.5 (88.4, 98.0)	46/47	97.9 (88.7, 99.9)	149/156	95.5 (91.0, 98.2)
Intolerant to other osteoporosis therapy	149/160	93.1 (88.0, 96.5)	37/39	94.9 (82.7, 99.4)	186/199	93.5 (89.1, 96.5)
Other	9/10	90.0 (55.5, 99.7)	16/17	94.1 (71.3, 99.9)	25/27	92.6 (75.7, 99.1)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections						
Physician specialty						
Rheumatologist	104/113	92.0 (85.4, 96.3)	128/136	94.1 (88.7, 97.4)	232/249	93.2 (89.3, 96.0)
Internist	139/154	90.3 (84.4, 94.4)	49/54	90.7 (79.7, 96.9)	188/208	90.4 (85.5, 94.0)
Endocrinologist	13/13	100.0 (75.3, 100.0)	47/51	92.2 (81.1, 97.8)	60/64	93.8 (84.8, 98.3)
Orthopedist	0/0	- (-, -)	59/59	100.0 (93.9, 100.0)	59/59	100.0 (93.9, 100.0)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	20/20	100.0 (83.2, 100.0)	30/32	93.8 (79.2, 99.2)	50/52	96.2 (86.8, 99.5)
≥ 10 years	256/280	91.4 (87.5, 94.4)	253/268	94.4 (90.9, 96.8)	509/548	92.9 (90.4, 94.9)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.3.5. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Sole physician						
Sole	116/124	93.5 (87.7, 97.2)	223/235	94.9 (91.3, 97.3)	339/359	94.4 (91.5, 96.6)
Group	160/176	90.9 (85.7, 94.7)	60/65	92.3 (83.0, 97.5)	220/241	91.3 (87.0, 94.5)
Group size						
2 - 3	96/106	90.6 (83.3, 95.4)	25/26	96.2 (80.4, 99.9)	121/132	91.7 (85.6, 95.8)
4 - 5	44/50	88.0 (75.7, 95.5)	23/25	92.0 (74.0, 99.0)	67/75	89.3 (80.1, 95.3)
6 - 10	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
> 10	0/0	- (-, -)	12/14	85.7 (57.2, 98.2)	12/14	85.7 (57.2, 98.2)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Table 14-4.3.5. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Center type						
Hospital	87/90	96.7 (90.6, 99.3)	108/117	92.3 (85.9, 96.4)	195/207	94.2 (90.1, 97.0)
Non-hospital	189/210	90.0 (85.1, 93.7)	175/183	95.6 (91.6, 98.1)	364/393	92.6 (89.6, 95.0)
Academic centre						
Academic	15/17	88.2 (63.6, 98.5)	62/63	98.4 (91.5, 100.0)	77/80	96.3 (89.4, 99.2)
Non-academic	261/283	92.2 (88.5, 95.1)	167/177	94.4 (89.9, 97.3)	428/460	93.0 (90.3, 95.2)
Both	0/0	- (-, -)	35/39	89.7 (75.8, 97.1)	35/39	89.7 (75.8, 97.1)
Not available	0/0	- (-, -)	19/21	90.5 (69.6, 98.8)	19/21	90.5 (69.6, 98.8)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
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Table 14-4.3.5. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Region						
Urban	258/280	92.1 (88.3, 95.0)	283/300	94.3 (91.1, 96.7)	541/580	93.3 (90.9, 95.2)
Rural	18/20	90.0 (68.3, 98.8)	0/0	- (-, -)	18/20	90.0 (68.3, 98.8)
Physician active reminder service for next Prolia® administration						
Yes	147/160	91.9 (86.5, 95.6)	242/256	94.5 (91.0, 97.0)	389/416	93.5 (90.7, 95.7)
No	129/140	92.1 (86.4, 96.0)	41/44	93.2 (81.3, 98.6)	170/184	92.4 (87.6, 95.8)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Types of reminders[a]						
Telephone call	78/87	89.7 (81.3, 95.2)	119/124	96.0 (90.8, 98.7)	197/211	93.4 (89.1, 96.3)
Appointment card	69/73	94.5 (86.6, 98.5)	82/91	90.1 (82.1, 95.4)	151/164	92.1 (86.8, 95.7)
Mailing	39/40	97.5 (86.8, 99.9)	70/74	94.6 (86.7, 98.5)	109/114	95.6 (90.1, 98.6)
Sticker from drug package	0/0	- (-, -)	30/30	100.0 (88.4, 100.0)	30/30	100.0 (88.4, 100.0)
Email/SMS	0/0	- (-, -)	23/25	92.0 (74.0, 99.0)	23/25	92.0 (74.0, 99.0)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2 post-baseline injections (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	129/138	93.5 (88.0, 97.0)	169/178	94.9 (90.6, 97.7)	298/316	94.3 (91.1, 96.6)
History of osteoporotic fracture	128/136	94.1 (88.7, 97.4)	52/55	94.5 (84.9, 98.9)	180/191	94.2 (89.9, 97.1)
Multiple risk factors for fracture	115/126	91.3 (84.9, 95.6)	58/60	96.7 (88.5, 99.6)	173/186	93.0 (88.3, 96.2)
Failed other available osteoporosis therapy	102/109	93.6 (87.2, 97.4)	44/47	93.6 (82.5, 98.7)	146/156	93.6 (88.5, 96.9)
Intolerant to other osteoporosis therapy	146/160	91.3 (85.8, 95.1)	36/39	92.3 (79.1, 98.4)	182/199	91.5 (86.7, 94.9)
Other	9/10	90.0 (55.5, 99.7)	14/17	82.4 (56.6, 96.2)	23/27	85.2 (66.3, 95.8)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections						
Physician specialty						
Rheumatologist	99/113	87.6 (80.1, 93.1)	124/136	91.2 (85.1, 95.4)	223/249	89.6 (85.1, 93.1)
Internist	131/154	85.1 (78.4, 90.3)	47/54	87.0 (75.1, 94.6)	178/208	85.6 (80.1, 90.1)
Endocrinologist	12/13	92.3 (64.0, 99.8)	46/51	90.2 (78.6, 96.7)	58/64	90.6 (80.7, 96.5)
Orthopedist	0/0	- (-, -)	59/59	100.0 (93.9, 100.0)	59/59	100.0 (93.9, 100.0)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	19/20	95.0 (75.1, 99.9)	30/32	93.8 (79.2, 99.2)	49/52	94.2 (84.1, 98.8)
≥ 10 years	243/280	86.8 (82.2, 90.5)	246/268	91.8 (87.8, 94.8)	489/548	89.2 (86.3, 91.7)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Sole physician						
Sole	112/124	90.3 (83.7, 94.9)	217/235	92.3 (88.2, 95.4)	329/359	91.6 (88.3, 94.3)
Group	150/176	85.2 (79.1, 90.1)	59/65	90.8 (81.0, 96.5)	209/241	86.7 (81.8, 90.7)
Group size						
2 - 3	89/106	84.0 (75.6, 90.4)	25/26	96.2 (80.4, 99.9)	114/132	86.4 (79.3, 91.7)
4 - 5	42/50	84.0 (70.9, 92.8)	22/25	88.0 (68.8, 97.5)	64/75	85.3 (75.3, 92.4)
6 - 10	19/20	95.0 (75.1, 99.9)	0/0	- (-, -)	19/20	95.0 (75.1, 99.9)
> 10	0/0	- (-, -)	12/14	85.7 (57.2, 98.2)	12/14	85.7 (57.2, 98.2)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Center type						
Hospital	81/90	90.0 (81.9, 95.3)	106/117	90.6 (83.8, 95.2)	187/207	90.3 (85.5, 94.0)
Non-hospital	181/210	86.2 (80.8, 90.6)	170/183	92.9 (88.2, 96.2)	351/393	89.3 (85.8, 92.2)
Academic centre						
Academic	12/17	70.6 (44.0, 89.7)	61/63	96.8 (89.0, 99.6)	73/80	91.3 (82.8, 96.4)
Non-academic	250/283	88.3 (84.0, 91.8)	162/177	91.5 (86.4, 95.2)	412/460	89.6 (86.4, 92.2)
Both	0/0	- (-, -)	34/39	87.2 (72.6, 95.7)	34/39	87.2 (72.6, 95.7)
Not available	0/0	- (-, -)	19/21	90.5 (69.6, 98.8)	19/21	90.5 (69.6, 98.8)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Region						
Urban	245/280	87.5 (83.0, 91.1)	276/300	92.0 (88.3, 94.8)	521/580	89.8 (87.1, 92.2)
Rural	17/20	85.0 (62.1, 96.8)	0/0	- (-, -)	17/20	85.0 (62.1, 96.8)
Physician active reminder service for next Prolia® administration						
Yes	138/160	86.3 (79.9, 91.2)	237/256	92.6 (88.7, 95.5)	375/416	90.1 (86.9, 92.8)
No	124/140	88.6 (82.1, 93.3)	39/44	88.6 (75.4, 96.2)	163/184	88.6 (83.1, 92.8)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Types of reminders[a]						
Telephone call	71/87	81.6 (71.9, 89.1)	117/124	94.4 (88.7, 97.7)	188/211	89.1 (84.1, 93.0)
Appointment card	67/73	91.8 (83.0, 96.9)	79/91	86.8 (78.1, 93.0)	146/164	89.0 (83.2, 93.4)
Mailing	37/40	92.5 (79.6, 98.4)	68/74	91.9 (83.2, 97.0)	105/114	92.1 (85.5, 96.3)
Sticker from drug package	0/0	- (-, -)	29/30	96.7 (82.8, 99.9)	29/30	96.7 (82.8, 99.9)
Email/SMS	0/0	- (-, -)	22/25	88.0 (68.8, 97.5)	22/25	88.0 (68.8, 97.5)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3 post-baseline injections (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	123/138	89.1 (82.7, 93.8)	168/178	94.4 (89.9, 97.3)	291/316	92.1 (88.5, 94.8)
History of osteoporotic fracture	119/136	87.5 (80.7, 92.5)	51/55	92.7 (82.4, 98.0)	170/191	89.0 (83.7, 93.1)
Multiple risk factors for fracture	108/126	85.7 (78.4, 91.3)	55/60	91.7 (81.6, 97.2)	163/186	87.6 (82.0, 92.0)
Failed other available osteoporosis therapy	97/109	89.0 (81.6, 94.2)	43/47	91.5 (79.6, 97.6)	140/156	89.7 (83.9, 94.0)
Intolerant to other osteoporosis therapy	138/160	86.3 (79.9, 91.2)	32/39	82.1 (66.5, 92.5)	170/199	85.4 (79.7, 90.0)
Other	8/10	80.0 (44.4, 97.5)	14/17	82.4 (56.6, 96.2)	22/27	81.5 (61.9, 93.7)

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N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections						
Physician specialty						
Rheumatologist	90/113	79.6 (71.0, 86.6)	109/136	80.1 (72.4, 86.5)	199/249	79.9 (74.4, 84.7)
Internist	125/154	81.2 (74.1, 87.0)	37/54	68.5 (54.4, 80.5)	162/208	77.9 (71.6, 83.3)
Endocrinologist	11/13	84.6 (54.6, 98.1)	40/51	78.4 (64.7, 88.7)	51/64	79.7 (67.8, 88.7)
Orthopedist	0/0	- (-, -)	57/59	96.6 (88.3, 99.6)	57/59	96.6 (88.3, 99.6)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	18/20	90.0 (68.3, 98.8)	26/32	81.3 (63.6, 92.8)	44/52	84.6 (71.9, 93.1)
≥ 10 years	228/280	81.4 (76.4, 85.8)	217/268	81.0 (75.8, 85.5)	445/548	81.2 (77.7, 84.4)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Sole physician						
Sole	106/124	85.5 (78.0, 91.2)	187/235	79.6 (73.8, 84.5)	293/359	81.6 (77.2, 85.5)
Group	140/176	79.5 (72.8, 85.2)	56/65	86.2 (75.3, 93.5)	196/241	81.3 (75.8, 86.0)
Group size						
2 - 3	81/106	76.4 (67.2, 84.1)	24/26	92.3 (74.9, 99.1)	105/132	79.5 (71.7, 86.1)
4 - 5	41/50	82.0 (68.6, 91.4)	21/25	84.0 (63.9, 95.5)	62/75	82.7 (72.2, 90.4)
6 - 10	18/20	90.0 (68.3, 98.8)	0/0	- (-, -)	18/20	90.0 (68.3, 98.8)
> 10	0/0	- (-, -)	11/14	78.6 (49.2, 95.3)	11/14	78.6 (49.2, 95.3)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Center type						
Hospital	75/90	83.3 (74.0, 90.4)	92/117	78.6 (70.1, 85.7)	167/207	80.7 (74.6, 85.8)
Non-hospital	171/210	81.4 (75.5, 86.4)	151/183	82.5 (76.2, 87.7)	322/393	81.9 (77.8, 85.6)
Academic centre						
Academic	8/17	47.1 (23.0, 72.2)	58/63	92.1 (82.4, 97.4)	66/80	82.5 (72.4, 90.1)
Non-academic	238/283	84.1 (79.3, 88.2)	134/177	75.7 (68.7, 81.8)	372/460	80.9 (77.0, 84.4)
Both	0/0	- (-, -)	32/39	82.1 (66.5, 92.5)	32/39	82.1 (66.5, 92.5)
Not available	0/0	- (-, -)	19/21	90.5 (69.6, 98.8)	19/21	90.5 (69.6, 98.8)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-005-fi-inj-prres-covar-sr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.3.5. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Region						
Urban	230/280	82.1 (77.1, 86.4)	243/300	81.0 (76.1, 85.3)	473/580	81.6 (78.2, 84.6)
Rural	16/20	80.0 (56.3, 94.3)	0/0	- (-, -)	16/20	80.0 (56.3, 94.3)
Physician active reminder service for next Prolia® administration						
Yes	131/160	81.9 (75.0, 87.5)	213/256	83.2 (78.0, 87.6)	344/416	82.7 (78.7, 86.2)
No	115/140	82.1 (74.8, 88.1)	30/44	68.2 (52.4, 81.4)	145/184	78.8 (72.2, 84.5)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-005-fi-inj-prres-covar-sr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.3.5. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Types of reminders[a]						
Telephone call	66/87	75.9 (65.5, 84.4)	113/124	91.1 (84.7, 95.5)	179/211	84.8 (79.3, 89.4)
Appointment card	65/73	89.0 (79.5, 95.1)	63/91	69.2 (58.7, 78.5)	128/164	78.0 (70.9, 84.1)
Mailing	37/40	92.5 (79.6, 98.4)	64/74	86.5 (76.5, 93.3)	101/114	88.6 (81.3, 93.8)
Sticker from drug package	0/0	- (-, -)	25/30	83.3 (65.3, 94.4)	25/30	83.3 (65.3, 94.4)
Email/SMS	0/0	- (-, -)	21/25	84.0 (63.9, 95.5)	21/25	84.0 (63.9, 95.5)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-005-fi-inj-prres-covar-sr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.3.5. Summary of Patients Receiving All Individual Prolia® Injections whether or not at the Initial Prescribing Site by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4 post-baseline injections (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	117/138	84.8 (77.7, 90.3)	148/178	83.1 (76.8, 88.3)	265/316	83.9 (79.3, 87.7)
History of osteoporotic fracture	114/136	83.8 (76.5, 89.6)	43/55	78.2 (65.0, 88.2)	157/191	82.2 (76.0, 87.3)
Multiple risk factors for fracture	100/126	79.4 (71.2, 86.1)	50/60	83.3 (71.5, 91.7)	150/186	80.6 (74.2, 86.1)
Failed other available osteoporosis therapy	95/109	87.2 (79.4, 92.8)	36/47	76.6 (62.0, 87.7)	131/156	84.0 (77.3, 89.4)
Intolerant to other osteoporosis therapy	131/160	81.9 (75.0, 87.5)	29/39	74.4 (57.9, 87.0)	160/199	80.4 (74.2, 85.7)
Other	7/10	70.0 (34.8, 93.3)	12/17	70.6 (44.0, 89.7)	19/27	70.4 (49.8, 86.2)

N = Number of patients in the full analysis set
n = Number of patients who received the post-baseline corresponding injection(s)
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-prres-covar.sas
Output: t14-04-003-005-fi-inj-prres-covar-sr-l.rtf (Date Generated: 14AUG2015: 4:42:08) Source Data: adam.apresc, adam.aslinfo, adam.aslbase, adam.apresc

Table 14-4.4.1. Summary of Referrals by the Prescribing Physician to Other Health Care Providers for Continuation or Follow-Up Care by Type of Physician
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	%(95% CI)	n/N1	%(95% CI)	n/N1	%(95% CI)
Has the patient been referred to other health care providers at end of study?						
Yes	0/35	0.0 (0.0, 10.0)	2/21	9.5 (1.2, 30.4)	2/56	3.6 (0.4, 12.3)
No	35/35	100.0 (90.0, 100.0)	19/21	90.5 (69.6, 98.8)	54/56	96.4 (87.7, 99.6)
Type of healthcare provider patient was referred to:						
Rheumatologist	0/35	0.0 (0.0, 10.0)	2/21	9.5 (1.2, 30.4)	2/56	3.6 (0.4, 12.3)

N = Number of patients in the full analysis set
N1 = Number of patients who have discontinued from the study
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-hu-referal.sas
Output: t14-04-004-001-hu-referal-l.rtf (Date Generated: 14AUG2015: 0:10:49) Source Data: adam.aslinfo

Table 14-4.5.1. Summary of the Types of Health Care Professionals Administering Injections of Prolia® by Visit (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Prescribing Physician	54/300	18.0 (13.8, 22.8)	84/300	28.0 (23.0, 33.4)	138/600	23.0 (19.7, 26.6)
Physician other than prescribing Physician	19/300	6.3 (3.9, 9.7)	21/300	7.0 (4.4, 10.5)	40/600	6.7 (4.8, 9.0)
Other health care professional	227/300	75.7 (70.4, 80.4)	195/300	65.0 (59.3, 70.4)	422/600	70.3 (66.5, 74.0)
Nurse[a]	227/227	100.0 (98.4, 100.0)	195/195	100.0 (98.1, 100.0)	422/422	100.0 (99.1, 100.0)
1st post-baseline injection						
Prescribing Physician	70/283	24.7 (19.8, 30.2)	109/293	37.2 (31.7, 43.0)	179/576	31.1 (27.3, 35.0)
Physician other than prescribing Physician	8/283	2.8 (1.2, 5.5)	0/293	0.0 (0.0, 1.3)	8/576	1.4 (0.6, 2.7)
Other health care professional	205/283	72.4 (66.8, 77.6)	184/293	62.8 (57.0, 68.3)	389/576	67.5 (63.5, 71.3)
Nurse[a]	205/205	100.0 (98.2, 100.0)	184/184	100.0 (98.0, 100.0)	389/389	100.0 (99.1, 100.0)

N = Number of patients in the full analysis set
n = Number of patients in the sub-group
N1 = Number of patients in the full analysis set within each sub-group at the corresponding visit
Percentages based on N1
[a] Derives from free text provided when chosen Other health care professional.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-hctyp.sas
Output: t14-04-005-001-fi-inj-hctyp-l.rtf (Date Generated: 14AUG2015: 0:08:05) Source Data: adam.apresc

Table 14-4.5.1. Summary of the Types of Health Care Professionals Administering Injections of Prolia® by Visit (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection						
Prescribing Physician	75/276	27.2 (22.0, 32.8)	104/283	36.7 (31.1, 42.7)	179/559	32.0 (28.2, 36.1)
Physician other than prescribing Physician	0/276	0.0 (0.0, 1.3)	0/283	0.0 (0.0, 1.3)	0/559	0.0 (0.0, 0.7)
Other health care professional	201/276	72.8 (67.2, 78.0)	179/283	63.3 (57.3, 68.9)	380/559	68.0 (63.9, 71.8)
Nurse[a]	201/201	100.0 (98.2, 100.0)	179/179	100.0 (98.0, 100.0)	380/380	100.0 (99.0, 100.0)
3rd post-baseline injection						
Prescribing Physician	69/262	26.3 (21.1, 32.1)	113/276	40.9 (35.1, 47.0)	182/538	33.8 (29.8, 38.0)
Physician other than prescribing Physician	4/262	1.5 (0.4, 3.9)	1/276	0.4 (0.0, 2.0)	5/538	0.9 (0.3, 2.2)
Other health care professional	189/262	72.1 (66.3, 77.5)	162/276	58.7 (52.6, 64.6)	351/538	65.2 (61.0, 69.3)
Nurse[a]	189/189	100.0 (98.1, 100.0)	162/162	100.0 (97.7, 100.0)	351/351	100.0 (99.0, 100.0)

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N = Number of patients in the full analysis set
n = Number of patients in the sub-group
N1 = Number of patients in the full analysis set within each sub-group at the corresponding visit
Percentages based on N1
[a] Derives from free text provided when chosen Other health care professional.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-hctyp.sas
Output: t14-04-005-001-fi-inj-hctyp-l.rtf (Date Generated: 14AUG2015: 0:08:05) Source Data: adam.apresc

Table 14-4.5.1. Summary of the Types of Health Care Professionals Administering Injections of Prolia® by Visit (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection						
Prescribing Physician	76/246	30.9 (25.2, 37.1)	93/243	38.3 (32.1, 44.7)	169/489	34.6 (30.3, 39.0)
Physician other than prescribing Physician	0/246	0.0 (0.0, 1.5)	6/243	2.5 (0.9, 5.3)	6/489	1.2 (0.5, 2.7)
Other health care professional	170/246	69.1 (62.9, 74.8)	144/243	59.3 (52.8, 65.5)	314/489	64.2 (59.8, 68.5)
Nurse[a]	170/170	100.0 (97.9, 100.0)	144/144	100.0 (97.5, 100.0)	314/314	100.0 (98.8, 100.0)

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N = Number of patients in the full analysis set
n = Number of patients in the sub-group
N1 = Number of patients in the full analysis set within each sub-group at the corresponding visit
Percentages based on N1
[a] Derives from free text provided when chosen Other health care professional.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-fi-inj-hctyp.sas
Output: t14-04-005-001-fi-inj-hctyp-l.rtf (Date Generated: 14AUG2015: 0:08:05) Source Data: adam.apresc

Table 14-4.6.1. Number of Post-Baseline Prolia® Injections Received (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of post-baseline Prolia® injections received			
0	17 (5.7)	7 (2.3)	24 (4.0)
1	7 (2.3)	10 (3.3)	17 (2.8)
2	14 (4.7)	7 (2.3)	21 (3.5)
3	16 (5.3)	33 (11.0)	49 (8.2)
4	246 (82.0)	243 (81.0)	489 (81.5)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-ex-nsc.sas
Output: t14-04-006-001-ex-nsc-l.rtf (Date Generated: 14AUG2015: 0:07:48) Source Data: adam.aslinfo, adam.aex

Table 14-4.7.1. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N	% (95% CI)	n/N	% (95% CI)	n/N	% (95% CI)
Has the patient had DXA assessment?						
Pre-baseline	297/300	99.0 (97.1, 99.8)	299/300	99.7 (98.2, 100.0)	596/600	99.3 (98.3, 99.8)
Post-baseline (During the Study)	253/300	84.3 (79.7, 88.3)	216/300	72.0 (66.6, 77.0)	469/600	78.2 (74.6, 81.4)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl.sas
Output: t14-04-007-001-base-dxabl-l.rtf (Date Generated: 14AUG2015: 0:02:16) Source Data: adam.aslbase

Table 14-4.7.2. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment						
Living situation						
At home with spouse/family	208/210	99.0 (96.6, 99.9)	236/237	99.6 (97.7, 100.0)	444/447	99.3 (98.1, 99.9)
At home with care/support	5/5	100.0 (47.8, 100.0)	1/1	100.0 (2.5, 100.0)	6/6	100.0 (54.1, 100.0)
At home alone	79/80	98.8 (93.2, 100.0)	32/32	100.0 (89.1, 100.0)	111/112	99.1 (95.1, 100.0)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	5/5	100.0 (47.8, 100.0)	28/28	100.0 (87.7, 100.0)	33/33	100.0 (89.4, 100.0)
Highest educational level						
University	29/29	100.0 (88.1, 100.0)	38/39	97.4 (86.5, 99.9)	67/68	98.5 (92.1, 100.0)
Secondary education	184/185	99.5 (97.0, 100.0)	167/167	100.0 (97.8, 100.0)	351/352	99.7 (98.4, 100.0)
Elementary education	84/86	97.7 (91.9, 99.7)	74/74	100.0 (95.1, 100.0)	158/160	98.8 (95.6, 99.8)
Not applicable	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)	20/20	100.0 (83.2, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-002-base-dxabl-covar-sd-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.2. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Employment status						
Retired	263/265	99.2 (97.3, 99.9)	201/202	99.5 (97.3, 100.0)	464/467	99.4 (98.1, 99.9)
Employed	24/25	96.0 (79.6, 99.9)	81/81	100.0 (95.5, 100.0)	105/106	99.1 (94.9, 100.0)
Self employed	6/6	100.0 (54.1, 100.0)	5/5	100.0 (47.8, 100.0)	11/11	100.0 (71.5, 100.0)
Unemployed	4/4	100.0 (39.8, 100.0)	7/7	100.0 (59.0, 100.0)	11/11	100.0 (71.5, 100.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)
Post-baseline DXA assessment (During the Study)						
Living situation						
At home with spouse/family	184/210	87.6 (82.4, 91.8)	164/237	69.2 (62.9, 75.0)	348/447	77.9 (73.7, 81.6)
At home with care/support	4/5	80.0 (28.4, 99.5)	1/1	100.0 (2.5, 100.0)	5/6	83.3 (35.9, 99.6)
At home alone	60/80	75.0 (64.1, 84.0)	24/32	75.0 (56.6, 88.5)	84/112	75.0 (65.9, 82.7)
Nursing home	0/0	- (-, -)	1/2	50.0 (1.3, 98.7)	1/2	50.0 (1.3, 98.7)
Not available	5/5	100.0 (47.8, 100.0)	26/28	92.9 (76.5, 99.1)	31/33	93.9 (79.8, 99.3)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-002-base-dxabl-covar-sd-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.2. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Highest educational level						
University	21/29	72.4 (52.8, 87.3)	28/39	71.8 (55.1, 85.0)	49/68	72.1 (59.9, 82.3)
Secondary education	159/185	85.9 (80.1, 90.6)	124/167	74.3 (66.9, 80.7)	283/352	80.4 (75.9, 84.4)
Elementary education	73/86	84.9 (75.5, 91.7)	46/74	62.2 (50.1, 73.2)	119/160	74.4 (66.9, 80.9)
Not applicable	0/0	- (-, -)	18/20	90.0 (68.3, 98.8)	18/20	90.0 (68.3, 98.8)
Employment status						
Retired	221/265	83.4 (78.4, 87.7)	141/202	69.8 (63.0, 76.0)	362/467	77.5 (73.5, 81.2)
Employed	22/25	88.0 (68.8, 97.5)	60/81	74.1 (63.1, 83.2)	82/106	77.4 (68.2, 84.9)
Self employed	6/6	100.0 (54.1, 100.0)	4/5	80.0 (28.4, 99.5)	10/11	90.9 (58.7, 99.8)
Unemployed	4/4	100.0 (39.8, 100.0)	6/7	85.7 (42.1, 99.6)	10/11	90.9 (58.7, 99.8)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-002-base-dxabl-covar-sd-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.3. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment						
Body mass index						
≤ 25 kg/m^2	151/151	100.0 (97.6, 100.0)	104/104	100.0 (96.5, 100.0)	255/255	100.0 (98.6, 100.0)
> 25 kg/m^2	143/145	98.6 (95.1, 99.8)	163/164	99.4 (96.6, 100.0)	306/309	99.0 (97.2, 99.8)
Missing	3/4	75.0 (19.4, 99.4)	32/32	100.0 (89.1, 100.0)	35/36	97.2 (85.5, 99.9)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	207/210	98.6 (95.9, 99.7)	198/199	99.5 (97.2, 100.0)	405/409	99.0 (97.5, 99.7)
> Median	90/90	100.0 (96.0, 100.0)	101/101	100.0 (96.4, 100.0)	191/191	100.0 (98.1, 100.0)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	161/163	98.8 (95.6, 99.9)	160/160	100.0 (97.7, 100.0)	303/305	99.3 (97.7, 99.9)
> Median	136/137	99.3 (96.0, 100.0)	139/140	99.3 (96.1, 100.0)	293/295	99.3 (97.6, 99.9)

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Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-003-base-dxabl-covar-cr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.3. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Cause of menopause						
Natural onset	245/248	98.8 (96.5, 99.7)	244/244	100.0 (98.5, 100.0)	489/492	99.4 (98.2, 99.9)
Clinically/surgically induced	51/51	100.0 (93.0, 100.0)	52/53	98.1 (89.9, 100.0)	103/104	99.0 (94.8, 100.0)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	36/36	100.0 (90.3, 100.0)	20/20	100.0 (83.2, 100.0)	56/56	100.0 (93.6, 100.0)
No	217/219	99.1 (96.7, 99.9)	221/222	99.5 (97.5, 100.0)	438/441	99.3 (98.0, 99.9)
Unknown	44/45	97.8 (88.2, 99.9)	58/58	100.0 (93.8, 100.0)	102/103	99.0 (94.7, 100.0)
Hospitalized for osteoporotic fracture						
Yes	63/63	100.0 (94.3, 100.0)	11/11	100.0 (71.5, 100.0)	74/74	100.0 (95.1, 100.0)
No	234/237	98.7 (96.3, 99.7)	288/289	99.7 (98.1, 100.0)	522/526	99.2 (98.1, 99.8)

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Percentages based on N1

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Table 14-4.7.3. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
≥ 1 Fall in the last 12 months						
Yes	58/61	95.1 (86.3, 99.0)	24/24	100.0 (85.8, 100.0)	82/85	96.5 (90.0, 99.3)
No	239/239	100.0 (98.5, 100.0)	275/276	99.6 (98.0, 100.0)	514/515	99.8 (98.9, 100.0)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	18/19	94.7 (74.0, 99.9)	6/6	100.0 (54.1, 100.0)	24/25	96.0 (79.6, 99.9)
No	279/281	99.3 (97.5, 99.9)	293/294	99.7 (98.1, 100.0)	572/575	99.5 (98.5, 99.9)
Glucocorticoid use						
Yes	32/33	97.0 (84.2, 99.9)	12/12	100.0 (73.5, 100.0)	44/45	97.8 (88.2, 99.9)
No	265/267	99.3 (97.3, 99.9)	287/288	99.7 (98.1, 100.0)	552/555	99.5 (98.4, 99.9)

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Percentages based on N1

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Table 14-4.7.3. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Secondary osteoporosis						
Yes	44/45	97.8 (88.2, 99.9)	22/23	95.7 (78.1, 99.9)	66/68	97.1 (89.8, 99.6)
No	253/255	99.2 (97.2, 99.9)	277/277	100.0 (98.7, 100.0)	530/532	99.6 (98.6, 100.0)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	297/300	99.0 (97.1, 99.8)	298/299	99.7 (98.2, 100.0)	595/599	99.3 (98.3, 99.8)
Former smoker						
Yes	35/35	100.0 (90.0, 100.0)	23/23	100.0 (85.2, 100.0)	58/58	100.0 (93.8, 100.0)
No	262/265	98.9 (96.7, 99.8)	276/277	99.6 (98.0, 100.0)	538/542	99.3 (98.1, 99.8)

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Table 14-4.7.3. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Current smoker						
Yes	39/39	100.0 (91.0, 100.0)	29/29	100.0 (88.1, 100.0)	68/68	100.0 (94.7, 100.0)
No	258/261	98.9 (96.7, 99.8)	270/271	99.6 (98.0, 100.0)	528/532	99.2 (98.1, 99.8)
Height loss since self-reported maximal height						
Yes	237/237	100.0 (98.5, 100.0)	110/111	99.1 (95.1, 100.0)	347/348	99.7 (98.4, 100.0)
No	60/63	95.2 (86.7, 99.0)	189/189	100.0 (98.1, 100.0)	249/252	98.8 (96.6, 99.8)
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	125/125	100.0 (97.1, 100.0)	56/56	100.0 (93.6, 100.0)	190/191	99.5 (97.1, 100.0)
> Median	111/111	100.0 (96.7, 100.0)	54/55	98.2 (90.3, 100.0)	156/156	100.0 (97.7, 100.0)
Missing	61/64	95.3 (86.9, 99.0)	189/189	100.0 (98.1, 100.0)	250/253	98.8 (96.6, 99.8)

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Percentages based on N1

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Table 14-4.7.3. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Previous fracture						
Yes	218/221	98.6 (96.1, 99.7)	100/100	100.0 (96.4, 100.0)	318/321	99.1 (97.3, 99.8)
No	79/79	100.0 (95.4, 100.0)	199/200	99.5 (97.2, 100.0)	278/279	99.6 (98.0, 100.0)
Previous hip fracture						
Yes	18/18	100.0 (81.5, 100.0)	5/5	100.0 (47.8, 100.0)	23/23	100.0 (85.2, 100.0)
No	279/282	98.9 (96.9, 99.8)	294/295	99.7 (98.1, 100.0)	573/577	99.3 (98.2, 99.8)
Previous vertebral fracture						
Yes	91/93	97.8 (92.4, 99.7)	21/21	100.0 (83.9, 100.0)	112/114	98.2 (93.8, 99.8)
No	206/207	99.5 (97.3, 100.0)	278/279	99.6 (98.0, 100.0)	484/486	99.6 (98.5, 100.0)

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Time since most recent historical fracture to first injection						
< 12 months	60/63	95.2 (86.7, 99.0)	29/29	100.0 (88.1, 100.0)	89/92	96.7 (90.8, 99.3)
≥ 12 months	158/158	100.0 (97.7, 100.0)	63/63	100.0 (94.3, 100.0)	221/221	100.0 (98.3, 100.0)
Baseline lumbar spine DXA BMD T-score						
> -2.5	69/70	98.6 (92.3, 100.0)	85/85	100.0 (95.8, 100.0)	154/155	99.4 (96.5, 100.0)
≤ -2.5	198/198	100.0 (98.2, 100.0)	187/188	99.5 (97.1, 100.0)	385/386	99.7 (98.6, 100.0)
Missing	30/32	93.8 (79.2, 99.2)	27/27	100.0 (87.2, 100.0)	57/59	96.6 (88.3, 99.6)
Baseline total hip DXA BMD T-score						
> -2.5	178/179	99.4 (96.9, 100.0)	220/220	100.0 (98.3, 100.0)	398/399	99.7 (98.6, 100.0)
≤ -2.5	84/84	100.0 (95.7, 100.0)	26/26	100.0 (86.8, 100.0)	110/110	100.0 (96.7, 100.0)
Missing	35/37	94.6 (81.8, 99.3)	53/54	98.1 (90.1, 100.0)	88/91	96.7 (90.7, 99.3)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Baseline femoral neck DXA BMD T-score						
> -2.5	158/159	99.4 (96.5, 100.0)	200/200	100.0 (98.2, 100.0)	358/359	99.7 (98.5, 100.0)
≤ -2.5	103/103	100.0 (96.5, 100.0)	72/73	98.6 (92.6, 100.0)	175/176	99.4 (96.9, 100.0)
Missing	36/38	94.7 (82.3, 99.4)	27/27	100.0 (87.2, 100.0)	63/65	96.9 (89.3, 99.6)
Post-baseline DXA assessment (During the Study)						
Body mass index						
≤ 25 kg/m^2	121/151	80.1 (72.9, 86.2)	78/104	75.0 (65.6, 83.0)	199/255	78.0 (72.5, 83.0)
> 25 kg/m^2	128/145	88.3 (81.9, 93.0)	117/164	71.3 (63.8, 78.1)	245/309	79.3 (74.3, 83.7)
Missing	4/4	100.0 (39.8, 100.0)	21/32	65.6 (46.8, 81.4)	25/36	69.4 (51.9, 83.7)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	173/210	82.4 (76.5, 87.3)	147/199	73.9 (67.2, 79.8)	320/409	78.2 (73.9, 82.1)
> Median	80/90	88.9 (80.5, 94.5)	69/101	68.3 (58.3, 77.2)	149/191	78.0 (71.5, 83.7)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	135/163	82.8 (76.1, 88.3)	117/160	73.1 (65.6, 79.8)	236/305	77.4 (72.3, 82.0)
> Median	118/137	86.1 (79.2, 91.4)	99/140	70.7 (62.4, 78.1)	233/295	79.0 (73.9, 83.5)
Cause of menopause						
Natural onset	211/248	85.1 (80.0, 89.3)	173/244	70.9 (64.8, 76.5)	384/492	78.0 (74.1, 81.6)
Clinically/surgically induced	41/51	80.4 (66.9, 90.2)	40/53	75.5 (61.7, 86.2)	81/104	77.9 (68.7, 85.4)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	30/36	83.3 (67.2, 93.6)	16/20	80.0 (56.3, 94.3)	46/56	82.1 (69.6, 91.1)
No	179/219	81.7 (76.0, 86.6)	156/222	70.3 (63.8, 76.2)	335/441	76.0 (71.7, 79.9)
Unknown	44/45	97.8 (88.2, 99.9)	44/58	75.9 (62.8, 86.1)	88/103	85.4 (77.1, 91.6)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	53/63	84.1 (72.7, 92.1)	11/11	100.0 (71.5, 100.0)	64/74	86.5 (76.5, 93.3)
No	200/237	84.4 (79.1, 88.8)	205/289	70.9 (65.3, 76.1)	405/526	77.0 (73.2, 80.5)
≥ 1 Fall in the last 12 months						
Yes	53/61	86.9 (75.8, 94.2)	19/24	79.2 (57.8, 92.9)	72/85	84.7 (75.3, 91.6)
No	200/239	83.7 (78.4, 88.1)	197/276	71.4 (65.7, 76.6)	397/515	77.1 (73.2, 80.6)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	14/19	73.7 (48.8, 90.9)	4/6	66.7 (22.3, 95.7)	18/25	72.0 (50.6, 87.9)
No	239/281	85.1 (80.3, 89.0)	212/294	72.1 (66.6, 77.2)	451/575	78.4 (74.8, 81.7)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Glucocorticoid use						
Yes	25/33	75.8 (57.7, 88.9)	6/12	50.0 (21.1, 78.9)	31/45	68.9 (53.4, 81.8)
No	228/267	85.4 (80.6, 89.4)	210/288	72.9 (67.4, 78.0)	438/555	78.9 (75.3, 82.2)
Secondary osteoporosis						
Yes	37/45	82.2 (67.9, 92.0)	17/23	73.9 (51.6, 89.8)	54/68	79.4 (67.9, 88.3)
No	216/255	84.7 (79.7, 88.9)	199/277	71.8 (66.1, 77.1)	415/532	78.0 (74.2, 81.5)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	253/300	84.3 (79.7, 88.3)	215/299	71.9 (66.4, 76.9)	468/599	78.1 (74.6, 81.4)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Former smoker						
Yes	32/35	91.4 (76.9, 98.2)	15/23	65.2 (42.7, 83.6)	47/58	81.0 (68.6, 90.1)
No	221/265	83.4 (78.4, 87.7)	201/277	72.6 (66.9, 77.7)	422/542	77.9 (74.1, 81.3)
Current smoker						
Yes	31/39	79.5 (63.5, 90.7)	25/29	86.2 (68.3, 96.1)	56/68	82.4 (71.2, 90.5)
No	222/261	85.1 (80.1, 89.2)	191/271	70.5 (64.7, 75.8)	413/532	77.6 (73.8, 81.1)
Height loss since self-reported maximal height						
Yes	205/237	86.5 (81.5, 90.6)	91/111	82.0 (73.6, 88.6)	296/348	85.1 (80.9, 88.6)
No	48/63	76.2 (63.8, 86.0)	125/189	66.1 (58.9, 72.8)	173/252	68.7 (62.5, 74.3)

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Percentages based on N1

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(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	114/125	91.2 (84.8, 95.5)	47/56	83.9 (71.7, 92.4)	170/191	89.0 (83.7, 93.1)
> Median	90/111	81.1 (72.5, 87.9)	44/55	80.0 (67.0, 89.6)	125/156	80.1 (73.0, 86.1)
Missing	49/64	76.6 (64.3, 86.2)	125/189	66.1 (58.9, 72.8)	174/253	68.8 (62.7, 74.4)
Previous fracture						
Yes	186/221	84.2 (78.7, 88.7)	80/100	80.0 (70.8, 87.3)	266/321	82.9 (78.3, 86.8)
No	67/79	84.8 (75.0, 91.9)	136/200	68.0 (61.1, 74.4)	203/279	72.8 (67.1, 77.9)
Previous hip fracture						
Yes	14/18	77.8 (52.4, 93.6)	5/5	100.0 (47.8, 100.0)	19/23	82.6 (61.2, 95.0)
No	239/282	84.8 (80.0, 88.7)	211/295	71.5 (66.0, 76.6)	450/577	78.0 (74.4, 81.3)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-003-base-dxabl-covar-cr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.3. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Previous vertebral fracture						
Yes	77/93	82.8 (73.6, 89.8)	17/21	81.0 (58.1, 94.6)	94/114	82.5 (74.2, 88.9)
No	176/207	85.0 (79.4, 89.6)	199/279	71.3 (65.6, 76.6)	375/486	77.2 (73.2, 80.8)
Time since most recent historical fracture to first injection						
< 12 months	53/63	84.1 (72.7, 92.1)	25/29	86.2 (68.3, 96.1)	78/92	84.8 (75.8, 91.4)
≥ 12 months	133/158	84.2 (77.5, 89.5)	51/63	81.0 (69.1, 89.8)	184/221	83.3 (77.7, 87.9)
Baseline lumbar spine DXA BMD T-score						
> -2.5	60/70	85.7 (75.3, 92.9)	56/85	65.9 (54.8, 75.8)	116/155	74.8 (67.2, 81.5)
≤ -2.5	165/198	83.3 (77.4, 88.2)	138/188	73.4 (66.5, 79.6)	303/386	78.5 (74.1, 82.5)
Missing	28/32	87.5 (71.0, 96.5)	22/27	81.5 (61.9, 93.7)	50/59	84.7 (73.0, 92.8)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-003-base-dxabl-covar-cr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.3. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Condition Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	151/179	84.4 (78.2, 89.3)	159/220	72.3 (65.9, 78.1)	310/399	77.7 (73.3, 81.7)
≤ -2.5	70/84	83.3 (73.6, 90.6)	12/26	46.2 (26.6, 66.6)	82/110	74.5 (65.4, 82.4)
Missing	32/37	86.5 (71.2, 95.5)	45/54	83.3 (70.7, 92.1)	77/91	84.6 (75.5, 91.3)
Baseline femoral neck DXA BMD T-score						
> -2.5	137/159	86.2 (79.8, 91.1)	145/200	72.5 (65.8, 78.6)	282/359	78.6 (73.9, 82.7)
≤ -2.5	83/103	80.6 (71.6, 87.7)	49/73	67.1 (55.1, 77.7)	132/176	75.0 (67.9, 81.2)
Missing	33/38	86.8 (71.9, 95.6)	22/27	81.5 (61.9, 93.7)	55/65	84.6 (73.5, 92.4)

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N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-003-base-dxabl-covar-cr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.4. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	155/157	98.7 (95.5, 99.8)	151/151	100.0 (97.6, 100.0)	312/315	99.0 (97.2, 99.8)
> Median	142/143	99.3 (96.2, 100.0)	148/149	99.3 (96.3, 100.0)	284/285	99.6 (98.1, 100.0)
Age group						
< 65 years	88/90	97.8 (92.2, 99.7)	164/164	100.0 (97.8, 100.0)	252/254	99.2 (97.2, 99.9)
≥ 65 - < 75 years	121/121	100.0 (97.0, 100.0)	97/98	99.0 (94.4, 100.0)	218/219	99.5 (97.5, 100.0)
≥ 75 years	88/89	98.9 (93.9, 100.0)	38/38	100.0 (90.7, 100.0)	126/127	99.2 (95.7, 100.0)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	148/151	98.0 (94.3, 99.6)	151/151	100.0 (97.6, 100.0)	298/301	99.0 (97.1, 99.8)
> Median	149/149	100.0 (97.6, 100.0)	148/149	99.3 (96.3, 100.0)	298/299	99.7 (98.2, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-004-base-dxabl-covar-pr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.4. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	157/158	99.4 (96.5, 100.0)	194/194	100.0 (98.1, 100.0)	368/369	99.7 (98.5, 100.0)
> Median	140/142	98.6 (95.0, 99.8)	105/106	99.1 (94.9, 100.0)	228/231	98.7 (96.3, 99.7)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	184/186	98.9 (96.2, 99.9)	186/187	99.5 (97.1, 100.0)	325/328	99.1 (97.4, 99.8)
> Median	113/114	99.1 (95.2, 100.0)	113/113	100.0 (96.8, 100.0)	271/272	99.6 (98.0, 100.0)
Any chronic medical condition						
Yes	276/278	99.3 (97.4, 99.9)	241/242	99.6 (97.7, 100.0)	517/520	99.4 (98.3, 99.9)
No	21/22	95.5 (77.2, 99.9)	58/58	100.0 (93.8, 100.0)	79/80	98.8 (93.2, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-004-base-dxabl-covar-pr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.4. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Type of chronic medical condition						
Diabetes	19/20	95.0 (75.1, 99.9)	23/23	100.0 (85.2, 100.0)	42/43	97.7 (87.7, 99.9)
Osteoporosis	252/253	99.6 (97.8, 100.0)	85/86	98.8 (93.7, 100.0)	337/339	99.4 (97.9, 99.9)
Hypertension	148/149	99.3 (96.3, 100.0)	159/159	100.0 (97.7, 100.0)	307/308	99.7 (98.2, 100.0)
Other	184/186	98.9 (96.2, 99.9)	131/132	99.2 (95.9, 100.0)	315/318	99.1 (97.3, 99.8)
Any prior PMO therapy						
Yes	255/255	100.0 (98.6, 100.0)	145/146	99.3 (96.2, 100.0)	400/401	99.8 (98.6, 100.0)
No	42/45	93.3 (81.7, 98.6)	154/154	100.0 (97.6, 100.0)	196/199	98.5 (95.7, 99.7)
Any PMO therapy within the 12 months prior to enrollment						
Yes	240/240	100.0 (98.5, 100.0)	118/119	99.2 (95.4, 100.0)	358/359	99.7 (98.5, 100.0)
No	57/60	95.0 (86.1, 99.0)	181/181	100.0 (98.0, 100.0)	238/241	98.8 (96.4, 99.7)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-004-base-dxabl-covar-pr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.4. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Prior calcium and/or vitamin D supplement						
Yes	151/151	100.0 (97.6, 100.0)	19/19	100.0 (82.4, 100.0)	170/170	100.0 (97.9, 100.0)
No	146/149	98.0 (94.2, 99.6)	280/281	99.6 (98.0, 100.0)	426/430	99.1 (97.6, 99.7)
Post-baseline DXA assessment (During the Study)						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	134/157	85.4 (78.8, 90.5)	111/151	73.5 (65.7, 80.4)	248/315	78.7 (73.8, 83.1)
> Median	119/143	83.2 (76.1, 88.9)	105/149	70.5 (62.5, 77.7)	221/285	77.5 (72.2, 82.3)
Age group						
< 65 years	77/90	85.6 (76.6, 92.1)	120/164	73.2 (65.7, 79.8)	197/254	77.6 (71.9, 82.5)
≥ 65 - < 75 years	101/121	83.5 (75.6, 89.6)	71/98	72.4 (62.5, 81.0)	172/219	78.5 (72.5, 83.8)
≥ 75 years	75/89	84.3 (75.0, 91.1)	25/38	65.8 (48.6, 80.4)	100/127	78.7 (70.6, 85.5)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-004-base-dxabl-covar-pr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.4. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment(During the Study) (Cont'd)						
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	126/151	83.4 (76.5, 89.0)	105/151	69.5 (61.5, 76.8)	228/301	75.7 (70.5, 80.5)
> Median	127/149	85.2 (78.5, 90.5)	111/149	74.5 (66.7, 81.3)	241/299	80.6 (75.7, 84.9)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	135/158	85.4 (79.0, 90.5)	139/194	71.6 (64.8, 77.9)	278/369	75.3 (70.6, 79.7)
> Median	118/142	83.1 (75.9, 88.9)	77/106	72.6 (63.1, 80.9)	191/231	82.7 (77.2, 87.3)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	160/186	86.0 (80.2, 90.7)	132/187	70.6 (63.5, 77.0)	255/328	77.7 (72.8, 82.1)
> Median	93/114	81.6 (73.2, 88.2)	84/113	74.3 (65.3, 82.1)	214/272	78.7 (73.3, 83.4)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-004-base-dxabl-covar-pr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.4. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment(During the Study) (Cont'd)						
Any chronic medical condition						
Yes	233/278	83.8 (78.9, 87.9)	177/242	73.1 (67.1, 78.6)	410/520	78.8 (75.1, 82.3)
No	20/22	90.9 (70.8, 98.9)	39/58	67.2 (53.7, 79.0)	59/80	73.8 (62.7, 83.0)
Type of chronic medical condition						
Diabetes	17/20	85.0 (62.1, 96.8)	14/23	60.9 (38.5, 80.3)	31/43	72.1 (56.3, 84.7)
Osteoporosis	210/253	83.0 (77.8, 87.4)	66/86	76.7 (66.4, 85.2)	276/339	81.4 (76.9, 85.4)
Hypertension	122/149	81.9 (74.7, 87.7)	112/159	70.4 (62.7, 77.4)	234/308	76.0 (70.8, 80.6)
Other	153/186	82.3 (76.0, 87.5)	104/132	78.8 (70.8, 85.4)	257/318	80.8 (76.1, 85.0)
Any prior PMO therapy						
Yes	210/255	82.4 (77.1, 86.8)	110/146	75.3 (67.5, 82.1)	320/401	79.8 (75.5, 83.6)
No	43/45	95.6 (84.9, 99.5)	106/154	68.8 (60.9, 76.0)	149/199	74.9 (68.3, 80.7)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-004-base-dxabl-covar-pr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.4. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment(During the Study) (Cont'd)						
Any PMO therapy within the 12 months prior to enrollment						
Yes	197/240	82.1 (76.6, 86.7)	87/119	73.1 (64.2, 80.8)	284/359	79.1 (74.5, 83.2)
No	56/60	93.3 (83.8, 98.2)	129/181	71.3 (64.1, 77.7)	185/241	76.8 (70.9, 81.9)
Prior calcium and/or vitamin D supplement						
Yes	122/151	80.8 (73.6, 86.7)	16/19	84.2 (60.4, 96.6)	138/170	81.2 (74.5, 86.8)
No	131/149	87.9 (81.6, 92.7)	200/281	71.2 (65.5, 76.4)	331/430	77.0 (72.7, 80.9)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-004-base-dxabl-covar-pr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment						
Physician specialty						
Rheumatologist	113/113	100.0 (96.8, 100.0)	136/136	100.0 (97.3, 100.0)	249/249	100.0 (98.5, 100.0)
Internist	151/154	98.1 (94.4, 99.6)	54/54	100.0 (93.4, 100.0)	205/208	98.6 (95.8, 99.7)
Endocrinologist	13/13	100.0 (75.3, 100.0)	50/51	98.0 (89.6, 100.0)	63/64	98.4 (91.6, 100.0)
Orthopedist	0/0	- (-, -)	59/59	100.0 (93.9, 100.0)	59/59	100.0 (93.9, 100.0)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	17/20	85.0 (62.1, 96.8)	32/32	100.0 (89.1, 100.0)	49/52	94.2 (84.1, 98.8)
≥ 10 years	280/280	100.0 (98.7, 100.0)	267/268	99.6 (97.9, 100.0)	547/548	99.8 (99.0, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Sole physician						
Sole	124/124	100.0 (97.1, 100.0)	234/235	99.6 (97.7, 100.0)	358/359	99.7 (98.5, 100.0)
Group	173/176	98.3 (95.1, 99.6)	65/65	100.0 (94.5, 100.0)	238/241	98.8 (96.4, 99.7)
Group size						
2 - 3	106/106	100.0 (96.6, 100.0)	26/26	100.0 (86.8, 100.0)	132/132	100.0 (97.2, 100.0)
4 - 5	50/50	100.0 (92.9, 100.0)	25/25	100.0 (86.3, 100.0)	75/75	100.0 (95.2, 100.0)
6 - 10	17/20	85.0 (62.1, 96.8)	0/0	- (-, -)	17/20	85.0 (62.1, 96.8)
> 10	0/0	- (-, -)	14/14	100.0 (76.8, 100.0)	14/14	100.0 (76.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Center type						
Hospital	87/90	96.7 (90.6, 99.3)	116/117	99.1 (95.3, 100.0)	203/207	98.1 (95.1, 99.5)
Non-hospital	210/210	100.0 (98.3, 100.0)	183/183	100.0 (98.0, 100.0)	393/393	100.0 (99.1, 100.0)
Academic centre						
Academic	17/17	100.0 (80.5, 100.0)	62/63	98.4 (91.5, 100.0)	79/80	98.8 (93.2, 100.0)
Non-academic	280/283	98.9 (96.9, 99.8)	177/177	100.0 (97.9, 100.0)	457/460	99.3 (98.1, 99.9)
Both	0/0	- (-, -)	39/39	100.0 (91.0, 100.0)	39/39	100.0 (91.0, 100.0)
Not available	0/0	- (-, -)	21/21	100.0 (83.9, 100.0)	21/21	100.0 (83.9, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Region						
Urban	277/280	98.9 (96.9, 99.8)	299/300	99.7 (98.2, 100.0)	576/580	99.3 (98.2, 99.8)
Rural	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician active reminder service for next Prolia® administration						
Yes	160/160	100.0 (97.7, 100.0)	255/256	99.6 (97.8, 100.0)	415/416	99.8 (98.7, 100.0)
No	137/140	97.9 (93.9, 99.6)	44/44	100.0 (92.0, 100.0)	181/184	98.4 (95.3, 99.7)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Types of reminders[a]						
Telephone call	87/87	100.0 (95.8, 100.0)	123/124	99.2 (95.6, 100.0)	210/211	99.5 (97.4, 100.0)
Appointment card	73/73	100.0 (95.1, 100.0)	91/91	100.0 (96.0, 100.0)	164/164	100.0 (97.8, 100.0)
Mailing	40/40	100.0 (91.2, 100.0)	74/74	100.0 (95.1, 100.0)	114/114	100.0 (96.8, 100.0)
Sticker from drug package	0/0	- (-, -)	30/30	100.0 (88.4, 100.0)	30/30	100.0 (88.4, 100.0)
Email/SMS	0/0	- (-, -)	25/25	100.0 (86.3, 100.0)	25/25	100.0 (86.3, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Pre-baseline DXA assessment (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	138/138	100.0 (97.4, 100.0)	177/178	99.4 (96.9, 100.0)	315/316	99.7 (98.2, 100.0)
History of osteoporotic fracture	133/136	97.8 (93.7, 99.5)	55/55	100.0 (93.5, 100.0)	188/191	98.4 (95.5, 99.7)
Multiple risk factors for fracture	125/126	99.2 (95.7, 100.0)	59/60	98.3 (91.1, 100.0)	184/186	98.9 (96.2, 99.9)
Failed other available osteoporosis therapy	109/109	100.0 (96.7, 100.0)	47/47	100.0 (92.5, 100.0)	156/156	100.0 (97.7, 100.0)
Intolerant to other osteoporosis therapy	160/160	100.0 (97.7, 100.0)	39/39	100.0 (91.0, 100.0)	199/199	100.0 (98.2, 100.0)
Other	10/10	100.0 (69.2, 100.0)	17/17	100.0 (80.5, 100.0)	27/27	100.0 (87.2, 100.0)

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N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study)						
Physician specialty						
Rheumatologist	89/113	78.8 (70.1, 85.9)	92/136	67.6 (59.1, 75.4)	181/249	72.7 (66.7, 78.1)
Internist	131/154	85.1 (78.4, 90.3)	46/54	85.2 (72.9, 93.4)	177/208	85.1 (79.5, 89.6)
Endocrinologist	13/13	100.0 (75.3, 100.0)	42/51	82.4 (69.1, 91.6)	55/64	85.9 (75.0, 93.4)
Orthopedist	0/0	- (-, -)	36/59	61.0 (47.4, 73.5)	36/59	61.0 (47.4, 73.5)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	18/20	90.0 (68.3, 98.8)	27/32	84.4 (67.2, 94.7)	45/52	86.5 (74.2, 94.4)
≥ 10 years	235/280	83.9 (79.1, 88.0)	189/268	70.5 (64.7, 75.9)	424/548	77.4 (73.6, 80.8)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Sole physician						
Sole	101/124	81.5 (73.5, 87.9)	157/235	66.8 (60.4, 72.8)	258/359	71.9 (66.9, 76.5)
Group	152/176	86.4 (80.4, 91.1)	59/65	90.8 (81.0, 96.5)	211/241	87.6 (82.7, 91.4)
Group size						
2 - 3	89/106	84.0 (75.6, 90.4)	25/26	96.2 (80.4, 99.9)	114/132	86.4 (79.3, 91.7)
4 - 5	45/50	90.0 (78.2, 96.7)	23/25	92.0 (74.0, 99.0)	68/75	90.7 (81.7, 96.2)
6 - 10	18/20	90.0 (68.3, 98.8)	0/0	- (-, -)	18/20	90.0 (68.3, 98.8)
> 10	0/0	- (-, -)	11/14	78.6 (49.2, 95.3)	11/14	78.6 (49.2, 95.3)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Center type						
Hospital	85/90	94.4 (87.5, 98.2)	82/117	70.1 (60.9, 78.2)	167/207	80.7 (74.6, 85.8)
Non-hospital	168/210	80.0 (73.9, 85.2)	134/183	73.2 (66.2, 79.5)	302/393	76.8 (72.4, 80.9)
Academic centre						
Academic	15/17	88.2 (63.6, 98.5)	37/63	58.7 (45.6, 71.0)	52/80	65.0 (53.5, 75.3)
Non-academic	238/283	84.1 (79.3, 88.2)	126/177	71.2 (63.9, 77.7)	364/460	79.1 (75.1, 82.8)
Both	0/0	- (-, -)	34/39	87.2 (72.6, 95.7)	34/39	87.2 (72.6, 95.7)
Not available	0/0	- (-, -)	19/21	90.5 (69.6, 98.8)	19/21	90.5 (69.6, 98.8)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Region						
Urban	235/280	83.9 (79.1, 88.0)	216/300	72.0 (66.6, 77.0)	451/580	77.8 (74.2, 81.1)
Rural	18/20	90.0 (68.3, 98.8)	0/0	- (-, -)	18/20	90.0 (68.3, 98.8)
Physician active reminder service for next Prolia® administration						
Yes	132/160	82.5 (75.7, 88.0)	180/256	70.3 (64.3, 75.8)	312/416	75.0 (70.5, 79.1)
No	121/140	86.4 (79.6, 91.6)	36/44	81.8 (67.3, 91.8)	157/184	85.3 (79.4, 90.1)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Types of reminders[a]						
Telephone call	78/87	89.7 (81.3, 95.2)	86/124	69.4 (60.4, 77.3)	164/211	77.7 (71.5, 83.2)
Appointment card	54/73	74.0 (62.4, 83.5)	69/91	75.8 (65.7, 84.2)	123/164	75.0 (67.7, 81.4)
Mailing	38/40	95.0 (83.1, 99.4)	44/74	59.5 (47.4, 70.7)	82/114	71.9 (62.7, 79.9)
Sticker from drug package	0/0	- (-, -)	17/30	56.7 (37.4, 74.5)	17/30	56.7 (37.4, 74.5)
Email/SMS	0/0	- (-, -)	23/25	92.0 (74.0, 99.0)	23/25	92.0 (74.0, 99.0)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.7.5. Summary of Occurrence DXA Assessment at Pre-Baseline and During the Study by Physician Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Post-baseline DXA assessment (During the Study) (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	122/138	88.4 (81.9, 93.2)	122/178	68.5 (61.2, 75.3)	244/316	77.2 (72.2, 81.7)
History of osteoporotic fracture	116/136	85.3 (78.2, 90.8)	46/55	83.6 (71.2, 92.2)	162/191	84.8 (78.9, 89.6)
Multiple risk factors for fracture	111/126	88.1 (81.1, 93.2)	46/60	76.7 (64.0, 86.6)	157/186	84.4 (78.4, 89.3)
Failed other available osteoporosis therapy	91/109	83.5 (75.2, 89.9)	34/47	72.3 (57.4, 84.4)	125/156	80.1 (73.0, 86.1)
Intolerant to other osteoporosis therapy	128/160	80.0 (73.0, 85.9)	30/39	76.9 (60.7, 88.9)	158/199	79.4 (73.1, 84.8)
Other	9/10	90.0 (55.5, 99.7)	14/17	82.4 (56.6, 96.2)	23/27	85.2 (66.3, 95.8)

N = Number of patients in the full analysis set
n = Number of patients who had DXA assessment in the sub-group
N1 = Number of patients in the full analysis set with non-missing covariate
Percentages based on N1
[a] Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-base-dxabl-covar.sas
Output: t14-04-007-005-base-dxabl-covar-sr-l.rtf (Date Generated: 14AUG2015: 2:35:11) Source Data: adam.aslbase

Table 14-4.8.1. Osteoporosis Related Laboratory Examinations
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection	230/300	76.7 (71.5, 81.3)	260/300	86.7 (82.3, 90.3)	490/600	81.7 (78.3, 84.7)
1st post-baseline injection	148/285	51.9 (46.0, 57.9)	207/294	70.4 (64.8, 75.6)	355/579	61.3 (57.2, 65.3)
2nd post-baseline injection	162/280	57.9 (51.8, 63.7)	224/286	78.3 (73.1, 83.0)	386/566	68.2 (64.2, 72.0)
3rd post-baseline injection	163/270	60.4 (54.3, 66.2)	226/280	80.7 (75.6, 85.2)	389/550	70.7 (66.7, 74.5)
4th post-baseline injection	174/262	66.4 (60.3, 72.1)	223/263	84.8 (79.9, 88.9)	397/525	75.6 (71.7, 79.2)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab.sas
Output: t14-04-008-001-qs-oste-lab-l.rtf (Date Generated: 14AUG2015: 3:09:11) Source Data: adam.aqspq, adam.aslinfo

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Living situation						
At home with spouse/family	173/210	82.4 (76.5, 87.3)	204/237	86.1 (81.0, 90.2)	377/447	84.3 (80.6, 87.6)
At home with care/support	4/5	80.0 (28.4, 99.5)	1/1	100.0 (2.5, 100.0)	5/6	83.3 (35.9, 99.6)
At home alone	51/80	63.8 (52.2, 74.2)	27/32	84.4 (67.2, 94.7)	78/112	69.6 (60.2, 78.0)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	2/5	40.0 (5.3, 85.3)	26/28	92.9 (76.5, 99.1)	28/33	84.8 (68.1, 94.9)
Highest educational level						
University	20/29	69.0 (49.2, 84.7)	34/39	87.2 (72.6, 95.7)	54/68	79.4 (67.9, 88.3)
Secondary education	142/185	76.8 (70.0, 82.6)	141/167	84.4 (78.0, 89.6)	283/352	80.4 (75.9, 84.4)
Elementary education	68/86	79.1 (69.0, 87.1)	65/74	87.8 (78.2, 94.3)	133/160	83.1 (76.4, 88.6)
Not applicable	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)	20/20	100.0 (83.2, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Employment status						
Retired	205/265	77.4 (71.8, 82.3)	171/202	84.7 (78.9, 89.3)	376/467	80.5 (76.6, 84.0)
Employed	18/25	72.0 (50.6, 87.9)	75/81	92.6 (84.6, 97.2)	93/106	87.7 (79.9, 93.3)
Self employed	4/6	66.7 (22.3, 95.7)	4/5	80.0 (28.4, 99.5)	8/11	72.7 (39.0, 94.0)
Unemployed	3/4	75.0 (19.4, 99.4)	5/7	71.4 (29.0, 96.3)	8/11	72.7 (39.0, 94.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection						
Living situation						
At home with spouse/family	120/202	59.4 (52.3, 66.2)	156/232	67.2 (60.8, 73.2)	276/434	63.6 (58.9, 68.1)
At home with care/support	2/5	40.0 (5.3, 85.3)	1/1	100.0 (2.5, 100.0)	3/6	50.0 (11.8, 88.2)
At home alone	26/73	35.6 (24.7, 47.7)	21/31	67.7 (48.6, 83.3)	47/104	45.2 (35.4, 55.3)
Nursing home	0/0	- (-, -)	1/2	50.0 (1.3, 98.7)	1/2	50.0 (1.3, 98.7)
Not available	0/5	0.0 (0.0, 52.2)	28/28	100.0 (87.7, 100.0)	28/33	84.8 (68.1, 94.9)
Highest educational level						
University	17/26	65.4 (44.3, 82.8)	28/38	73.7 (56.9, 86.6)	45/64	70.3 (57.6, 81.1)
Secondary education	91/177	51.4 (43.8, 59.0)	120/166	72.3 (64.8, 78.9)	211/343	61.5 (56.1, 66.7)
Elementary education	40/82	48.8 (37.6, 60.1)	41/71	57.7 (45.4, 69.4)	81/153	52.9 (44.7, 61.1)
Not applicable	0/0	- (-, -)	18/19	94.7 (74.0, 99.9)	18/19	94.7 (74.0, 99.9)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Employment status						
Retired	133/250	53.2 (46.8, 59.5)	132/197	67.0 (60.0, 73.5)	265/447	59.3 (54.6, 63.9)
Employed	10/25	40.0 (21.1, 61.3)	61/81	75.3 (64.5, 84.2)	71/106	67.0 (57.2, 75.8)
Self employed	1/6	16.7 (0.4, 64.1)	3/4	75.0 (19.4, 99.4)	4/10	40.0 (12.2, 73.8)
Unemployed	4/4	100.0 (39.8, 100.0)	6/7	85.7 (42.1, 99.6)	10/11	90.9 (58.7, 99.8)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection						
Living situation						
At home with spouse/family	128/199	64.3 (57.2, 71.0)	169/227	74.4 (68.3, 80.0)	297/426	69.7 (65.1, 74.0)
At home with care/support	3/5	60.0 (14.7, 94.7)	1/1	100.0 (2.5, 100.0)	4/6	66.7 (22.3, 95.7)
At home alone	31/71	43.7 (31.9, 56.0)	26/30	86.7 (69.3, 96.2)	57/101	56.4 (46.2, 66.3)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	0/5	0.0 (0.0, 52.2)	26/26	100.0 (86.8, 100.0)	26/31	83.9 (66.3, 94.5)
Highest educational level						
University	16/26	61.5 (40.6, 79.8)	34/36	94.4 (81.3, 99.3)	50/62	80.6 (68.6, 89.6)
Secondary education	104/173	60.1 (52.4, 67.5)	118/162	72.8 (65.3, 79.5)	222/335	66.3 (60.9, 71.3)
Elementary education	42/81	51.9 (40.5, 63.1)	54/70	77.1 (65.6, 86.3)	96/151	63.6 (55.4, 71.2)
Not applicable	0/0	- (-, -)	18/18	100.0 (81.5, 100.0)	18/18	100.0 (81.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Employment status						
Retired	145/245	59.2 (52.7, 65.4)	139/192	72.4 (65.5, 78.6)	284/437	65.0 (60.3, 69.5)
Employed	13/25	52.0 (31.3, 72.2)	70/78	89.7 (80.8, 95.5)	83/103	80.6 (71.6, 87.7)
Self employed	1/6	16.7 (0.4, 64.1)	4/4	100.0 (39.8, 100.0)	5/10	50.0 (18.7, 81.3)
Unemployed	3/4	75.0 (19.4, 99.4)	6/7	85.7 (42.1, 99.6)	9/11	81.8 (48.2, 97.7)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection						
Living situation						
At home with spouse/family	127/193	65.8 (58.6, 72.5)	175/222	78.8 (72.9, 84.0)	302/415	72.8 (68.2, 77.0)
At home with care/support	3/5	60.0 (14.7, 94.7)	1/1	100.0 (2.5, 100.0)	4/6	66.7 (22.3, 95.7)
At home alone	31/67	46.3 (34.0, 58.9)	23/30	76.7 (57.7, 90.1)	54/97	55.7 (45.2, 65.8)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	2/5	40.0 (5.3, 85.3)	25/25	100.0 (86.3, 100.0)	27/30	90.0 (73.5, 97.9)
Highest educational level						
University	16/26	61.5 (40.6, 79.8)	27/34	79.4 (62.1, 91.3)	43/60	71.7 (58.6, 82.5)
Secondary education	96/165	58.2 (50.3, 65.8)	124/159	78.0 (70.7, 84.2)	220/324	67.9 (62.5, 73.0)
Elementary education	51/79	64.6 (53.0, 75.0)	57/69	82.6 (71.6, 90.7)	108/148	73.0 (65.1, 79.9)
Not applicable	0/0	- (-, -)	18/18	100.0 (81.5, 100.0)	18/18	100.0 (81.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Employment status						
Retired	147/236	62.3 (55.8, 68.5)	145/187	77.5 (70.9, 83.3)	292/423	69.0 (64.4, 73.4)
Employed	10/24	41.7 (22.1, 63.4)	68/77	88.3 (79.0, 94.5)	78/101	77.2 (67.8, 85.0)
Self employed	3/6	50.0 (11.8, 88.2)	3/4	75.0 (19.4, 99.4)	6/10	60.0 (26.2, 87.8)
Unemployed	3/4	75.0 (19.4, 99.4)	5/7	71.4 (29.0, 96.3)	8/11	72.7 (39.0, 94.0)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection						
Living situation						
At home with spouse/family	129/188	68.6 (61.5, 75.2)	173/209	82.8 (77.0, 87.6)	302/397	76.1 (71.6, 80.2)
At home with care/support	2/5	40.0 (5.3, 85.3)	0/0	- (-, -)	2/5	40.0 (5.3, 85.3)
At home alone	41/64	64.1 (51.1, 75.7)	24/28	85.7 (67.3, 96.0)	65/92	70.7 (60.2, 79.7)
Nursing home	0/0	- (-, -)	2/2	100.0 (15.8, 100.0)	2/2	100.0 (15.8, 100.0)
Not available	2/5	40.0 (5.3, 85.3)	24/24	100.0 (85.8, 100.0)	26/29	89.7 (72.6, 97.8)
Highest educational level						
University	16/24	66.7 (44.7, 84.4)	32/33	97.0 (84.2, 99.9)	48/57	84.2 (72.1, 92.5)
Secondary education	116/162	71.6 (64.0, 78.4)	124/151	82.1 (75.1, 87.9)	240/313	76.7 (71.6, 81.2)
Elementary education	42/76	55.3 (43.4, 66.7)	50/62	80.6 (68.6, 89.6)	92/138	66.7 (58.1, 74.5)
Not applicable	0/0	- (-, -)	17/17	100.0 (80.5, 100.0)	17/17	100.0 (80.5, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.2. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Socio-Demographic Related Covariates
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Employment status						
Retired	155/230	67.4 (60.9, 73.4)	144/177	81.4 (74.8, 86.8)	299/407	73.5 (68.9, 77.7)
Employed	13/23	56.5 (34.5, 76.8)	65/70	92.9 (84.1, 97.6)	78/93	83.9 (74.8, 90.7)
Self employed	3/6	50.0 (11.8, 88.2)	4/4	100.0 (39.8, 100.0)	7/10	70.0 (34.8, 93.3)
Unemployed	3/3	100.0 (29.2, 100.0)	5/7	71.4 (29.0, 96.3)	8/10	80.0 (44.4, 97.5)
Missing	0/0	- (-, -)	5/5	100.0 (47.8, 100.0)	5/5	100.0 (47.8, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-002-qs-oste-lab-covar-sd-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslinfo, adam.apresc

Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Body mass index						
≤ 25 kg/m^2	113/151	74.8 (67.1, 81.5)	89/104	85.6 (77.3, 91.7)	202/255	79.2 (73.7, 84.0)
> 25 kg/m^2	115/145	79.3 (71.8, 85.6)	140/164	85.4 (79.0, 90.4)	255/309	82.5 (77.8, 86.6)
Missing	2/4	50.0 (6.8, 93.2)	31/32	96.9 (83.8, 99.9)	33/36	91.7 (77.5, 98.2)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	158/210	75.2 (68.8, 80.9)	173/199	86.9 (81.4, 91.3)	331/409	80.9 (76.8, 84.6)
> Median	72/90	80.0 (70.2, 87.7)	87/101	86.1 (77.8, 92.2)	159/191	83.2 (77.2, 88.2)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	120/163	73.6 (66.2, 80.2)	143/160	89.4 (83.5, 93.7)	252/305	82.6 (77.9, 86.7)
> Median	110/137	80.3 (72.6, 86.6)	117/140	83.6 (76.4, 89.3)	238/295	80.7 (75.7, 85.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-003-qs-oste-lab-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo

Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Cause of menopause						
Natural onset	193/248	77.8 (72.1, 82.8)	212/244	86.9 (82.0, 90.9)	405/492	82.3 (78.7, 85.6)
Clinically/surgically induced	36/51	70.6 (56.2, 82.5)	45/53	84.9 (72.4, 93.3)	81/104	77.9 (68.7, 85.4)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	32/36	88.9 (73.9, 96.9)	17/20	85.0 (62.1, 96.8)	49/56	87.5 (75.9, 94.8)
No	157/219	71.7 (65.2, 77.6)	198/222	89.2 (84.3, 92.9)	355/441	80.5 (76.5, 84.1)
Unknown	41/45	91.1 (78.8, 97.5)	45/58	77.6 (64.7, 87.5)	86/103	83.5 (74.9, 90.1)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-003-qs-oste-lab-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo

Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	47/63	74.6 (62.1, 84.7)	10/11	90.9 (58.7, 99.8)	57/74	77.0 (65.8, 86.0)
No	183/237	77.2 (71.3, 82.4)	250/289	86.5 (82.0, 90.2)	433/526	82.3 (78.8, 85.5)
≥ 1 Fall in the last 12 months						
Yes	47/61	77.0 (64.5, 86.8)	23/24	95.8 (78.9, 99.9)	70/85	82.4 (72.6, 89.8)
No	183/239	76.6 (70.7, 81.8)	237/276	85.9 (81.2, 89.8)	420/515	81.6 (77.9, 84.8)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	13/19	68.4 (43.4, 87.4)	6/6	100.0 (54.1, 100.0)	19/25	76.0 (54.9, 90.6)
No	217/281	77.2 (71.9, 82.0)	254/294	86.4 (81.9, 90.1)	471/575	81.9 (78.5, 85.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-003-qs-oste-lab-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo

Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Glucocorticoid use						
Yes	25/33	75.8 (57.7, 88.9)	11/12	91.7 (61.5, 99.8)	36/45	80.0 (65.4, 90.4)
No	205/267	76.8 (71.2, 81.7)	249/288	86.5 (82.0, 90.2)	454/555	81.8 (78.3, 84.9)
Secondary osteoporosis						
Yes	34/45	75.6 (60.5, 87.1)	18/23	78.3 (56.3, 92.5)	52/68	76.5 (64.6, 85.9)
No	196/255	76.9 (71.2, 81.9)	242/277	87.4 (82.9, 91.0)	438/532	82.3 (78.8, 85.5)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	230/300	76.7 (71.5, 81.3)	259/299	86.6 (82.2, 90.3)	489/599	81.6 (78.3, 84.7)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Former smoker						
Yes	29/35	82.9 (66.4, 93.4)	19/23	82.6 (61.2, 95.0)	48/58	82.8 (70.6, 91.4)
No	201/265	75.8 (70.2, 80.9)	241/277	87.0 (82.5, 90.7)	442/542	81.5 (78.0, 84.7)
Current smoker						
Yes	31/39	79.5 (63.5, 90.7)	28/29	96.6 (82.2, 99.9)	59/68	86.8 (76.4, 93.8)
No	199/261	76.2 (70.6, 81.3)	232/271	85.6 (80.9, 89.6)	431/532	81.0 (77.4, 84.3)
Height loss since self-reported maximal height						
Yes	192/237	81.0 (75.4, 85.8)	97/111	87.4 (79.7, 92.9)	289/348	83.0 (78.7, 86.8)
No	38/63	60.3 (47.2, 72.4)	163/189	86.2 (80.5, 90.8)	201/252	79.8 (74.3, 84.5)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	104/125	83.2 (75.5, 89.3)	48/56	85.7 (73.8, 93.6)	158/191	82.7 (76.6, 87.8)
> Median	87/111	78.4 (69.6, 85.6)	49/55	89.1 (77.8, 95.9)	130/156	83.3 (76.5, 88.8)
Missing	39/64	60.9 (47.9, 72.9)	163/189	86.2 (80.5, 90.8)	202/253	79.8 (74.4, 84.6)
Previous fracture						
Yes	166/221	75.1 (68.9, 80.7)	89/100	89.0 (81.2, 94.4)	255/321	79.4 (74.6, 83.7)
No	64/79	81.0 (70.6, 89.0)	171/200	85.5 (79.8, 90.1)	235/279	84.2 (79.4, 88.3)
Previous hip fracture						
Yes	12/18	66.7 (41.0, 86.7)	5/5	100.0 (47.8, 100.0)	17/23	73.9 (51.6, 89.8)
No	218/282	77.3 (72.0, 82.1)	255/295	86.4 (82.0, 90.1)	473/577	82.0 (78.6, 85.0)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Previous vertebral fracture						
Yes	66/93	71.0 (60.6, 79.9)	20/21	95.2 (76.2, 99.9)	86/114	75.4 (66.5, 83.0)
No	164/207	79.2 (73.1, 84.5)	240/279	86.0 (81.4, 89.9)	404/486	83.1 (79.5, 86.4)
Time since most recent historical fracture to first injection						
< 12 months	43/63	68.3 (55.3, 79.4)	26/29	89.7 (72.6, 97.8)	69/92	75.0 (64.9, 83.4)
≥ 12 months	123/158	77.8 (70.6, 84.1)	56/63	88.9 (78.4, 95.4)	179/221	81.0 (75.2, 85.9)
Baseline lumbar spine DXA BMD T-score						
> -2.5	52/70	74.3 (62.4, 84.0)	63/85	74.1 (63.5, 83.0)	115/155	74.2 (66.6, 80.9)
≤ -2.5	159/198	80.3 (74.1, 85.6)	175/188	93.1 (88.5, 96.3)	334/386	86.5 (82.7, 89.8)
Missing	19/32	59.4 (40.6, 76.3)	22/27	81.5 (61.9, 93.7)	41/59	69.5 (56.1, 80.8)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	142/179	79.3 (72.7, 85.0)	205/220	93.2 (89.0, 96.1)	347/399	87.0 (83.3, 90.1)
≤ -2.5	65/84	77.4 (67.0, 85.8)	20/26	76.9 (56.4, 91.0)	85/110	77.3 (68.3, 84.7)
Missing	23/37	62.2 (44.8, 77.5)	35/54	64.8 (50.6, 77.3)	58/91	63.7 (53.0, 73.6)
Baseline femoral neck DXA BMD T-score						
> -2.5	126/159	79.2 (72.1, 85.3)	175/200	87.5 (82.1, 91.7)	301/359	83.8 (79.6, 87.5)
≤ -2.5	80/103	77.7 (68.4, 85.3)	63/73	86.3 (76.2, 93.2)	143/176	81.3 (74.7, 86.7)
Missing	24/38	63.2 (46.0, 78.2)	22/27	81.5 (61.9, 93.7)	46/65	70.8 (58.2, 81.4)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection						
Body mass index						
≤ 25 kg/m^2	70/140	50.0 (41.4, 58.6)	75/104	72.1 (62.5, 80.5)	145/244	59.4 (53.0, 65.6)
> 25 kg/m^2	77/141	54.6 (46.0, 63.0)	107/159	67.3 (59.4, 74.5)	184/300	61.3 (55.6, 66.9)
Missing	1/4	25.0 (0.6, 80.6)	25/31	80.6 (62.5, 92.5)	26/35	74.3 (56.7, 87.5)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	104/198	52.5 (45.3, 59.6)	137/194	70.6 (63.7, 76.9)	241/392	61.5 (56.5, 66.3)
> Median	44/87	50.6 (39.6, 61.5)	70/100	70.0 (60.0, 78.8)	114/187	61.0 (53.6, 68.0)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	82/154	53.2 (45.0, 61.3)	114/159	71.7 (64.0, 78.5)	194/301	64.5 (58.8, 69.9)
> Median	66/131	50.4 (41.5, 59.2)	93/135	68.9 (60.4, 76.6)	161/278	57.9 (51.9, 63.8)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Cause of menopause						
Natural onset	126/237	53.2 (46.6, 59.7)	161/239	67.4 (61.0, 73.3)	287/476	60.3 (55.7, 64.7)
Clinically/surgically induced	21/47	44.7 (30.2, 59.9)	43/52	82.7 (69.7, 91.8)	64/99	64.6 (54.4, 74.0)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	18/33	54.5 (36.4, 71.9)	15/19	78.9 (54.4, 93.9)	33/52	63.5 (49.0, 76.4)
No	102/208	49.0 (42.1, 56.0)	147/219	67.1 (60.5, 73.3)	249/427	58.3 (53.5, 63.0)
Unknown	28/44	63.6 (47.8, 77.6)	45/56	80.4 (67.6, 89.8)	73/100	73.0 (63.2, 81.4)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	26/61	42.6 (30.0, 55.9)	10/11	90.9 (58.7, 99.8)	36/72	50.0 (38.0, 62.0)
No	122/224	54.5 (47.7, 61.1)	197/283	69.6 (63.9, 74.9)	319/507	62.9 (58.6, 67.1)
≥ 1 Fall in the last 12 months						
Yes	26/58	44.8 (31.7, 58.5)	19/23	82.6 (61.2, 95.0)	45/81	55.6 (44.1, 66.6)
No	122/227	53.7 (47.0, 60.4)	188/271	69.4 (63.5, 74.8)	310/498	62.2 (57.8, 66.5)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	8/17	47.1 (23.0, 72.2)	4/6	66.7 (22.3, 95.7)	12/23	52.2 (30.6, 73.2)
No	140/268	52.2 (46.1, 58.4)	203/288	70.5 (64.9, 75.7)	343/556	61.7 (57.5, 65.7)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Glucocorticoid use						
Yes	19/33	57.6 (39.2, 74.5)	10/12	83.3 (51.6, 97.9)	29/45	64.4 (48.8, 78.1)
No	129/252	51.2 (44.8, 57.5)	197/282	69.9 (64.1, 75.2)	326/534	61.0 (56.8, 65.2)
Secondary osteoporosis						
Yes	20/43	46.5 (31.2, 62.3)	19/23	82.6 (61.2, 95.0)	39/66	59.1 (46.3, 71.0)
No	128/242	52.9 (46.4, 59.3)	188/271	69.4 (63.5, 74.8)	316/513	61.6 (57.2, 65.8)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	148/285	51.9 (46.0, 57.9)	206/293	70.3 (64.7, 75.5)	354/578	61.2 (57.1, 65.2)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Former smoker						
Yes	18/32	56.3 (37.7, 73.6)	14/22	63.6 (40.7, 82.8)	32/54	59.3 (45.0, 72.4)
No	130/253	51.4 (45.0, 57.7)	193/272	71.0 (65.2, 76.3)	323/525	61.5 (57.2, 65.7)
Current smoker						
Yes	20/38	52.6 (35.8, 69.0)	23/29	79.3 (60.3, 92.0)	43/67	64.2 (51.5, 75.5)
No	128/247	51.8 (45.4, 58.2)	184/265	69.4 (63.5, 74.9)	312/512	60.9 (56.6, 65.2)
Height loss since self-reported maximal height						
Yes	118/225	52.4 (45.7, 59.1)	88/109	80.7 (72.1, 87.7)	206/334	61.7 (56.2, 66.9)
No	30/60	50.0 (36.8, 63.2)	119/185	64.3 (57.0, 71.2)	149/245	60.8 (54.4, 67.0)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	71/121	58.7 (49.4, 67.6)	45/56	80.4 (67.6, 89.8)	126/187	67.4 (60.2, 74.0)
> Median	47/103	45.6 (35.8, 55.7)	43/53	81.1 (68.0, 90.6)	80/146	54.8 (46.4, 63.0)
Missing	30/61	49.2 (36.1, 62.3)	119/185	64.3 (57.0, 71.2)	149/246	60.6 (54.2, 66.7)
Previous fracture						
Yes	107/211	50.7 (43.8, 57.6)	88/98	89.8 (82.0, 95.0)	195/309	63.1 (57.5, 68.5)
No	41/74	55.4 (43.4, 67.0)	119/196	60.7 (53.5, 67.6)	160/270	59.3 (53.1, 65.2)
Previous hip fracture						
Yes	5/17	29.4 (10.3, 56.0)	5/5	100.0 (47.8, 100.0)	10/22	45.5 (24.4, 67.8)
No	143/268	53.4 (47.2, 59.5)	202/289	69.9 (64.2, 75.1)	345/557	61.9 (57.8, 66.0)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Previous vertebral fracture						
Yes	47/89	52.8 (41.9, 63.5)	18/21	85.7 (63.7, 97.0)	65/110	59.1 (49.3, 68.4)
No	101/196	51.5 (44.3, 58.7)	189/273	69.2 (63.4, 74.7)	290/469	61.8 (57.3, 66.3)
Time since most recent historical fracture to first injection						
< 12 months	33/60	55.0 (41.6, 67.9)	25/28	89.3 (71.8, 97.7)	58/88	65.9 (55.0, 75.7)
≥ 12 months	74/151	49.0 (40.8, 57.3)	58/63	92.1 (82.4, 97.4)	132/214	61.7 (54.8, 68.2)
Baseline lumbar spine DXA BMD T-score						
> -2.5	26/65	40.0 (28.0, 52.9)	57/83	68.7 (57.6, 78.4)	83/148	56.1 (47.7, 64.2)
≤ -2.5	106/188	56.4 (49.0, 63.6)	132/184	71.7 (64.6, 78.1)	238/372	64.0 (58.9, 68.9)
Missing	16/32	50.0 (31.9, 68.1)	18/27	66.7 (46.0, 83.5)	34/59	57.6 (44.1, 70.4)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	92/167	55.1 (47.2, 62.8)	158/214	73.8 (67.4, 79.6)	250/381	65.6 (60.6, 70.4)
≤ -2.5	38/81	46.9 (35.7, 58.3)	11/26	42.3 (23.4, 63.1)	49/107	45.8 (36.1, 55.7)
Missing	18/37	48.6 (31.9, 65.6)	38/54	70.4 (56.4, 82.0)	56/91	61.5 (50.8, 71.6)
Baseline femoral neck DXA BMD T-score						
> -2.5	85/149	57.0 (48.7, 65.1)	141/195	72.3 (65.5, 78.5)	226/344	65.7 (60.4, 70.7)
≤ -2.5	45/98	45.9 (35.8, 56.3)	50/72	69.4 (57.5, 79.8)	95/170	55.9 (48.1, 63.5)
Missing	18/38	47.4 (31.0, 64.2)	16/27	59.3 (38.8, 77.6)	34/65	52.3 (39.5, 64.9)

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Percentages based on N1
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Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-003-qs-oste-lab-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo

Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection						
Body mass index						
≤ 25 kg/m^2	70/139	50.4 (41.8, 58.9)	78/102	76.5 (67.0, 84.3)	148/241	61.4 (54.9, 67.6)
> 25 kg/m^2	90/137	65.7 (57.1, 73.6)	123/155	79.4 (72.1, 85.4)	213/292	72.9 (67.5, 78.0)
Missing	2/4	50.0 (6.8, 93.2)	23/29	79.3 (60.3, 92.0)	25/33	75.8 (57.7, 88.9)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	114/193	59.1 (51.8, 66.1)	152/189	80.4 (74.0, 85.8)	266/382	69.6 (64.8, 74.2)
> Median	48/87	55.2 (44.1, 65.9)	72/97	74.2 (64.3, 82.6)	120/184	65.2 (57.9, 72.1)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	86/150	57.3 (49.0, 65.4)	126/153	82.4 (75.4, 88.0)	210/293	71.7 (66.1, 76.8)
> Median	76/130	58.5 (49.5, 67.0)	98/133	73.7 (65.3, 80.9)	176/273	64.5 (58.5, 70.1)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Cause of menopause						
Natural onset	136/235	57.9 (51.3, 64.3)	175/233	75.1 (69.0, 80.5)	311/468	66.5 (62.0, 70.7)
Clinically/surgically induced	25/44	56.8 (41.0, 71.7)	46/50	92.0 (80.8, 97.8)	71/94	75.5 (65.6, 83.8)
Not available	1/1	100.0 (2.5, 100.0)	3/3	100.0 (29.2, 100.0)	4/4	100.0 (39.8, 100.0)
Parental hip fracture						
Yes	19/32	59.4 (40.6, 76.3)	15/18	83.3 (58.6, 96.4)	34/50	68.0 (53.3, 80.5)
No	112/204	54.9 (47.8, 61.9)	160/212	75.5 (69.1, 81.1)	272/416	65.4 (60.6, 70.0)
Unknown	31/44	70.5 (54.8, 83.2)	49/56	87.5 (75.9, 94.8)	80/100	80.0 (70.8, 87.3)

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Percentages based on N1
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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	34/60	56.7 (43.2, 69.4)	10/11	90.9 (58.7, 99.8)	44/71	62.0 (49.7, 73.2)
No	128/220	58.2 (51.4, 64.8)	214/275	77.8 (72.4, 82.6)	342/495	69.1 (64.8, 73.1)
≥ 1 Fall in the last 12 months						
Yes	32/57	56.1 (42.4, 69.3)	19/22	86.4 (65.1, 97.1)	51/79	64.6 (53.0, 75.0)
No	130/223	58.3 (51.5, 64.8)	205/264	77.7 (72.1, 82.5)	335/487	68.8 (64.5, 72.9)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	7/16	43.8 (19.8, 70.1)	5/5	100.0 (47.8, 100.0)	12/21	57.1 (34.0, 78.2)
No	155/264	58.7 (52.5, 64.7)	219/281	77.9 (72.6, 82.6)	374/545	68.6 (64.5, 72.5)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Glucocorticoid use						
Yes	19/32	59.4 (40.6, 76.3)	11/12	91.7 (61.5, 99.8)	30/44	68.2 (52.4, 81.4)
No	143/248	57.7 (51.2, 63.9)	213/274	77.7 (72.3, 82.5)	356/522	68.2 (64.0, 72.2)
Secondary osteoporosis						
Yes	19/42	45.2 (29.8, 61.3)	21/22	95.5 (77.2, 99.9)	40/64	62.5 (49.5, 74.3)
No	143/238	60.1 (53.6, 66.4)	203/264	76.9 (71.3, 81.8)	346/502	68.9 (64.7, 73.0)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	162/280	57.9 (51.8, 63.7)	223/285	78.2 (73.0, 82.9)	385/565	68.1 (64.1, 72.0)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Former smoker						
Yes	22/32	68.8 (50.0, 83.9)	19/20	95.0 (75.1, 99.9)	41/52	78.8 (65.3, 88.9)
No	140/248	56.5 (50.0, 62.7)	205/266	77.1 (71.5, 82.0)	345/514	67.1 (62.9, 71.2)
Current smoker						
Yes	22/36	61.1 (43.5, 76.9)	27/29	93.1 (77.2, 99.2)	49/65	75.4 (63.1, 85.2)
No	140/244	57.4 (50.9, 63.7)	197/257	76.7 (71.0, 81.7)	337/501	67.3 (63.0, 71.4)
Height loss since self-reported maximal height						
Yes	132/220	60.0 (53.2, 66.5)	83/105	79.0 (70.0, 86.4)	215/325	66.2 (60.7, 71.3)
No	30/60	50.0 (36.8, 63.2)	141/181	77.9 (71.1, 83.7)	171/241	71.0 (64.8, 76.6)

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Percentages based on N1
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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	76/118	64.4 (55.1, 73.0)	44/54	81.5 (68.6, 90.7)	127/182	69.8 (62.5, 76.4)
> Median	56/101	55.4 (45.2, 65.3)	39/51	76.5 (62.5, 87.2)	88/142	62.0 (53.5, 70.0)
Missing	30/61	49.2 (36.1, 62.3)	141/181	77.9 (71.1, 83.7)	171/242	70.7 (64.5, 76.3)
Previous fracture						
Yes	112/208	53.8 (46.8, 60.8)	81/95	85.3 (76.5, 91.7)	193/303	63.7 (58.0, 69.1)
No	50/72	69.4 (57.5, 79.8)	143/191	74.9 (68.1, 80.9)	193/263	73.4 (67.6, 78.6)
Previous hip fracture						
Yes	10/17	58.8 (32.9, 81.6)	4/5	80.0 (28.4, 99.5)	14/22	63.6 (40.7, 82.8)
No	152/263	57.8 (51.6, 63.8)	220/281	78.3 (73.0, 83.0)	372/544	68.4 (64.3, 72.3)

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Percentages based on N1
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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Previous vertebral fracture						
Yes	51/87	58.6 (47.6, 69.1)	17/21	81.0 (58.1, 94.6)	68/108	63.0 (53.1, 72.1)
No	111/193	57.5 (50.2, 64.6)	207/265	78.1 (72.6, 82.9)	318/458	69.4 (65.0, 73.6)
Time since most recent historical fracture to first injection						
< 12 months	30/58	51.7 (38.2, 65.0)	26/28	92.9 (76.5, 99.1)	56/86	65.1 (54.1, 75.1)
≥ 12 months	82/150	54.7 (46.3, 62.8)	51/60	85.0 (73.4, 92.9)	133/210	63.3 (56.4, 69.9)
Baseline lumbar spine DXA BMD T-score						
> -2.5	32/65	49.2 (36.6, 61.9)	53/81	65.4 (54.0, 75.7)	85/146	58.2 (49.8, 66.3)
≤ -2.5	113/183	61.7 (54.3, 68.8)	148/178	83.1 (76.8, 88.3)	261/361	72.3 (67.4, 76.9)
Missing	17/32	53.1 (34.7, 70.9)	23/27	85.2 (66.3, 95.8)	40/59	67.8 (54.4, 79.4)

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Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	99/163	60.7 (52.8, 68.3)	166/206	80.6 (74.5, 85.8)	265/369	71.8 (66.9, 76.4)
≤ -2.5	42/80	52.5 (41.0, 63.8)	14/26	53.8 (33.4, 73.4)	56/106	52.8 (42.9, 62.6)
Missing	21/37	56.8 (39.5, 72.9)	44/54	81.5 (68.6, 90.7)	65/91	71.4 (61.0, 80.4)
Baseline femoral neck DXA BMD T-score						
> -2.5	95/146	65.1 (56.7, 72.8)	149/189	78.8 (72.3, 84.4)	244/335	72.8 (67.7, 77.5)
≤ -2.5	46/96	47.9 (37.6, 58.4)	53/70	75.7 (64.0, 85.2)	99/166	59.6 (51.8, 67.2)
Missing	21/38	55.3 (38.3, 71.4)	22/27	81.5 (61.9, 93.7)	43/65	66.2 (53.4, 77.4)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection						
Body mass index						
≤ 25 kg/m^2	76/134	56.7 (47.9, 65.2)	82/100	82.0 (73.1, 89.0)	158/234	67.5 (61.1, 73.5)
> 25 kg/m^2	83/132	62.9 (54.0, 71.1)	119/152	78.3 (70.9, 84.6)	202/284	71.1 (65.5, 76.3)
Missing	4/4	100.0 (39.8, 100.0)	25/28	89.3 (71.8, 97.7)	29/32	90.6 (75.0, 98.0)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	114/184	62.0 (54.5, 69.0)	151/185	81.6 (75.3, 86.9)	265/369	71.8 (66.9, 76.4)
> Median	49/86	57.0 (45.8, 67.6)	75/95	78.9 (69.4, 86.6)	124/181	68.5 (61.2, 75.2)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	92/148	62.2 (53.8, 70.0)	127/151	84.1 (77.3, 89.5)	215/288	74.7 (69.2, 79.6)
> Median	71/122	58.2 (48.9, 67.1)	99/129	76.7 (68.5, 83.7)	174/262	66.4 (60.3, 72.1)

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Percentages based on N1
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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Cause of menopause						
Natural onset	136/228	59.6 (53.0, 66.1)	178/229	77.7 (71.8, 82.9)	314/457	68.7 (64.2, 72.9)
Clinically/surgically induced	26/41	63.4 (46.9, 77.9)	47/49	95.9 (86.0, 99.5)	73/90	81.1 (71.5, 88.6)
Not available	1/1	100.0 (2.5, 100.0)	1/2	50.0 (1.3, 98.7)	2/3	66.7 (9.4, 99.2)
Parental hip fracture						
Yes	18/32	56.3 (37.7, 73.6)	16/18	88.9 (65.3, 98.6)	34/50	68.0 (53.3, 80.5)
No	104/195	53.3 (46.1, 60.5)	158/208	76.0 (69.6, 81.6)	262/403	65.0 (60.1, 69.7)
Unknown	41/43	95.3 (84.2, 99.4)	52/54	96.3 (87.3, 99.5)	93/97	95.9 (89.8, 98.9)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	29/57	50.9 (37.3, 64.4)	11/11	100.0 (71.5, 100.0)	40/68	58.8 (46.2, 70.6)
No	134/213	62.9 (56.0, 69.4)	215/269	79.9 (74.6, 84.5)	349/482	72.4 (68.2, 76.4)
≥ 1 Fall in the last 12 months						
Yes	28/53	52.8 (38.6, 66.7)	19/22	86.4 (65.1, 97.1)	47/75	62.7 (50.7, 73.6)
No	135/217	62.2 (55.4, 68.7)	207/258	80.2 (74.8, 84.9)	342/475	72.0 (67.7, 76.0)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	8/16	50.0 (24.7, 75.3)	4/5	80.0 (28.4, 99.5)	12/21	57.1 (34.0, 78.2)
No	155/254	61.0 (54.7, 67.1)	222/275	80.7 (75.6, 85.2)	377/529	71.3 (67.2, 75.1)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
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Percentages based on N1
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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Glucocorticoid use						
Yes	22/30	73.3 (54.1, 87.7)	10/11	90.9 (58.7, 99.8)	32/41	78.0 (62.4, 89.4)
No	141/240	58.8 (52.2, 65.0)	216/269	80.3 (75.0, 84.9)	357/509	70.1 (66.0, 74.1)
Secondary osteoporosis						
Yes	27/40	67.5 (50.9, 81.4)	22/22	100.0 (84.6, 100.0)	49/62	79.0 (66.8, 88.3)
No	136/230	59.1 (52.5, 65.5)	204/258	79.1 (73.6, 83.9)	340/488	69.7 (65.4, 73.7)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	163/270	60.4 (54.3, 66.2)	225/279	80.6 (75.5, 85.1)	388/549	70.7 (66.7, 74.5)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Former smoker						
Yes	21/32	65.6 (46.8, 81.4)	15/19	78.9 (54.4, 93.9)	36/51	70.6 (56.2, 82.5)
No	142/238	59.7 (53.1, 66.0)	211/261	80.8 (75.5, 85.4)	353/499	70.7 (66.5, 74.7)
Current smoker						
Yes	22/34	64.7 (46.5, 80.3)	22/29	75.9 (56.5, 89.7)	44/63	69.8 (57.0, 80.8)
No	141/236	59.7 (53.2, 66.1)	204/251	81.3 (75.9, 85.9)	345/487	70.8 (66.6, 74.8)
Height loss since self-reported maximal height						
Yes	126/210	60.0 (53.0, 66.7)	87/101	86.1 (77.8, 92.2)	213/311	68.5 (63.0, 73.6)
No	37/60	61.7 (48.2, 73.9)	139/179	77.7 (70.8, 83.5)	176/239	73.6 (67.6, 79.1)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	69/115	60.0 (50.4, 69.0)	44/51	86.3 (73.7, 94.3)	123/176	69.9 (62.5, 76.6)
> Median	56/94	59.6 (49.0, 69.6)	43/50	86.0 (73.3, 94.2)	89/134	66.4 (57.8, 74.3)
Missing	38/61	62.3 (49.0, 74.4)	139/179	77.7 (70.8, 83.5)	177/240	73.8 (67.7, 79.2)
Previous fracture						
Yes	119/200	59.5 (52.3, 66.4)	87/94	92.6 (85.3, 97.0)	206/294	70.1 (64.5, 75.2)
No	44/70	62.9 (50.5, 74.1)	139/186	74.7 (67.9, 80.8)	183/256	71.5 (65.5, 76.9)
Previous hip fracture						
Yes	9/17	52.9 (27.8, 77.0)	5/5	100.0 (47.8, 100.0)	14/22	63.6 (40.7, 82.8)
No	154/253	60.9 (54.6, 66.9)	221/275	80.4 (75.2, 84.9)	375/528	71.0 (66.9, 74.9)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Previous vertebral fracture						
Yes	51/84	60.7 (49.5, 71.2)	18/20	90.0 (68.3, 98.8)	69/104	66.3 (56.4, 75.3)
No	112/186	60.2 (52.8, 67.3)	208/260	80.0 (74.6, 84.7)	320/446	71.7 (67.3, 75.9)
Time since most recent historical fracture to first injection						
< 12 months	36/56	64.3 (50.4, 76.6)	27/27	100.0 (87.2, 100.0)	63/83	75.9 (65.3, 84.6)
≥ 12 months	83/144	57.6 (49.1, 65.8)	55/60	91.7 (81.6, 97.2)	138/204	67.6 (60.8, 74.0)
Baseline lumbar spine DXA BMD T-score						
> -2.5	30/61	49.2 (36.1, 62.3)	58/77	75.3 (64.2, 84.4)	88/138	63.8 (55.2, 71.8)
≤ -2.5	112/178	62.9 (55.4, 70.0)	146/177	82.5 (76.1, 87.8)	258/355	72.7 (67.7, 77.2)
Missing	21/31	67.7 (48.6, 83.3)	22/26	84.6 (65.1, 95.6)	43/57	75.4 (62.2, 85.9)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	98/158	62.0 (54.0, 69.6)	167/201	83.1 (77.2, 88.0)	265/359	73.8 (68.9, 78.3)
≤ -2.5	41/76	53.9 (42.1, 65.5)	13/26	50.0 (29.9, 70.1)	54/102	52.9 (42.8, 62.9)
Missing	24/36	66.7 (49.0, 81.4)	46/53	86.8 (74.7, 94.5)	70/89	78.7 (68.7, 86.6)
Baseline femoral neck DXA BMD T-score						
> -2.5	86/141	61.0 (52.4, 69.1)	152/186	81.7 (75.4, 87.0)	238/327	72.8 (67.6, 77.5)
≤ -2.5	52/92	56.5 (45.8, 66.8)	54/68	79.4 (67.9, 88.3)	106/160	66.3 (58.4, 73.5)
Missing	25/37	67.6 (50.2, 82.0)	20/26	76.9 (56.4, 91.0)	45/63	71.4 (58.7, 82.1)

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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection						
Body mass index						
≤ 25 kg/m^2	82/132	62.1 (53.3, 70.4)	80/94	85.1 (76.3, 91.6)	162/226	71.7 (65.3, 77.5)
> 25 kg/m^2	91/126	72.2 (63.5, 79.8)	121/146	82.9 (75.8, 88.6)	212/272	77.9 (72.5, 82.7)
Missing	1/4	25.0 (0.6, 80.6)	22/23	95.7 (78.1, 99.9)	23/27	85.2 (66.3, 95.8)
Age at menopause (years) (Czech Republic median = 50.0, Slovakia median = 50.0, Overall median = 50.0)						
≤ Median	118/177	66.7 (59.2, 73.6)	152/174	87.4 (81.5, 91.9)	270/351	76.9 (72.2, 81.2)
> Median	56/85	65.9 (54.8, 75.8)	71/89	79.8 (69.9, 87.6)	127/174	73.0 (65.7, 79.4)
Years since menopause (Czech Republic median = 21.0, Slovakia median = 15.0, Overall median = 17.0)						
≤ Median	101/145	69.7 (61.5, 77.0)	128/143	89.5 (83.3, 94.0)	222/278	79.9 (74.7, 84.4)
> Median	73/117	62.4 (53.0, 71.2)	95/120	79.2 (70.8, 86.0)	175/247	70.9 (64.8, 76.4)

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Percentages based on N1
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Table 14-4.8.3. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Condition Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Cause of menopause						
Natural onset	150/223	67.3 (60.7, 73.4)	176/214	82.2 (76.5, 87.1)	326/437	74.6 (70.2, 78.6)
Clinically/surgically induced	23/38	60.5 (43.4, 76.0)	45/47	95.7 (85.5, 99.5)	68/85	80.0 (69.9, 87.9)
Not available	1/1	100.0 (2.5, 100.0)	2/2	100.0 (15.8, 100.0)	3/3	100.0 (29.2, 100.0)
Parental hip fracture						
Yes	23/31	74.2 (55.4, 88.1)	17/18	94.4 (72.7, 99.9)	40/49	81.6 (68.0, 91.2)
No	121/188	64.4 (57.1, 71.2)	159/196	81.1 (74.9, 86.3)	280/384	72.9 (68.2, 77.3)
Unknown	30/43	69.8 (53.9, 82.8)	47/49	95.9 (86.0, 99.5)	77/92	83.7 (74.5, 90.6)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Hospitalized for osteoporotic fracture						
Yes	35/55	63.6 (49.6, 76.2)	10/11	90.9 (58.7, 99.8)	45/66	68.2 (55.6, 79.1)
No	139/207	67.1 (60.3, 73.5)	213/252	84.5 (79.5, 88.8)	352/459	76.7 (72.5, 80.5)
≥ 1 Fall in the last 12 months						
Yes	35/50	70.0 (55.4, 82.1)	19/19	100.0 (82.4, 100.0)	54/69	78.3 (66.7, 87.3)
No	139/212	65.6 (58.8, 71.9)	204/244	83.6 (78.4, 88.0)	343/456	75.2 (71.0, 79.1)
≥ 1 Occurrence of immobility in the past 12 months						
Yes	8/16	50.0 (24.7, 75.3)	4/4	100.0 (39.8, 100.0)	12/20	60.0 (36.1, 80.9)
No	166/246	67.5 (61.2, 73.3)	219/259	84.6 (79.6, 88.7)	385/505	76.2 (72.3, 79.9)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Glucocorticoid use						
Yes	20/29	69.0 (49.2, 84.7)	11/11	100.0 (71.5, 100.0)	31/40	77.5 (61.5, 89.2)
No	154/233	66.1 (59.6, 72.1)	212/252	84.1 (79.0, 88.4)	366/485	75.5 (71.4, 79.2)
Secondary osteoporosis						
Yes	22/39	56.4 (39.6, 72.2)	22/22	100.0 (84.6, 100.0)	44/61	72.1 (59.2, 82.9)
No	152/223	68.2 (61.6, 74.2)	201/241	83.4 (78.1, 87.9)	353/464	76.1 (71.9, 79.9)
Alcohol 3 or more units per day						
Yes	0/0	- (-, -)	1/1	100.0 (2.5, 100.0)	1/1	100.0 (2.5, 100.0)
No	174/262	66.4 (60.3, 72.1)	222/262	84.7 (79.8, 88.9)	396/524	75.6 (71.7, 79.2)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Former smoker						
Yes	23/29	79.3 (60.3, 92.0)	15/16	93.8 (69.8, 99.8)	38/45	84.4 (70.5, 93.5)
No	151/233	64.8 (58.3, 70.9)	208/247	84.2 (79.1, 88.5)	359/480	74.8 (70.7, 78.6)
Current smoker						
Yes	24/34	70.6 (52.5, 84.9)	25/28	89.3 (71.8, 97.7)	49/62	79.0 (66.8, 88.3)
No	150/228	65.8 (59.2, 71.9)	198/235	84.3 (79.0, 88.7)	348/463	75.2 (71.0, 79.0)
Height loss since self-reported maximal height						
Yes	136/205	66.3 (59.4, 72.8)	86/95	90.5 (82.8, 95.6)	222/300	74.0 (68.6, 78.9)
No	38/57	66.7 (52.9, 78.6)	137/168	81.5 (74.8, 87.1)	175/225	77.8 (71.8, 83.0)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Height loss since self-reported maximal height (cm) (Czech Republic median = 4.0, Slovakia median = 3.5, Overall median = 4.0)						
≤ Median	73/112	65.2 (55.6, 73.9)	43/49	87.8 (75.2, 95.4)	125/171	73.1 (65.8, 79.6)
> Median	63/92	68.5 (58.0, 77.8)	43/46	93.5 (82.1, 98.6)	97/128	75.8 (67.4, 82.9)
Missing	38/58	65.5 (51.9, 77.5)	137/168	81.5 (74.8, 87.1)	175/226	77.4 (71.4, 82.7)
Previous fracture						
Yes	125/192	65.1 (57.9, 71.8)	80/88	90.9 (82.9, 96.0)	205/280	73.2 (67.6, 78.3)
No	49/70	70.0 (57.9, 80.4)	143/175	81.7 (75.2, 87.1)	192/245	78.4 (72.7, 83.4)
Previous hip fracture						
Yes	10/16	62.5 (35.4, 84.8)	5/5	100.0 (47.8, 100.0)	15/21	71.4 (47.8, 88.7)
No	164/246	66.7 (60.4, 72.5)	218/258	84.5 (79.5, 88.7)	382/504	75.8 (71.8, 79.5)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Previous vertebral fracture						
Yes	48/79	60.8 (49.1, 71.6)	17/20	85.0 (62.1, 96.8)	65/99	65.7 (55.4, 74.9)
No	126/183	68.9 (61.6, 75.5)	206/243	84.8 (79.6, 89.0)	332/426	77.9 (73.7, 81.8)
Time since most recent historical fracture to first injection						
< 12 months	33/54	61.1 (46.9, 74.1)	25/26	96.2 (80.4, 99.9)	58/80	72.5 (61.4, 81.9)
≥ 12 months	92/138	66.7 (58.1, 74.5)	51/56	91.1 (80.4, 97.0)	143/194	73.7 (66.9, 79.8)
Baseline lumbar spine DXA BMD T-score						
> -2.5	35/61	57.4 (44.1, 70.0)	54/75	72.0 (60.4, 81.8)	89/136	65.4 (56.8, 73.4)
≤ -2.5	126/172	73.3 (66.0, 79.7)	145/164	88.4 (82.5, 92.9)	271/336	80.7 (76.0, 84.7)
Missing	13/29	44.8 (26.4, 64.3)	24/24	100.0 (85.8, 100.0)	37/53	69.8 (55.7, 81.7)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Baseline total hip DXA BMD T-score						
> -2.5	107/154	69.5 (61.6, 76.6)	164/190	86.3 (80.6, 90.9)	271/344	78.8 (74.1, 83.0)
≤ -2.5	49/74	66.2 (54.3, 76.8)	11/23	47.8 (26.8, 69.4)	60/97	61.9 (51.4, 71.5)
Missing	18/34	52.9 (35.1, 70.2)	48/50	96.0 (86.3, 99.5)	66/84	78.6 (68.3, 86.8)
Baseline femoral neck DXA BMD T-score						
> -2.5	97/138	70.3 (61.9, 77.8)	147/174	84.5 (78.2, 89.5)	244/312	78.2 (73.2, 82.7)
≤ -2.5	59/89	66.3 (55.5, 76.0)	53/65	81.5 (70.0, 90.1)	112/154	72.7 (65.0, 79.6)
Missing	18/35	51.4 (34.0, 68.6)	23/24	95.8 (78.9, 99.9)	41/59	69.5 (56.1, 80.8)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-003-qs-oste-lab-covar-cr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	117/157	74.5 (67.0, 81.1)	134/151	88.7 (82.6, 93.3)	263/315	83.5 (78.9, 87.4)
> Median	113/143	79.0 (71.4, 85.4)	126/149	84.6 (77.7, 90.0)	227/285	79.6 (74.5, 84.2)
Age group						
< 65 years	68/90	75.6 (65.4, 84.0)	144/164	87.8 (81.8, 92.4)	212/254	83.5 (78.3, 87.8)
≥ 65 - < 75 years	89/121	73.6 (64.8, 81.2)	82/98	83.7 (74.8, 90.4)	171/219	78.1 (72.0, 83.4)
≥ 75 years	73/89	82.0 (72.5, 89.4)	34/38	89.5 (75.2, 97.1)	107/127	84.3 (76.7, 90.1)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	121/151	80.1 (72.9, 86.2)	128/151	84.8 (78.0, 90.1)	255/301	84.7 (80.1, 88.6)
> Median	109/149	73.2 (65.3, 80.1)	132/149	88.6 (82.4, 93.2)	235/299	78.6 (73.5, 83.1)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	120/158	75.9 (68.5, 82.4)	178/194	91.8 (87.0, 95.2)	317/369	85.9 (81.9, 89.3)
> Median	110/142	77.5 (69.7, 84.0)	82/106	77.4 (68.2, 84.9)	173/231	74.9 (68.8, 80.3)
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	137/186	73.7 (66.7, 79.8)	166/187	88.8 (83.3, 92.9)	267/328	81.4 (76.8, 85.5)
> Median	93/114	81.6 (73.2, 88.2)	94/113	83.2 (75.0, 89.6)	223/272	82.0 (76.9, 86.4)
Any chronic medical condition						
Yes	214/278	77.0 (71.6, 81.8)	205/242	84.7 (79.5, 89.0)	419/520	80.6 (76.9, 83.9)
No	16/22	72.7 (49.8, 89.3)	55/58	94.8 (85.6, 98.9)	71/80	88.8 (79.7, 94.7)

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n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Type of chronic medical condition						
Diabetes	16/20	80.0 (56.3, 94.3)	14/23	60.9 (38.5, 80.3)	30/43	69.8 (53.9, 82.8)
Osteoporosis	193/253	76.3 (70.6, 81.4)	71/86	82.6 (72.9, 89.9)	264/339	77.9 (73.1, 82.2)
Hypertension	118/149	79.2 (71.8, 85.4)	131/159	82.4 (75.6, 88.0)	249/308	80.8 (76.0, 85.1)
Other	139/186	74.7 (67.9, 80.8)	115/132	87.1 (80.2, 92.3)	254/318	79.9 (75.0, 84.1)
Any prior PMO therapy						
Yes	193/255	75.7 (69.9, 80.8)	133/146	91.1 (85.3, 95.2)	326/401	81.3 (77.1, 85.0)
No	37/45	82.2 (67.9, 92.0)	127/154	82.5 (75.5, 88.1)	164/199	82.4 (76.4, 87.4)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Any PMO therapy within the 12 months prior to enrollment						
Yes	181/240	75.4 (69.5, 80.7)	108/119	90.8 (84.1, 95.3)	289/359	80.5 (76.0, 84.5)
No	49/60	81.7 (69.6, 90.5)	152/181	84.0 (77.8, 89.0)	201/241	83.4 (78.1, 87.9)
Prior calcium and/or vitamin D supplement						
Yes	105/151	69.5 (61.5, 76.8)	18/19	94.7 (74.0, 99.9)	123/170	72.4 (65.0, 78.9)
No	125/149	83.9 (77.0, 89.4)	242/281	86.1 (81.5, 89.9)	367/430	85.3 (81.6, 88.6)
1st post-baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	80/149	53.7 (45.3, 61.9)	104/149	69.8 (61.7, 77.0)	201/308	65.3 (59.7, 70.6)
> Median	68/136	50.0 (41.3, 58.7)	103/145	71.0 (62.9, 78.3)	154/271	56.8 (50.7, 62.8)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Age group						
< 65 years	53/88	60.2 (49.2, 70.5)	114/162	70.4 (62.7, 77.3)	167/250	66.8 (60.6, 72.6)
≥ 65 - < 75 years	50/113	44.2 (34.9, 53.9)	68/96	70.8 (60.7, 79.7)	118/209	56.5 (49.4, 63.3)
≥ 75 years	45/84	53.6 (42.4, 64.5)	25/36	69.4 (51.9, 83.7)	70/120	58.3 (49.0, 67.3)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	82/142	57.7 (49.2, 66.0)	93/148	62.8 (54.5, 70.6)	174/290	60.0 (54.1, 65.7)
> Median	66/143	46.2 (37.8, 54.7)	114/146	78.1 (70.5, 84.5)	181/289	62.6 (56.8, 68.2)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	81/151	53.6 (45.4, 61.8)	124/191	64.9 (57.7, 71.7)	225/357	63.0 (57.8, 68.0)
> Median	67/134	50.0 (41.2, 58.8)	83/103	80.6 (71.6, 87.7)	130/222	58.6 (51.8, 65.1)

N = Number of patients in the full analysis set
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N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	88/178	49.4 (41.9, 57.0)	127/185	68.6 (61.4, 75.3)	192/320	60.0 (54.4, 65.4)
> Median	60/107	56.1 (46.1, 65.7)	80/109	73.4 (64.1, 81.4)	163/259	62.9 (56.7, 68.8)
Any chronic medical condition						
Yes	136/265	51.3 (45.1, 57.5)	167/237	70.5 (64.2, 76.2)	303/502	60.4 (55.9, 64.7)
No	12/20	60.0 (36.1, 80.9)	40/57	70.2 (56.6, 81.6)	52/77	67.5 (55.9, 77.8)

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n = Number of patients who had osteoporosis related laboratory examination
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Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Type of chronic medical condition						
Diabetes	9/18	50.0 (26.0, 74.0)	15/21	71.4 (47.8, 88.7)	24/39	61.5 (44.6, 76.6)
Osteoporosis	123/240	51.3 (44.7, 57.7)	61/84	72.6 (61.8, 81.8)	184/324	56.8 (51.2, 62.3)
Hypertension	75/142	52.8 (44.3, 61.2)	104/155	67.1 (59.1, 74.4)	179/297	60.3 (54.5, 65.9)
Other	87/177	49.2 (41.6, 56.8)	102/129	79.1 (71.0, 85.7)	189/306	61.8 (56.1, 67.2)
Any prior PMO therapy						
Yes	123/241	51.0 (44.5, 57.5)	112/143	78.3 (70.7, 84.8)	235/384	61.2 (56.1, 66.1)
No	25/44	56.8 (41.0, 71.7)	95/151	62.9 (54.7, 70.6)	120/195	61.5 (54.3, 68.4)

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n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Any PMO therapy within the 12 months prior to enrollment						
Yes	115/226	50.9 (44.2, 57.6)	90/118	76.3 (67.6, 83.6)	205/344	59.6 (54.2, 64.8)
No	33/59	55.9 (42.4, 68.8)	117/176	66.5 (59.0, 73.4)	150/235	63.8 (57.3, 70.0)
Prior calcium and/or vitamin D supplement						
Yes	73/142	51.4 (42.9, 59.9)	16/19	84.2 (60.4, 96.6)	89/161	55.3 (47.3, 63.1)
No	75/143	52.4 (43.9, 60.9)	191/275	69.5 (63.6, 74.8)	266/418	63.6 (58.8, 68.3)
2nd post-baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	88/145	60.7 (52.2, 68.7)	118/144	81.9 (74.7, 87.9)	220/299	73.6 (68.2, 78.5)
> Median	74/135	54.8 (46.0, 63.4)	106/142	74.6 (66.7, 81.6)	166/267	62.2 (56.1, 68.0)

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n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Age group						
< 65 years	57/86	66.3 (55.3, 76.1)	129/157	82.2 (75.3, 87.8)	186/243	76.5 (70.7, 81.7)
≥ 65 - < 75 years	51/111	45.9 (36.4, 55.7)	70/94	74.5 (64.4, 82.9)	121/205	59.0 (52.0, 65.8)
≥ 75 years	54/83	65.1 (53.8, 75.2)	25/35	71.4 (53.7, 85.4)	79/118	66.9 (57.7, 75.3)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	80/139	57.6 (48.9, 65.9)	109/143	76.2 (68.4, 82.9)	198/282	70.2 (64.5, 75.5)
> Median	82/141	58.2 (49.6, 66.4)	115/143	80.4 (73.0, 86.6)	188/284	66.2 (60.4, 71.7)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	86/150	57.3 (49.0, 65.4)	134/187	71.7 (64.6, 78.0)	246/350	70.3 (65.2, 75.0)
> Median	76/130	58.5 (49.5, 67.0)	90/99	90.9 (83.4, 95.8)	140/216	64.8 (58.0, 71.2)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	95/177	53.7 (46.0, 61.2)	139/180	77.2 (70.4, 83.1)	212/315	67.3 (61.8, 72.5)
> Median	67/103	65.0 (55.0, 74.2)	85/106	80.2 (71.3, 87.3)	174/251	69.3 (63.2, 75.0)
Any chronic medical condition						
Yes	149/260	57.3 (51.0, 63.4)	185/231	80.1 (74.3, 85.0)	334/491	68.0 (63.7, 72.1)
No	13/20	65.0 (40.8, 84.6)	39/55	70.9 (57.1, 82.4)	52/75	69.3 (57.6, 79.5)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Type of chronic medical condition						
Diabetes	11/18	61.1 (35.7, 82.7)	13/20	65.0 (40.8, 84.6)	24/38	63.2 (46.0, 78.2)
Osteoporosis	135/235	57.4 (50.9, 63.9)	76/83	91.6 (83.4, 96.5)	211/318	66.4 (60.9, 71.5)
Hypertension	84/137	61.3 (52.6, 69.5)	112/151	74.2 (66.4, 80.9)	196/288	68.1 (62.3, 73.4)
Other	90/173	52.0 (44.3, 59.7)	113/125	90.4 (83.8, 94.9)	203/298	68.1 (62.5, 73.4)
Any prior PMO therapy						
Yes	134/237	56.5 (50.0, 62.9)	110/139	79.1 (71.4, 85.6)	244/376	64.9 (59.8, 69.7)
No	28/43	65.1 (49.1, 79.0)	114/147	77.6 (69.9, 84.0)	142/190	74.7 (67.9, 80.7)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Any PMO therapy within the 12 months prior to enrollment						
Yes	125/222	56.3 (49.5, 62.9)	87/114	76.3 (67.4, 83.8)	212/336	63.1 (57.7, 68.3)
No	37/58	63.8 (50.1, 76.0)	137/172	79.7 (72.9, 85.4)	174/230	75.7 (69.6, 81.1)
Prior calcium and/or vitamin D supplement						
Yes	71/140	50.7 (42.1, 59.3)	12/19	63.2 (38.4, 83.7)	83/159	52.2 (44.1, 60.2)
No	91/140	65.0 (56.5, 72.9)	212/267	79.4 (74.0, 84.1)	303/407	74.4 (69.9, 78.6)
3rd post-baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	91/141	64.5 (56.0, 72.4)	117/143	81.8 (74.5, 87.8)	226/294	76.9 (71.6, 81.6)
> Median	72/129	55.8 (46.8, 64.5)	109/137	79.6 (71.8, 86.0)	163/256	63.7 (57.5, 69.6)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-004-qs-oste-lab-covar-pr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.amh

Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Age group						
< 65 years	57/85	67.1 (56.0, 76.9)	128/156	82.1 (75.1, 87.7)	185/241	76.8 (70.9, 81.9)
≥ 65 - < 75 years	60/106	56.6 (46.6, 66.2)	71/90	78.9 (69.0, 86.8)	131/196	66.8 (59.8, 73.4)
≥ 75 years	46/79	58.2 (46.6, 69.2)	27/34	79.4 (62.1, 91.3)	73/113	64.6 (55.0, 73.4)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	88/134	65.7 (57.0, 73.7)	100/142	70.4 (62.2, 77.8)	201/277	72.6 (66.9, 77.7)
> Median	75/136	55.1 (46.4, 63.7)	126/138	91.3 (85.3, 95.4)	188/273	68.9 (63.0, 74.3)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	80/146	54.8 (46.4, 63.0)	141/181	77.9 (71.1, 83.7)	246/343	71.7 (66.6, 76.4)
> Median	83/124	66.9 (57.9, 75.1)	85/99	85.9 (77.4, 92.0)	143/207	69.1 (62.3, 75.3)

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n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	95/174	54.6 (46.9, 62.1)	142/177	80.2 (73.6, 85.8)	216/310	69.7 (64.2, 74.7)
> Median	68/96	70.8 (60.7, 79.7)	84/103	81.6 (72.7, 88.5)	173/240	72.1 (65.9, 77.7)
Any chronic medical condition						
Yes	150/250	60.0 (53.6, 66.1)	183/228	80.3 (74.5, 85.2)	333/478	69.7 (65.3, 73.8)
No	13/20	65.0 (40.8, 84.6)	43/52	82.7 (69.7, 91.8)	56/72	77.8 (66.4, 86.7)

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n = Number of patients who had osteoporosis related laboratory examination
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Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Type of chronic medical condition						
Diabetes	13/17	76.5 (50.1, 93.2)	15/20	75.0 (50.9, 91.3)	28/37	75.7 (58.8, 88.2)
Osteoporosis	132/225	58.7 (51.9, 65.2)	69/81	85.2 (75.6, 92.1)	201/306	65.7 (60.1, 71.0)
Hypertension	85/130	65.4 (56.5, 73.5)	109/149	73.2 (65.3, 80.1)	194/279	69.5 (63.8, 74.9)
Other	102/166	61.4 (53.6, 68.9)	113/124	91.1 (84.7, 95.5)	215/290	74.1 (68.7, 79.1)
Any prior PMO therapy						
Yes	134/228	58.8 (52.1, 65.2)	123/135	91.1 (85.0, 95.3)	257/363	70.8 (65.8, 75.4)
No	29/42	69.0 (52.9, 82.4)	103/145	71.0 (62.9, 78.3)	132/187	70.6 (63.5, 77.0)

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n = Number of patients who had osteoporosis related laboratory examination
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Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Any PMO therapy within the 12 months prior to enrollment						
Yes	126/213	59.2 (52.2, 65.8)	98/110	89.1 (81.7, 94.2)	224/323	69.3 (64.0, 74.3)
No	37/57	64.9 (51.1, 77.1)	128/170	75.3 (68.1, 81.6)	165/227	72.7 (66.4, 78.4)
Prior calcium and/or vitamin D supplement						
Yes	74/134	55.2 (46.4, 63.8)	18/18	100.0 (81.5, 100.0)	92/152	60.5 (52.3, 68.4)
No	89/136	65.4 (56.8, 73.4)	208/262	79.4 (74.0, 84.1)	297/398	74.6 (70.0, 78.8)
4th post-baseline injection						
Age (years) (Czech Republic median = 69.0, Slovakia median = 63.0, Overall median = 66.0)						
≤ Median	97/138	70.3 (61.9, 77.8)	120/135	88.9 (82.3, 93.6)	229/282	81.2 (76.1, 85.6)
> Median	77/124	62.1 (52.9, 70.7)	103/128	80.5 (72.5, 86.9)	168/243	69.1 (62.9, 74.9)

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Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Age group						
< 65 years	63/83	75.9 (65.3, 84.6)	129/147	87.8 (81.3, 92.6)	192/230	83.5 (78.0, 88.0)
≥ 65 - < 75 years	58/104	55.8 (45.7, 65.5)	72/87	82.8 (73.2, 90.0)	130/191	68.1 (60.9, 74.6)
≥ 75 years	53/75	70.7 (59.0, 80.6)	22/29	75.9 (56.5, 89.7)	75/104	72.1 (62.5, 80.5)
Time since PMO diagnosis (years) (Czech Republic median = 4.7, Slovakia median = 1.0, Overall median = 2.6)						
≤ Median	87/130	66.9 (58.1, 74.9)	105/134	78.4 (70.4, 85.0)	194/263	73.8 (68.0, 79.0)
> Median	87/132	65.9 (57.2, 73.9)	118/129	91.5 (85.3, 95.7)	203/262	77.5 (71.9, 82.4)
Number of prescription medications taken at baseline (Czech Republic median = 3.0, Slovakia median = 1.0, Overall median = 2.0)						
≤ Median	91/142	64.1 (55.6, 72.0)	132/166	79.5 (72.6, 85.4)	251/325	77.2 (72.3, 81.7)
> Median	83/120	69.2 (60.1, 77.3)	91/97	93.8 (87.0, 97.7)	146/200	73.0 (66.3, 79.0)

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Percentages based on N1
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Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Number of comorbidities (Czech Republic median = 4.0, Slovakia median = 3.0, Overall median = 3.0)						
≤ Median	109/169	64.5 (56.8, 71.7)	145/166	87.3 (81.3, 92.0)	231/297	77.8 (72.6, 82.4)
> Median	65/93	69.9 (59.5, 79.0)	78/97	80.4 (71.1, 87.8)	166/228	72.8 (66.5, 78.5)
Any chronic medical condition						
Yes	160/243	65.8 (59.5, 71.8)	183/217	84.3 (78.8, 88.9)	343/460	74.6 (70.3, 78.5)
No	14/19	73.7 (48.8, 90.9)	40/46	87.0 (73.7, 95.1)	54/65	83.1 (71.7, 91.2)

N = Number of patients in the full analysis set
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N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Type of chronic medical condition						
Diabetes	11/15	73.3 (44.9, 92.2)	14/19	73.7 (48.8, 90.9)	25/34	73.5 (55.6, 87.1)
Osteoporosis	146/220	66.4 (59.7, 72.6)	75/79	94.9 (87.5, 98.6)	221/299	73.9 (68.5, 78.8)
Hypertension	85/124	68.5 (59.6, 76.6)	111/141	78.7 (71.0, 85.2)	196/265	74.0 (68.2, 79.1)
Other	98/161	60.9 (52.9, 68.5)	116/122	95.1 (89.6, 98.2)	214/283	75.6 (70.2, 80.5)
Any prior PMO therapy						
Yes	147/222	66.2 (59.6, 72.4)	116/127	91.3 (85.0, 95.6)	263/349	75.4 (70.5, 79.8)
No	27/40	67.5 (50.9, 81.4)	107/136	78.7 (70.8, 85.2)	134/176	76.1 (69.1, 82.2)

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Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.4. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Patient Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Any PMO therapy within the 12 months prior to enrollment						
Yes	136/207	65.7 (58.8, 72.1)	94/105	89.5 (82.0, 94.7)	230/312	73.7 (68.5, 78.5)
No	38/55	69.1 (55.2, 80.9)	129/158	81.6 (74.7, 87.3)	167/213	78.4 (72.3, 83.7)
Prior calcium and/or vitamin D supplement						
Yes	84/132	63.6 (54.8, 71.8)	14/16	87.5 (61.7, 98.4)	98/148	66.2 (58.0, 73.8)
No	90/130	69.2 (60.5, 77.0)	209/247	84.6 (79.5, 88.9)	299/377	79.3 (74.9, 83.3)

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n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.

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Table 14-4.8.5. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Physician Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection						
Physician specialty						
Rheumatologist	82/113	72.6 (63.4, 80.5)	123/136	90.4 (84.2, 94.8)	205/249	82.3 (77.0, 86.9)
Internist	115/154	74.7 (67.0, 81.3)	54/54	100.0 (93.4, 100.0)	169/208	81.3 (75.3, 86.3)
Endocrinologist	13/13	100.0 (75.3, 100.0)	34/51	66.7 (52.1, 79.2)	47/64	73.4 (60.9, 83.7)
Orthopedist	0/0	- (-, -)	49/59	83.1 (71.0, 91.6)	49/59	83.1 (71.0, 91.6)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	14/20	70.0 (45.7, 88.1)	26/32	81.3 (63.6, 92.8)	40/52	76.9 (63.2, 87.5)
≥ 10 years	216/280	77.1 (71.8, 81.9)	234/268	87.3 (82.7, 91.1)	450/548	82.1 (78.6, 85.2)

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n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-005-qs-oste-lab-covar-sr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.apresc

Table 14-4.8.5. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Physician Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Sole physician						
Sole	103/124	83.1 (75.3, 89.2)	198/235	84.3 (79.0, 88.7)	301/359	83.8 (79.6, 87.5)
Group	127/176	72.2 (64.9, 78.6)	62/65	95.4 (87.1, 99.0)	189/241	78.4 (72.7, 83.4)
Group size						
2 - 3	87/106	82.1 (73.4, 88.8)	25/26	96.2 (80.4, 99.9)	112/132	84.8 (77.6, 90.5)
4 - 5	26/50	52.0 (37.4, 66.3)	24/25	96.0 (79.6, 99.9)	50/75	66.7 (54.8, 77.1)
6 - 10	14/20	70.0 (45.7, 88.1)	0/0	- (-, -)	14/20	70.0 (45.7, 88.1)
> 10	0/0	- (-, -)	13/14	92.9 (66.1, 99.8)	13/14	92.9 (66.1, 99.8)

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n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.
[a]Site may have more than one service
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Table 14-4.8.5. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Physician Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Center type						
Hospital	83/90	92.2 (84.6, 96.8)	97/117	82.9 (74.8, 89.2)	180/207	87.0 (81.6, 91.2)
Non-hospital	147/210	70.0 (63.3, 76.1)	163/183	89.1 (83.6, 93.2)	310/393	78.9 (74.5, 82.8)
Academic centre						
Academic	16/17	94.1 (71.3, 99.9)	44/63	69.8 (57.0, 80.8)	60/80	75.0 (64.1, 84.0)
Non-academic	214/283	75.6 (70.2, 80.5)	158/177	89.3 (83.7, 93.4)	372/460	80.9 (77.0, 84.4)
Both	0/0	- (-, -)	37/39	94.9 (82.7, 99.4)	37/39	94.9 (82.7, 99.4)
Not available	0/0	- (-, -)	21/21	100.0 (83.9, 100.0)	21/21	100.0 (83.9, 100.0)

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n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

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Output: t14-04-008-005-qs-oste-lab-covar-sr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.apresc

Table 14-4.8.5. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Physician Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Region						
Urban	210/280	75.0 (69.5, 80.0)	260/300	86.7 (82.3, 90.3)	470/580	81.0 (77.6, 84.1)
Rural	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician active reminder service for next Prolia® administration						
Yes	108/160	67.5 (59.7, 74.7)	218/256	85.2 (80.2, 89.3)	326/416	78.4 (74.1, 82.2)
No	122/140	87.1 (80.4, 92.2)	42/44	95.5 (84.5, 99.4)	164/184	89.1 (83.7, 93.2)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	62/87	71.3 (60.6, 80.5)	103/124	83.1 (75.3, 89.2)	165/211	78.2 (72.0, 83.6)
Appointment card	46/73	63.0 (50.9, 74.0)	89/91	97.8 (92.3, 99.7)	135/164	82.3 (75.6, 87.8)
Mailing	40/40	100.0 (91.2, 100.0)	60/74	81.1 (70.3, 89.3)	100/114	87.7 (80.3, 93.1)
Sticker from drug package	0/0	- (-, -)	23/30	76.7 (57.7, 90.1)	23/30	76.7 (57.7, 90.1)
Email/SMS	0/0	- (-, -)	24/25	96.0 (79.6, 99.9)	24/25	96.0 (79.6, 99.9)

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	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
Baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	111/138	80.4 (72.8, 86.7)	148/178	83.1 (76.8, 88.3)	259/316	82.0 (77.3, 86.0)
History of osteoporotic fracture	105/136	77.2 (69.2, 84.0)	47/55	85.5 (73.3, 93.5)	152/191	79.6 (73.2, 85.1)
Multiple risk factors for fracture	96/126	76.2 (67.8, 83.3)	49/60	81.7 (69.6, 90.5)	145/186	78.0 (71.3, 83.7)
Failed other available osteoporosis therapy	82/109	75.2 (66.0, 83.0)	43/47	91.5 (79.6, 97.6)	125/156	80.1 (73.0, 86.1)
Intolerant to other osteoporosis therapy	116/160	72.5 (64.9, 79.3)	38/39	97.4 (86.5, 99.9)	154/199	77.4 (70.9, 83.0)
Other	10/10	100.0 (69.2, 100.0)	15/17	88.2 (63.6, 98.5)	25/27	92.6 (75.7, 99.1)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection						
Physician specialty						
Rheumatologist	38/108	35.2 (26.2, 45.0)	83/133	62.4 (53.6, 70.7)	121/241	50.2 (43.7, 56.7)
Internist	77/144	53.5 (45.0, 61.8)	53/53	100.0 (93.3, 100.0)	130/197	66.0 (58.9, 72.6)
Endocrinologist	13/13	100.0 (75.3, 100.0)	49/49	100.0 (92.7, 100.0)	62/62	100.0 (94.2, 100.0)
Orthopedist	0/0	- (-, -)	22/59	37.3 (25.0, 50.9)	22/59	37.3 (25.0, 50.9)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	2/20	10.0 (1.2, 31.7)	29/31	93.5 (78.6, 99.2)	31/51	60.8 (46.1, 74.2)
≥ 10 years	146/265	55.1 (48.9, 61.2)	178/263	67.7 (61.7, 73.3)	324/528	61.4 (57.1, 65.5)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Sole physician						
Sole	69/121	57.0 (47.7, 66.0)	148/230	64.3 (57.8, 70.5)	217/351	61.8 (56.5, 66.9)
Group	79/164	48.2 (40.3, 56.1)	59/64	92.2 (82.7, 97.4)	138/228	60.5 (53.9, 66.9)
Group size						
2 - 3	57/98	58.2 (47.8, 68.1)	21/26	80.8 (60.6, 93.4)	78/124	62.9 (53.8, 71.4)
4 - 5	20/46	43.5 (28.9, 58.9)	25/25	100.0 (86.3, 100.0)	45/71	63.4 (51.1, 74.5)
6 - 10	2/20	10.0 (1.2, 31.7)	0/0	- (-, -)	2/20	10.0 (1.2, 31.7)
> 10	0/0	- (-, -)	13/13	100.0 (75.3, 100.0)	13/13	100.0 (75.3, 100.0)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Center type						
Hospital	55/88	62.5 (51.5, 72.6)	85/113	75.2 (66.2, 82.9)	140/201	69.7 (62.8, 75.9)
Non-hospital	93/197	47.2 (40.1, 54.4)	122/181	67.4 (60.1, 74.2)	215/378	56.9 (51.7, 61.9)
Academic centre						
Academic	0/15	0.0 (0.0, 21.8)	38/63	60.3 (47.2, 72.4)	38/78	48.7 (37.2, 60.3)
Non-academic	148/270	54.8 (48.7, 60.9)	110/172	64.0 (56.3, 71.1)	258/442	58.4 (53.6, 63.0)
Both	0/0	- (-, -)	38/38	100.0 (90.7, 100.0)	38/38	100.0 (90.7, 100.0)
Not available	0/0	- (-, -)	21/21	100.0 (83.9, 100.0)	21/21	100.0 (83.9, 100.0)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Region						
Urban	140/266	52.6 (46.4, 58.8)	207/294	70.4 (64.8, 75.6)	347/560	62.0 (57.8, 66.0)
Rural	8/19	42.1 (20.3, 66.5)	0/0	- (-, -)	8/19	42.1 (20.3, 66.5)
Physician active reminder service for next Prolia® administration						
Yes	65/152	42.8 (34.8, 51.0)	185/252	73.4 (67.5, 78.8)	250/404	61.9 (56.9, 66.6)
No	83/133	62.4 (53.6, 70.7)	22/42	52.4 (36.4, 68.0)	105/175	60.0 (52.3, 67.3)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	39/81	48.1 (36.9, 59.5)	86/123	69.9 (61.0, 77.9)	125/204	61.3 (54.2, 68.0)
Appointment card	26/71	36.6 (25.5, 48.9)	73/88	83.0 (73.4, 90.1)	99/159	62.3 (54.2, 69.8)
Mailing	39/40	97.5 (86.8, 99.9)	48/73	65.8 (53.7, 76.5)	87/113	77.0 (68.1, 84.4)
Sticker from drug package	0/0	- (-, -)	16/30	53.3 (34.3, 71.7)	16/30	53.3 (34.3, 71.7)
Email/SMS	0/0	- (-, -)	25/25	100.0 (86.3, 100.0)	25/25	100.0 (86.3, 100.0)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
1st post-baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	70/132	53.0 (44.2, 61.8)	121/176	68.8 (61.3, 75.5)	191/308	62.0 (56.3, 67.5)
History of osteoporotic fracture	73/132	55.3 (46.4, 64.0)	51/54	94.4 (84.6, 98.8)	124/186	66.7 (59.4, 73.4)
Multiple risk factors for fracture	52/120	43.3 (34.3, 52.7)	42/59	71.2 (57.9, 82.2)	94/179	52.5 (44.9, 60.0)
Failed other available osteoporosis therapy	48/103	46.6 (36.7, 56.7)	32/46	69.6 (54.2, 82.3)	80/149	53.7 (45.3, 61.9)
Intolerant to other osteoporosis therapy	79/151	52.3 (44.0, 60.5)	28/37	75.7 (58.8, 88.2)	107/188	56.9 (49.5, 64.1)
Other	5/9	55.6 (21.2, 86.3)	16/16	100.0 (79.4, 100.0)	21/25	84.0 (63.9, 95.5)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection						
Physician specialty						
Rheumatologist	57/106	53.8 (43.8, 63.5)	98/129	76.0 (67.7, 83.1)	155/235	66.0 (59.5, 72.0)
Internist	74/141	52.5 (43.9, 60.9)	49/50	98.0 (89.4, 99.9)	123/191	64.4 (57.2, 71.2)
Endocrinologist	11/13	84.6 (54.6, 98.1)	48/48	100.0 (92.6, 100.0)	59/61	96.7 (88.7, 99.6)
Orthopedist	0/0	- (-, -)	29/59	49.2 (35.9, 62.5)	29/59	49.2 (35.9, 62.5)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	3/20	15.0 (3.2, 37.9)	30/30	100.0 (88.4, 100.0)	33/50	66.0 (51.2, 78.8)
≥ 10 years	159/260	61.2 (54.9, 67.1)	194/256	75.8 (70.1, 80.9)	353/516	68.4 (64.2, 72.4)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Sole physician						
Sole	72/118	61.0 (51.6, 69.9)	164/226	72.6 (66.3, 78.3)	236/344	68.6 (63.4, 73.5)
Group	90/162	55.6 (47.6, 63.4)	60/60	100.0 (94.0, 100.0)	150/222	67.6 (61.0, 73.7)
Group size						
2 - 3	66/97	68.0 (57.8, 77.1)	25/25	100.0 (86.3, 100.0)	91/122	74.6 (65.9, 82.0)
4 - 5	21/45	46.7 (31.7, 62.1)	23/23	100.0 (85.2, 100.0)	44/68	64.7 (52.2, 75.9)
6 - 10	3/20	15.0 (3.2, 37.9)	0/0	- (-, -)	3/20	15.0 (3.2, 37.9)
> 10	0/0	- (-, -)	12/12	100.0 (73.5, 100.0)	12/12	100.0 (73.5, 100.0)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Center type						
Hospital	63/88	71.6 (61.0, 80.7)	91/110	82.7 (74.3, 89.3)	154/198	77.8 (71.3, 83.4)
Non-hospital	99/192	51.6 (44.3, 58.8)	133/176	75.6 (68.5, 81.7)	232/368	63.0 (57.9, 68.0)
Academic centre						
Academic	10/15	66.7 (38.4, 88.2)	59/62	95.2 (86.5, 99.0)	69/77	89.6 (80.6, 95.4)
Non-academic	152/265	57.4 (51.2, 63.4)	111/169	65.7 (58.0, 72.8)	263/434	60.6 (55.8, 65.2)
Both	0/0	- (-, -)	35/35	100.0 (90.0, 100.0)	35/35	100.0 (90.0, 100.0)
Not available	0/0	- (-, -)	19/20	95.0 (75.1, 99.9)	19/20	95.0 (75.1, 99.9)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Region						
Urban	156/262	59.5 (53.3, 65.5)	224/286	78.3 (73.1, 83.0)	380/548	69.3 (65.3, 73.2)
Rural	6/18	33.3 (13.3, 59.0)	0/0	- (-, -)	6/18	33.3 (13.3, 59.0)
Physician active reminder service for next Prolia® administration						
Yes	77/149	51.7 (43.4, 59.9)	192/244	78.7 (73.0, 83.7)	269/393	68.4 (63.6, 73.0)
No	85/131	64.9 (56.1, 73.0)	32/42	76.2 (60.5, 87.9)	117/173	67.6 (60.1, 74.5)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	50/80	62.5 (51.0, 73.1)	110/119	92.4 (86.1, 96.5)	160/199	80.4 (74.2, 85.7)
Appointment card	27/69	39.1 (27.6, 51.6)	60/84	71.4 (60.5, 80.8)	87/153	56.9 (48.6, 64.8)
Mailing	39/40	97.5 (86.8, 99.9)	44/70	62.9 (50.5, 74.1)	83/110	75.5 (66.3, 83.2)
Sticker from drug package	0/0	- (-, -)	23/30	76.7 (57.7, 90.1)	23/30	76.7 (57.7, 90.1)
Email/SMS	0/0	- (-, -)	23/23	100.0 (85.2, 100.0)	23/23	100.0 (85.2, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
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Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.
[a]Site may have more than one service
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Table 14-4.8.5. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Physician Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
2nd post-baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	79/131	60.3 (51.4, 68.7)	130/171	76.0 (68.9, 82.2)	209/302	69.2 (63.7, 74.4)
History of osteoporotic fracture	79/129	61.2 (52.3, 69.7)	45/52	86.5 (74.2, 94.4)	124/181	68.5 (61.2, 75.2)
Multiple risk factors for fracture	65/118	55.1 (45.7, 64.3)	50/59	84.7 (73.0, 92.8)	115/177	65.0 (57.5, 72.0)
Failed other available osteoporosis therapy	62/102	60.8 (50.6, 70.3)	32/45	71.1 (55.7, 83.6)	94/147	63.9 (55.6, 71.7)
Intolerant to other osteoporosis therapy	85/149	57.0 (48.7, 65.1)	30/36	83.3 (67.2, 93.6)	115/185	62.2 (54.8, 69.2)
Other	6/9	66.7 (29.9, 92.5)	15/15	100.0 (78.2, 100.0)	21/24	87.5 (67.6, 97.3)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
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Percentages based on N1
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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection						
Physician specialty						
Rheumatologist	44/101	43.6 (33.7, 53.8)	105/124	84.7 (77.1, 90.5)	149/225	66.2 (59.6, 72.4)
Internist	98/136	72.1 (63.7, 79.4)	49/49	100.0 (92.7, 100.0)	147/185	79.5 (72.9, 85.0)
Endocrinologist	2/13	15.4 (1.9, 45.4)	47/48	97.9 (88.9, 99.9)	49/61	80.3 (68.2, 89.4)
Orthopedist	0/0	- (-, -)	25/59	42.4 (29.6, 55.9)	25/59	42.4 (29.6, 55.9)
Other	19/20	95.0 (75.1, 99.9)	0/0	- (-, -)	19/20	95.0 (75.1, 99.9)
Physician years of practice						
5 to 9 years	17/19	89.5 (66.9, 98.7)	29/30	96.7 (82.8, 99.9)	46/49	93.9 (83.1, 98.7)
≥ 10 years	146/251	58.2 (51.8, 64.3)	197/250	78.8 (73.2, 83.7)	343/501	68.5 (64.2, 72.5)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
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Percentages based on N1
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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Sole physician						
Sole	70/115	60.9 (51.3, 69.8)	172/221	77.8 (71.8, 83.1)	242/336	72.0 (66.9, 76.8)
Group	93/155	60.0 (51.8, 67.8)	54/59	91.5 (81.3, 97.2)	147/214	68.7 (62.0, 74.8)
Group size						
2 - 3	47/92	51.1 (40.4, 61.7)	21/25	84.0 (63.9, 95.5)	68/117	58.1 (48.6, 67.2)
4 - 5	29/44	65.9 (50.1, 79.5)	22/22	100.0 (84.6, 100.0)	51/66	77.3 (65.3, 86.7)
6 - 10	17/19	89.5 (66.9, 98.7)	0/0	- (-, -)	17/19	89.5 (66.9, 98.7)
> 10	0/0	- (-, -)	11/12	91.7 (61.5, 99.8)	11/12	91.7 (61.5, 99.8)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Center type						
Hospital	61/83	73.5 (62.7, 82.6)	91/108	84.3 (76.0, 90.6)	152/191	79.6 (73.2, 85.1)
Non-hospital	102/187	54.5 (47.1, 61.8)	135/172	78.5 (71.6, 84.4)	237/359	66.0 (60.9, 70.9)
Academic centre						
Academic	4/12	33.3 (9.9, 65.1)	45/61	73.8 (60.9, 84.2)	49/73	67.1 (55.1, 77.7)
Non-academic	159/258	61.6 (55.4, 67.6)	129/166	77.7 (70.6, 83.8)	288/424	67.9 (63.3, 72.3)
Both	0/0	- (-, -)	33/34	97.1 (84.7, 99.9)	33/34	97.1 (84.7, 99.9)
Not available	0/0	- (-, -)	19/19	100.0 (82.4, 100.0)	19/19	100.0 (82.4, 100.0)

N = Number of patients in the full analysis set
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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Region						
Urban	154/252	61.1 (54.8, 67.2)	226/280	80.7 (75.6, 85.2)	380/532	71.4 (67.4, 75.2)
Rural	9/18	50.0 (26.0, 74.0)	0/0	- (-, -)	9/18	50.0 (26.0, 74.0)
Physician active reminder service for next Prolia® administration						
Yes	70/143	49.0 (40.5, 57.4)	195/239	81.6 (76.1, 86.3)	265/382	69.4 (64.5, 74.0)
No	93/127	73.2 (64.6, 80.7)	31/41	75.6 (59.7, 87.6)	124/168	73.8 (66.5, 80.3)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	52/74	70.3 (58.5, 80.3)	98/117	83.8 (75.8, 89.9)	150/191	78.5 (72.0, 84.1)
Appointment card	18/69	26.1 (16.3, 38.1)	79/81	97.5 (91.4, 99.7)	97/150	64.7 (56.5, 72.3)
Mailing	38/38	100.0 (90.7, 100.0)	42/68	61.8 (49.2, 73.3)	80/106	75.5 (66.2, 83.3)
Sticker from drug package	0/0	- (-, -)	27/29	93.1 (77.2, 99.2)	27/29	93.1 (77.2, 99.2)
Email/SMS	0/0	- (-, -)	22/22	100.0 (84.6, 100.0)	22/22	100.0 (84.6, 100.0)

N = Number of patients in the full analysis set
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Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.
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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
3rd post-baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	90/124	72.6 (63.8, 80.2)	127/168	75.6 (68.4, 81.9)	217/292	74.3 (68.9, 79.2)
History of osteoporotic fracture	81/123	65.9 (56.8, 74.2)	50/51	98.0 (89.6, 100.0)	131/174	75.3 (68.2, 81.5)
Multiple risk factors for fracture	74/111	66.7 (57.1, 75.3)	45/55	81.8 (69.1, 90.9)	119/166	71.7 (64.2, 78.4)
Failed other available osteoporosis therapy	64/99	64.6 (54.4, 74.0)	38/43	88.4 (74.9, 96.1)	102/142	71.8 (63.7, 79.1)
Intolerant to other osteoporosis therapy	84/143	58.7 (50.2, 66.9)	32/35	91.4 (76.9, 98.2)	116/178	65.2 (57.7, 72.1)
Other	3/9	33.3 (7.5, 70.1)	15/15	100.0 (78.2, 100.0)	18/24	75.0 (53.3, 90.2)

N = Number of patients in the full analysis set
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N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
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Table 14-4.8.5. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Physician Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection						
Physician specialty						
Rheumatologist	57/95	60.0 (49.4, 69.9)	108/116	93.1 (86.9, 97.0)	165/211	78.2 (72.0, 83.6)
Internist	85/134	63.4 (54.7, 71.6)	47/47	100.0 (92.5, 100.0)	132/181	72.9 (65.8, 79.3)
Endocrinologist	12/13	92.3 (64.0, 99.8)	43/43	100.0 (91.8, 100.0)	55/56	98.2 (90.4, 100.0)
Orthopedist	0/0	- (-, -)	25/57	43.9 (30.7, 57.6)	25/57	43.9 (30.7, 57.6)
Other	20/20	100.0 (83.2, 100.0)	0/0	- (-, -)	20/20	100.0 (83.2, 100.0)
Physician years of practice						
5 to 9 years	3/18	16.7 (3.6, 41.4)	28/28	100.0 (87.7, 100.0)	31/46	67.4 (52.0, 80.5)
≥ 10 years	171/244	70.1 (63.9, 75.8)	195/235	83.0 (77.6, 87.6)	366/479	76.4 (72.3, 80.1)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Sole physician						
Sole	67/108	62.0 (52.2, 71.2)	167/207	80.7 (74.6, 85.8)	234/315	74.3 (69.1, 79.0)
Group	107/154	69.5 (61.6, 76.6)	56/56	100.0 (93.6, 100.0)	163/210	77.6 (71.4, 83.1)
Group size						
2 - 3	71/92	77.2 (67.2, 85.3)	24/24	100.0 (85.8, 100.0)	95/116	81.9 (73.7, 88.4)
4 - 5	33/44	75.0 (59.7, 86.8)	21/21	100.0 (83.9, 100.0)	54/65	83.1 (71.7, 91.2)
6 - 10	3/18	16.7 (3.6, 41.4)	0/0	- (-, -)	3/18	16.7 (3.6, 41.4)
> 10	0/0	- (-, -)	11/11	100.0 (71.5, 100.0)	11/11	100.0 (71.5, 100.0)

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n = Number of patients who had osteoporosis related laboratory examination
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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Center type						
Hospital	65/81	80.2 (69.9, 88.3)	92/100	92.0 (84.8, 96.5)	157/181	86.7 (80.9, 91.3)
Non-hospital	109/181	60.2 (52.7, 67.4)	131/163	80.4 (73.4, 86.2)	240/344	69.8 (64.6, 74.6)
Academic centre						
Academic	12/12	100.0 (73.5, 100.0)	54/58	93.1 (83.3, 98.1)	66/70	94.3 (86.0, 98.4)
Non-academic	162/250	64.8 (58.5, 70.7)	118/154	76.6 (69.1, 83.1)	280/404	69.3 (64.6, 73.8)
Both	0/0	- (-, -)	32/32	100.0 (89.1, 100.0)	32/32	100.0 (89.1, 100.0)
Not available	0/0	- (-, -)	19/19	100.0 (82.4, 100.0)	19/19	100.0 (82.4, 100.0)

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Percentages based on N1
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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Region						
Urban	170/245	69.4 (63.2, 75.1)	223/263	84.8 (79.9, 88.9)	393/508	77.4 (73.5, 80.9)
Rural	4/17	23.5 (6.8, 49.9)	0/0	- (-, -)	4/17	23.5 (6.8, 49.9)
Physician active reminder service for next Prolia® administration						
Yes	88/141	62.4 (53.9, 70.4)	197/230	85.7 (80.4, 89.9)	285/371	76.8 (72.2, 81.0)
No	86/121	71.1 (62.1, 79.0)	26/33	78.8 (61.1, 91.0)	112/154	72.7 (65.0, 79.6)

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	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Types of reminders[a]						
Telephone call	62/73	84.9 (74.6, 92.2)	109/113	96.5 (91.2, 99.0)	171/186	91.9 (87.0, 95.4)
Appointment card	26/68	38.2 (26.7, 50.8)	74/78	94.9 (87.4, 98.6)	100/146	68.5 (60.3, 75.9)
Mailing	37/37	100.0 (90.5, 100.0)	39/64	60.9 (47.9, 72.9)	76/101	75.2 (65.7, 83.3)
Sticker from drug package	0/0	- (-, -)	27/27	100.0 (87.2, 100.0)	27/27	100.0 (87.2, 100.0)
Email/SMS	0/0	- (-, -)	21/21	100.0 (83.9, 100.0)	21/21	100.0 (83.9, 100.0)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-005-qs-oste-lab-covar-sr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.apresc

Table 14-4.8.5. Osteoporosis Related Laboratory Examinations at Each Prolia® Injection by Physician Related Covariates (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300)		Slovakia (N = 300)		Overall (N = 600)	
	n/N1	% (95% CI)	n/N1	% (95% CI)	n/N1	% (95% CI)
4th post-baseline injection (Cont'd)						
Reason for prescribing Prolia® for each individual subject[b]						
Low BMD T-Score	90/123	73.2 (64.4, 80.8)	122/157	77.7 (70.4, 84.0)	212/280	75.7 (70.3, 80.6)
History of osteoporotic fracture	86/120	71.7 (62.7, 79.5)	43/47	91.5 (79.6, 97.6)	129/167	77.2 (70.1, 83.4)
Multiple risk factors for fracture	77/104	74.0 (64.5, 82.1)	47/51	92.2 (81.1, 97.8)	124/155	80.0 (72.8, 86.0)
Failed other available osteoporosis therapy	67/98	68.4 (58.2, 77.4)	35/38	92.1 (78.6, 98.3)	102/136	75.0 (66.9, 82.0)
Intolerant to other osteoporosis therapy	92/140	65.7 (57.2, 73.5)	32/35	91.4 (76.9, 98.2)	124/175	70.9 (63.5, 77.5)
Other	7/9	77.8 (40.0, 97.2)	13/13	100.0 (75.3, 100.0)	20/22	90.9 (70.8, 98.9)

N = Number of patients in the full analysis set
n = Number of patients who had osteoporosis related laboratory examination
N1 = Number of patients in full analysis set attended corresponding visit
Percentages based on N1
Patients may not have been given Prolia® injection when they attended corresponding visit.
[a]Site may have more than one service
[b] A patient may have 1 or more reasons for being prescribed Prolia®

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-qs-oste-lab-covar.sas
Output: t14-04-008-005-qs-oste-lab-covar-sr-l.rtf (Date Generated: 14AUG2015: 1:01:32) Source Data: adam.aqspq, adam.aslbase, adam.aslinfo, adam.apresc

Table 14-4.9.1. DXA BMD T-score by Location and Visit (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Lumbar spine BMD T-score Baseline			
n	268	273	541
Mean	-2.74	-2.57	-2.66
SD	1.03	0.85	0.95
Median	-2.80	-2.70	-2.70
Q1, Q3	-3.40, -2.40	-3.00, -2.20	-3.20, -2.30
Min, Max	-5.0, 3.2	-5.0, 1.7	-5.0, 3.2
≤ -2.5 – n (%)	198 (66.0)	188 (62.7)	386 (64.3)
> -2.5 – n (%)	70 (23.3)	85 (28.3)	155 (25.8)
Missing – n (%)	32 (10.7)	27 (9.0)	59 (9.8)
Lumbar spine BMD T-score Month 6			
n	12	20	32
Mean	-2.06	-2.01	-2.03
SD	1.80	0.82	1.25
Median	-2.60	-2.03	-2.30
Q1, Q3	-3.05, -1.95	-2.60, -1.65	-2.80, -1.65
Min, Max	-4.2, 2.1	-3.3, 0.1	-4.2, 2.1
≤ -2.5 – n (%)	6 (2.0)	8 (2.7)	14 (2.3)
> -2.5 – n (%)	6 (2.0)	12 (4.0)	18 (3.0)
Missing – n (%)	288 (96.0)	280 (93.3)	568 (94.7)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-visit.sas
Output: t14-04-009-001-dxa-ts-visit-p.rtf (Date Generated: 14AUG2015: 0:06:58) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.1. DXA BMD T-score by Location and Visit (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Lumbar spine BMD T-score Month 12			
n	196	88	284
Mean	-2.29	-2.15	-2.25
SD	1.06	0.93	1.03
Median	-2.40	-2.30	-2.40
Q1, Q3	-2.95, -1.85	-2.75, -1.65	-2.90, -1.80
Min, Max	-4.6, 3.8	-3.5, 0.9	-4.6, 3.8
≤ -2.5 – n (%)	93 (31.0)	37 (12.3)	130 (21.7)
> -2.5 – n (%)	103 (34.3)	51 (17.0)	154 (25.7)
Missing – n (%)	104 (34.7)	212 (70.7)	316 (52.7)
Lumbar spine BMD T-score Month 18			
n	36	20	56
Mean	-1.98	-1.81	-1.92
SD	1.20	0.87	1.09
Median	-2.00	-1.75	-1.90
Q1, Q3	-2.85, -1.55	-2.55, -1.40	-2.70, -1.40
Min, Max	-3.7, 2.6	-3.5, 0.3	-3.7, 2.6
≤ -2.5 – n (%)	14 (4.7)	6 (2.0)	20 (3.3)
> -2.5 – n (%)	22 (7.3)	14 (4.7)	36 (6.0)
Missing – n (%)	264 (88.0)	280 (93.3)	544 (90.7)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-visit.sas
Output: t14-04-009-001-dxa-ts-visit-p.rtf (Date Generated: 14AUG2015: 0:06:58) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.1. DXA BMD T-score by Location and Visit
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Lumbar spine BMD T-score			
Month 24			
n	147	160	307
Mean	-2.19	-1.91	-2.04
SD	1.00	0.97	0.99
Median	-2.30	-2.10	-2.20
Q1, Q3	-2.80, -1.80	-2.50, -1.45	-2.60, -1.70
Min, Max	-4.4, 1.4	-4.0, 2.3	-4.4, 2.3
≤ -2.5 – n (%)	60 (20.0)	46 (15.3)	106 (17.7)
> -2.5 – n (%)	87 (29.0)	114 (38.0)	201 (33.5)
Missing – n (%)	153 (51.0)	140 (46.7)	293 (48.8)
Total Hip BMD T-score			
Baseline			
n	263	246	509
Mean	-1.98	-1.28	-1.64
SD	0.84	0.92	0.94
Median	-2.00	-1.30	-1.70
Q1, Q3	-2.60, -1.40	-1.80, -0.70	-2.30, -1.00
Min, Max	-4.3, 0.6	-3.7, 2.2	-4.3, 2.2
≤ -2.5 – n (%)	84 (28.0)	26 (8.7)	110 (18.3)
> -2.5 – n (%)	179 (59.7)	220 (73.3)	399 (66.5)
Missing – n (%)	37 (12.3)	54 (18.0)	91 (15.2)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-visit.sas
Output: t14-04-009-001-dxa-ts-visit-p.rtf (Date Generated: 14AUG2015: 0:06:58) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.1. DXA BMD T-score by Location and Visit
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Total Hip BMD T-score Month 6			
n	11	18	29
Mean	-1.79	-0.78	-1.16
SD	1.15	0.74	1.03
Median	-1.90	-0.95	-1.00
Q1, Q3	-2.70, -0.90	-1.20, 0.00	-1.60, -0.20
Min, Max	-3.5, -0.2	-2.3, 0.3	-3.5, 0.3
≤ -2.5 – n (%)	3 (1.0)	0 (0.0)	3 (0.5)
> -2.5 – n (%)	8 (2.7)	18 (6.0)	26 (4.3)
Missing – n (%)	289 (96.3)	282 (94.0)	571 (95.2)
Total Hip BMD T-score Month 12			
n	194	85	279
Mean	-1.80	-1.10	-1.58
SD	0.83	0.81	0.89
Median	-1.80	-1.10	-1.60
Q1, Q3	-2.40, -1.20	-1.70, -0.50	-2.20, -1.00
Min, Max	-4.1, 0.5	-2.9, 0.6	-4.1, 0.6
≤ -2.5 – n (%)	41 (13.7)	4 (1.3)	45 (7.5)
> -2.5 – n (%)	153 (51.0)	81 (27.0)	234 (39.0)
Missing – n (%)	106 (35.3)	215 (71.7)	321 (53.5)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-visit.sas
Output: t14-04-009-001-dxa-ts-visit-p.rtf (Date Generated: 14AUG2015: 0:06:58) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.1. DXA BMD T-score by Location and Visit
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Total Hip BMD T-score Month 18			
n	34	16	50
Mean	-1.61	-1.15	-1.47
SD	1.11	1.13	1.12
Median	-1.55	-1.00	-1.30
Q1, Q3	-2.30, -0.80	-1.78, -0.20	-2.10, -0.80
Min, Max	-4.6, 0.8	-4.3, 0.2	-4.6, 0.8
≤ -2.5 – n (%)	8 (2.7)	1 (0.3)	9 (1.5)
> -2.5 – n (%)	26 (8.7)	15 (5.0)	41 (6.8)
Missing – n (%)	266 (88.7)	284 (94.7)	550 (91.7)
Total Hip BMD T-score Month 24			
n	146	151	297
Mean	-1.77	-1.07	-1.41
SD	0.90	0.85	0.94
Median	-1.90	-1.10	-1.40
Q1, Q3	-2.40, -1.20	-1.70, -0.40	-2.10, -0.80
Min, Max	-4.2, 0.7	-3.5, 1.0	-4.2, 1.0
≤ -2.5 – n (%)	33 (11.0)	7 (2.3)	40 (6.7)
> -2.5 – n (%)	113 (37.7)	144 (48.0)	257 (42.8)
Missing – n (%)	154 (51.3)	149 (49.7)	303 (50.5)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-visit.sas
Output: t14-04-009-001-dxa-ts-visit-p.rtf (Date Generated: 14AUG2015: 0:06:58) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.1. DXA BMD T-score by Location and Visit
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Femoral neck BMD T-score			
Baseline			
n	262	273	535
Mean	-2.16	-1.87	-2.02
SD	0.77	0.82	0.81
Median	-2.20	-1.90	-2.00
Q1, Q3	-2.70, -1.60	-2.50, -1.40	-2.60, -1.50
Min, Max	-4.7, 0.0	-4.8, 0.6	-4.8, 0.6
≤ -2.5 – n (%)	103 (34.3)	73 (24.3)	176 (29.3)
> -2.5 – n (%)	159 (53.0)	200 (66.7)	359 (59.8)
Missing – n (%)	38 (12.7)	27 (9.0)	65 (10.8)
Femoral neck BMD T-score			
Month 6			
n	11	19	30
Mean	-2.18	-1.62	-1.83
SD	1.04	0.67	0.85
Median	-2.30	-1.60	-1.70
Q1, Q3	-3.00, -1.20	-2.00, -1.20	-2.60, -1.20
Min, Max	-4.1, -0.8	-3.0, -0.4	-4.1, -0.4
≤ -2.5 – n (%)	5 (1.7)	3 (1.0)	8 (1.3)
> -2.5 – n (%)	6 (2.0)	16 (5.3)	22 (3.7)
Missing – n (%)	289 (96.3)	281 (93.7)	570 (95.0)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-visit.sas
Output: t14-04-009-001-dxa-ts-visit-p.rtf (Date Generated: 14AUG2015: 0:06:58) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.1. DXA BMD T-score by Location and Visit
(Full Analysis Set)
(24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Femoral neck BMD T-score			
Month 12			
n	195	89	284
Mean	-1.95	-1.83	-1.91
SD	0.71	0.73	0.72
Median	-2.00	-1.90	-2.00
Q1, Q3	-2.40, -1.40	-2.30, -1.40	-2.32, -1.40
Min, Max	-4.1, -0.1	-3.2, 0.3	-4.1, 0.3
≤ -2.5 – n (%)	43 (14.3)	18 (6.0)	61 (10.2)
> -2.5 – n (%)	152 (50.7)	71 (23.7)	223 (37.2)
Missing – n (%)	105 (35.0)	211 (70.3)	316 (52.7)
Femoral neck BMD T-score			
Month 18			
n	34	20	54
Mean	-2.06	-1.59	-1.88
SD	1.06	1.01	1.06
Median	-1.90	-1.45	-1.70
Q1, Q3	-2.60, -1.30	-1.80, -1.10	-2.40, -1.20
Min, Max	-4.7, -0.1	-4.7, 0.4	-4.7, 0.4
≤ -2.5 – n (%)	10 (3.3)	3 (1.0)	13 (2.2)
> -2.5 – n (%)	24 (8.0)	17 (5.7)	41 (6.8)
Missing – n (%)	266 (88.7)	280 (93.3)	546 (91.0)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-visit.sas
Output: t14-04-009-001-dxa-ts-visit-p.rtf (Date Generated: 14AUG2015: 0:06:58) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.1. DXA BMD T-score by Location and Visit (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Femoral neck BMD T-score			
Month 24			
n	146	160	306
Mean	-1.96	-1.67	-1.81
SD	0.77	0.80	0.80
Median	-2.10	-1.70	-1.90
Q1, Q3	-2.50, -1.50	-2.20, -1.15	-2.40, -1.30
Min, Max	-4.4, 0.4	-3.9, 0.7	-4.4, 0.7
≤ -2.5 – n (%)	39 (13.0)	25 (8.3)	64 (10.7)
> -2.5 – n (%)	107 (35.7)	135 (45.0)	242 (40.3)
Missing – n (%)	154 (51.3)	140 (46.7)	294 (49.0)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-visit.sas
Output: t14-04-009-001-dxa-ts-visit-p.rtf (Date Generated: 14AUG2015: 0:06:58) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.2. Change from Baseline in DXA BMD T-score by Location and Visit (Ful Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Change in lumbar spine BMD T-score Month 6			
n	8	16	24
Mean	0.31	0.33	0.32
SD	0.23	0.42	0.36
Median	0.25	0.35	0.30
Q1, Q3	0.10, 0.50	0.05, 0.45	0.10, 0.50
Min, Max	0.1, 0.7	-0.3, 1.4	-0.3, 1.4
Improving - n (%)	8 (2.7)	12 (4.0)	20 (3.3)
Unchanged - n (%)	0 (0.0)	1 (0.3)	1 (0.2)
Worsening - n (%)	0 (0.0)	3 (1.0)	3 (0.5)
Change in lumbar spine BMD T-score Month 12			
n	180	76	256
Mean	0.40	0.38	0.39
SD	0.41	0.57	0.46
Median	0.40	0.40	0.40
Q1, Q3	0.20, 0.60	0.10, 0.60	0.20, 0.60
Min, Max	-1.4, 2.0	-2.5, 1.9	-2.5, 2.0
Improving - n (%)	155 (51.7)	64 (21.3)	219 (36.5)
Unchanged - n (%)	13 (4.3)	2 (0.7)	15 (2.5)
Worsening - n (%)	12 (4.0)	10 (3.3)	22 (3.7)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-chg-visit.sas
Output: t14-04-009-002-dxa-ts-chg-visit-p.rtf (Date Generated: 17AUG2015: 5:45:49) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.2. Change from Baseline in DXA BMD T-score by Location and Visit (Ful Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Change in lumbar spine BMD T-score Month 18			
n	29	17	46
Mean	0.52	0.67	0.57
SD	0.46	0.54	0.49
Median	0.40	0.60	0.50
Q1, Q3	0.20, 0.80	0.30, 0.90	0.26, 0.90
Min, Max	-0.5, 1.4	-0.1, 2.1	-0.5, 2.1
Improving - n (%)	25 (8.3)	16 (5.3)	41 (6.8)
Unchanged - n (%)	3 (1.0)	0 (0.0)	3 (0.5)
Worsening - n (%)	1 (0.3)	1 (0.3)	2 (0.3)
Change in lumbar spine BMD T-score Month 24			
n	145	155	300
Mean	0.58	0.63	0.61
SD	0.47	0.53	0.50
Median	0.60	0.60	0.60
Q1, Q3	0.30, 0.80	0.40, 0.90	0.30, 0.80
Min, Max	-0.8, 2.5	-1.9, 2.6	-1.9, 2.6
Improving - n (%)	133 (44.3)	144 (48.0)	277 (46.2)
Unchanged - n (%)	4 (1.3)	2 (0.7)	6 (1.0)
Worsening - n (%)	8 (2.7)	9 (3.0)	17 (2.8)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-chg-visit.sas
Output: t14-04-009-002-dxa-ts-chg-visit-p.rtf (Date Generated: 17AUG2015: 5:45:49) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.2. Change from Baseline in DXA BMD T-score by Location and Visit (Ful Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Change in total hip BMD T-score Month 6			
n	7	15	22
Mean	0.16	0.21	0.19
SD	0.24	0.32	0.30
Median	0.10	0.30	0.30
Q1, Q3	-0.10, 0.30	0.00, 0.40	0.00, 0.40
Min, Max	-0.1, 0.6	-0.7, 0.6	-0.7, 0.6
Improving - n (%)	5 (1.7)	11 (3.7)	16 (2.7)
Unchanged - n (%)	0 (0.0)	2 (0.7)	2 (0.3)
Worsening - n (%)	2 (0.7)	2 (0.7)	4 (0.7)
Change in total hip BMD T-score Month 12			
n	181	77	258
Mean	0.15	0.27	0.18
SD	0.29	0.31	0.30
Median	0.10	0.20	0.10
Q1, Q3	0.00, 0.30	0.10, 0.40	0.10, 0.30
Min, Max	-1.3, 1.9	-0.5, 1.3	-1.3, 1.9
Improving - n (%)	131 (43.7)	64 (21.3)	195 (32.5)
Unchanged - n (%)	25 (8.3)	6 (2.0)	31 (5.2)
Worsening - n (%)	25 (8.3)	7 (2.3)	32 (5.3)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-chg-visit.sas
Output: t14-04-009-002-dxa-ts-chg-visit-p.rtf (Date Generated: 17AUG2015: 5:45:49) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.2. Change from Baseline in DXA BMD T-score by Location and Visit (Ful Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Change in total hip BMD T-score Month 18			
n	25	12	37
Mean	0.20	0.23	0.21
SD	0.27	0.46	0.34
Median	0.20	0.15	0.20
Q1, Q3	0.00, 0.40	-0.05, 0.50	0.00, 0.40
Min, Max	-0.3, 0.8	-0.5, 1.0	-0.5, 1.0
Improving - n (%)	17 (5.7)	7 (2.3)	24 (4.0)
Unchanged - n (%)	4 (1.3)	2 (0.7)	6 (1.0)
Worsening - n (%)	4 (1.3)	3 (1.0)	7 (1.2)
Change in total hip BMD T-score Month 24			
n	145	139	284
Mean	0.21	0.21	0.21
SD	0.25	0.45	0.36
Median	0.20	0.20	0.20
Q1, Q3	0.10, 0.30	0.10, 0.40	0.10, 0.40
Min, Max	-0.6, 1.4	-2.4, 1.8	-2.4, 1.8
Improving - n (%)	112 (37.3)	111 (37.0)	223 (37.2)
Unchanged - n (%)	18 (6.0)	11 (3.7)	29 (4.8)
Worsening - n (%)	15 (5.0)	17 (5.7)	32 (5.3)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-chg-visit.sas
Output: t14-04-009-002-dxa-ts-chg-visit-p.rtf (Date Generated: 17AUG2015: 5:45:49) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.2. Change from Baseline in DXA BMD T-score by Location and Visit (Ful Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Change in femoral neck BMD T-score Month 6			
n	7	15	22
Mean	0.04	0.10	0.08
SD	0.32	0.23	0.26
Median	0.00	0.20	0.15
Q1, Q3	-0.20, 0.20	-0.10, 0.20	-0.10, 0.20
Min, Max	-0.3, 0.6	-0.3, 0.5	-0.3, 0.6
Improving - n (%)	3 (1.0)	9 (3.0)	12 (2.0)
Unchanged - n (%)	1 (0.3)	2 (0.7)	3 (0.5)
Worsening - n (%)	3 (1.0)	4 (1.3)	7 (1.2)
Change in femoral neck BMD T-score Month 12			
n	181	78	259
Mean	0.16	0.10	0.14
SD	0.34	0.27	0.32
Median	0.20	0.10	0.10
Q1, Q3	0.00, 0.30	0.00, 0.30	0.00, 0.30
Min, Max	-0.7, 1.4	-0.6, 0.7	-0.7, 1.4
Improving - n (%)	120 (40.0)	50 (16.7)	170 (28.3)
Unchanged - n (%)	22 (7.3)	9 (3.0)	31 (5.2)
Worsening - n (%)	39 (13.0)	19 (6.3)	58 (9.7)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-chg-visit.sas
Output: t14-04-009-002-dxa-ts-chg-visit-p.rtf (Date Generated: 17AUG2015: 5:45:49) Source Data: adam.aslinfo, adam.abmdxa

Table 14-4.9.2. Change from Baseline in DXA BMD T-score by Location and Visit (Ful Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n(%)	Slovakia (N = 300) n(%)	Overall (N = 600) n(%)
Change in femoral neck BMD T-score Month 18			
n	25	17	42
Mean	0.09	0.28	0.17
SD	0.25	0.32	0.30
Median	0.10	0.20	0.15
Q1, Q3	0.00, 0.20	0.10, 0.40	0.00, 0.30
Min, Max	-0.4, 0.8	-0.2, 1.2	-0.4, 1.2
Improving - n (%)	17 (5.7)	14 (4.7)	31 (5.2)
Unchanged - n (%)	2 (0.7)	2 (0.7)	4 (0.7)
Worsening - n (%)	6 (2.0)	1 (0.3)	7 (1.2)
Change in femoral neck BMD T-score Month 24			
n	145	155	300
Mean	0.20	0.24	0.22
SD	0.36	0.36	0.36
Median	0.20	0.20	0.20
Q1, Q3	0.00, 0.40	0.00, 0.40	0.00, 0.40
Min, Max	-0.9, 1.7	-0.5, 1.7	-0.9, 1.7
Improving - n (%)	101 (33.7)	104 (34.7)	205 (34.2)
Unchanged - n (%)	16 (5.3)	21 (7.0)	37 (6.2)
Worsening - n (%)	28 (9.3)	30 (10.0)	58 (9.7)

N = Number of patients in the full analysis set
Percentages based on number of patients in the full analysis set

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-dxa-ts-chg-visit.sas
Output: t14-04-009-002-dxa-ts-chg-visit-p.rtf (Date Generated: 17AUG2015: 5:45:49) Source Data: adam.aslinfo, adam.abmdxa

Table 14-6.1.1. Summary of Patient Incidence of Adverse Drug Reactions (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
All adverse drug reactions	4 (1.3)	12 (4.0)	16 (2.7)
Leading to discontinuation of Prolia®	2 (0.7)	5 (1.7)	7 (1.2)
Fatal	0 (0.0)	0 (0.0)	0 (0.0)
All serious adverse drug reactions	0 (0.0)	1 (0.3)	1 (0.2)
Leading to discontinuation of Prolia®	0 (0.0)	0 (0.0)	0 (0.0)
Fatal	0 (0.0)	0 (0.0)	0 (0.0)

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N = Number of patients who received ≥ 1 dose of Prolia®
n = Number of patients reporting ≥ 1 event

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-ae-sum.sas Output: t14-06-001-001-ae-sum-p.rtf (Date Generated: 17AUG15:04:38:48) Source Data: adam.aslinfo, adam.aae

Table 14-6.3.1. Adverse Drug Reactions by System Organ Class and Preferred Term
(Full Analysis Set)
(24-month Final Analysis)

SYSTEM ORGAN CLASS Preferred Term	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting treatment-emergent adverse drug reactions	4 (1.3)	12 (4.0)	16 (2.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0 (0.0)	4 (1.3)	4 (0.7)
Alopecia	0 (0.0)	2 (0.7)	2 (0.3)
Rash	0 (0.0)	2 (0.7)	2 (0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.7)	1 (0.3)	3 (0.5)
Musculoskeletal pain	2 (0.7)	0 (0.0)	2 (0.3)
Back pain	0 (0.0)	1 (0.3)	1 (0.2)
CARDIAC DISORDERS	0 (0.0)	2 (0.7)	2 (0.3)
Myocardial infarction	0 (0.0)	1 (0.3)	1 (0.2)
Supraventricular tachycardia	0 (0.0)	1 (0.3)	1 (0.2)
GASTROINTESTINAL DISORDERS	0 (0.0)	2 (0.7)	2 (0.3)
Abdominal pain upper	0 (0.0)	1 (0.3)	1 (0.2)
Gingival swelling	0 (0.0)	1 (0.3)	1 (0.2)
METABOLISM AND NUTRITION DISORDERS	0 (0.0)	2 (0.7)	2 (0.3)
Hypocalcaemia	0 (0.0)	2 (0.7)	2 (0.3)
NERVOUS SYSTEM DISORDERS	1 (0.3)	1 (0.3)	2 (0.3)
Burning sensation	0 (0.0)	1 (0.3)	1 (0.2)
Headache	1 (0.3)	0 (0.0)	1 (0.2)

N = Number of patients who received ≥ 1 dose of Prolia®
n = Number of patients reporting ≥ 1 event
Patients may have more than one adverse drug reaction

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-ae.sas
Output: t14-06-003-001-ae-soc-pt-p.rtf (Date Generated: 17AUG15:05:44:27) Source Data: adam.aslinfo, adam.aae

Table 14-6.3.1. Adverse Drug Reactions by System Organ Class and Preferred Term
(Full Analysis Set)
(24-month Final Analysis)

SYSTEM ORGAN CLASS Preferred Term	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0 (0.0)	1 (0.3)	1 (0.2)
Pyrexia	0 (0.0)	1 (0.3)	1 (0.2)
INFECTIONS AND INFESTATIONS	1 (0.3)	0 (0.0)	1 (0.2)
Skin infection	1 (0.3)	0 (0.0)	1 (0.2)
RENAL AND URINARY DISORDERS	0 (0.0)	1 (0.3)	1 (0.2)
Dysuria	0 (0.0)	1 (0.3)	1 (0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0 (0.0)	1 (0.3)	1 (0.2)
Dyspnoea	0 (0.0)	1 (0.3)	1 (0.2)

N = Number of patients who received ≥ 1 dose of Prolia®
n = Number of patients reporting ≥ 1 event
Patients may have more than one adverse drug reaction

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-ae.sas
Output: t14-06-003-001-ae-soc-pt-p.rtf (Date Generated: 17AUG15:05:44:27) Source Data: adam.aslinfo, adam.aae

Table 14-6.4.1. Adverse Drug Reaction Leading to Discontinuation of Prolia® by System Organ Class and Preferred Term (Full Analysis Set) (24-month Final Analysis)

SYSTEM ORGAN CLASS Preferred Term	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting treatment-emergent adverse drug reactions	2 (0.7)	5 (1.7)	7 (1.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0 (0.0)	3 (1.0)	3 (0.5)
Alopecia	0 (0.0)	2 (0.7)	2 (0.3)
Rash	0 (0.0)	1 (0.3)	1 (0.2)
CARDIAC DISORDERS	0 (0.0)	1 (0.3)	1 (0.2)
Supraventricular tachycardia	0 (0.0)	1 (0.3)	1 (0.2)
GASTROINTESTINAL DISORDERS	0 (0.0)	1 (0.3)	1 (0.2)
Gingival swelling	0 (0.0)	1 (0.3)	1 (0.2)
INFECTIONS AND INFESTATIONS	1 (0.3)	0 (0.0)	1 (0.2)
Skin infection	1 (0.3)	0 (0.0)	1 (0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.3)	0 (0.0)	1 (0.2)
Musculoskeletal pain	1 (0.3)	0 (0.0)	1 (0.2)

N = Number of patients who received ≥ 1 dose of Prolia®
n = Number of patients reporting ≥ 1 event

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-ae.sas
Output: t14-06-004-001-ae-soc-dispro-p.rtf (Date Generated: 17AUG15:05:44:32) Source Data: adam.aslinfo, adam.aae

Table 14-6.5.1. Fatal Adverse Drug Reactions by System Organ Class and Preferred Term (Full Analysis Set) (24-month Final Analysis)

No events

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Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-ae.sas
Output: t14-06-005-001-sae-fatal-p.rtf (Date Generated: 17AUG15:05:44:34) Source Data: adam.aslinfo, adam.aae

Table 14-6.6.1. Summary of Patients Incidence of New Fractures (Full Analysis Set) (24-month Final Analysis)

	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting new fractures	18 (6.0)	4 (1.3)	22 (3.7)
Clinical fractures[a]	15 (5.0)	3 (1.0)	18 (3.0)

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N = Number of patients who received ≥ 1 dose of Prolia®
n = Number of patients with ≥ 1 event
Includes only treatment-emergent fractures
Patients may have more than one type of fracture.
[a] Clinical or osteoporotic fractures are defined as all fractures excluding skull, facial bones, mandible, metacarpus, finger phalanges, toe phalanges and cervical vertebrae and not associated with known high trauma severity (fall from higher than the height of stool, chair, first rung on a ladder or equivalent (> 20 inches) or severe trauma other than a fall) or pathological fractures.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-aefx.sas
Output: t14-06-006-001-aefx-p.rtf (Date Generated: 15DEC15:22:50:48) Source Data: adam.aslinfo, adam.aaefx

Table 14-6.6.2. New Fractures by Location
(Full Analysis Set)
(24-month Final Analysis)

Location	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting new fractures	18 (6.0)	4 (1.3)	22 (3.7)
Spine	3 (1.0)	1 (0.3)	4 (0.7)
Thoracic vertebral fracture	3 (1.0)	1 (0.3)	4 (0.7)
Forearm	3 (1.0)	0 (0.0)	3 (0.5)
Radius fracture	3 (1.0)	0 (0.0)	3 (0.5)
Hip	3 (1.0)	0 (0.0)	3 (0.5)
Femoral neck fracture	2 (0.7)	0 (0.0)	2 (0.3)
Femur fracture	1 (0.3)	0 (0.0)	1 (0.2)
Thorax	3 (1.0)	0 (0.0)	3 (0.5)
Clavicle fracture	1 (0.3)	0 (0.0)	1 (0.2)
Rib fracture	1 (0.3)	0 (0.0)	1 (0.2)
Sternal fracture	1 (0.3)	0 (0.0)	1 (0.2)
Foot	1 (0.3)	1 (0.3)	2 (0.3)
Foot fracture	1 (0.3)	1 (0.3)	2 (0.3)
Shoulder	1 (0.3)	1 (0.3)	2 (0.3)
Humerus fracture	1 (0.3)	1 (0.3)	2 (0.3)
Thigh	2 (0.7)	0 (0.0)	2 (0.3)
Femur fracture	1 (0.3)	0 (0.0)	1 (0.2)
Patella fracture	1 (0.3)	0 (0.0)	1 (0.2)
Hand	1 (0.3)	0 (0.0)	1 (0.2)
Hand fracture	1 (0.3)	0 (0.0)	1 (0.2)

N = Number of patients who received ≥ 1 dose of Prolia®
n = Number of patients with ≥ 1 event
Includes only new fractures

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-aefx-loc-pt.sas
Output: t14-06-006-002-aefx-loc-pt-p.rtf (Date Generated: 14AUG15:05:38:59) Source Data: adam.aslinfo, adam.aaefx

Table 14-6.6.2. New Fractures by Location (Full Analysis Set) (24-month Final Analysis)

Location	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Head	1 (0.3)	0 (0.0)	1 (0.2)
Facial bones fracture	1 (0.3)	0 (0.0)	1 (0.2)
Lower Leg	1 (0.3)	0 (0.0)	1 (0.2)
Fibula fracture	1 (0.3)	0 (0.0)	1 (0.2)
Pelvis	0 (0.0)	1 (0.3)	1 (0.2)
Ilium fracture	0 (0.0)	1 (0.3)	1 (0.2)

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N = Number of patients who received ≥ 1 dose of Prolia®
n = Number of patients with ≥ 1 event
Includes only new fractures

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-aefx-loc-pt.sas
Output: t14-06-006-002-aefx-loc-pt-p.rtf (Date Generated: 14AUG15:05:38:59) Source Data: adam.aslinfo, adam.aaefx

Table 14-6.6.3. Clinical Fractures by Location
(Full Analysis Set)
(24-month Final Analysis)

Location	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Number of patients reporting clinical fractures[a]	15 (5.0)	3 (1.0)	18 (3.0)
Forearm	3 (1.0)	0 (0.0)	3 (0.5)
Radius fracture	3 (1.0)	0 (0.0)	3 (0.5)
Hip	3 (1.0)	0 (0.0)	3 (0.5)
Femoral neck fracture	2 (0.7)	0 (0.0)	2 (0.3)
Femur fracture	1 (0.3)	0 (0.0)	1 (0.2)
Thorax	3 (1.0)	0 (0.0)	3 (0.5)
Clavicle fracture	1 (0.3)	0 (0.0)	1 (0.2)
Rib fracture	1 (0.3)	0 (0.0)	1 (0.2)
Sternal fracture	1 (0.3)	0 (0.0)	1 (0.2)
Foot	1 (0.3)	1 (0.3)	2 (0.3)
Foot fracture	1 (0.3)	1 (0.3)	2 (0.3)
Shoulder	1 (0.3)	1 (0.3)	2 (0.3)
Humerus fracture	1 (0.3)	1 (0.3)	2 (0.3)
Spine	2 (0.7)	0 (0.0)	2 (0.3)
Thoracic vertebral fracture	2 (0.7)	0 (0.0)	2 (0.3)
Thigh	2 (0.7)	0 (0.0)	2 (0.3)
Femur fracture	1 (0.3)	0 (0.0)	1 (0.2)
Patella fracture	1 (0.3)	0 (0.0)	1 (0.2)
Lower Leg	1 (0.3)	0 (0.0)	1 (0.2)

N = Number of patients who received ≥ 1 dose of Prolia®
n = Number of patients with ≥ 1 event
Includes only new fractures
[a] Clinical fractures or osteoporotic fractures are defined as all fractures excluding skull, facial bones, mandible, metacarpus, finger phalanges, toe phalanges and cervical vertebrae and not associated with known high trauma severity (fall from higher than the height of stool, chair, first rung on a ladder or equivalent (> 20 inches) or severe trauma other than a fall) or pathological fractures.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-aefx-loc-pt.sas Output: t14-06-006-003-clinfx-loc-pt-p.rtf (Date Generated: 14AUG15:05:39:03) Source Data: adam.aslinfo, adam.aaefx

Table 14-6.6.3. Clinical Fractures by Location (Full Analysis Set) (24-month Final Analysis)

Location	Czech Republic (N = 300) n (%)	Slovakia (N = 300) n (%)	Overall (N = 600) n (%)
Lower Leg (Cont'd)			
Fibula fracture	1 (0.3)	0 (0.0)	1 (0.2)
Pelvis	0 (0.0)	1 (0.3)	1 (0.2)
Ilium fracture	0 (0.0)	1 (0.3)	1 (0.2)

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N = Number of patients who received ≥ 1 dose of Prolia®
n = Number of patients with ≥ 1 event
Includes only new fractures
[a] Clinical fractures or osteoporotic fractures are defined as all fractures excluding skull, facial bones, mandible, metacarpus, finger phalanges, toe phalanges and cervical vertebrae and not associated with known high trauma severity (fall from higher than the height of stool, chair, first rung on a ladder or equivalent (> 20 inches) or severe trauma other than a fall) or pathological fractures.

Program: /userdata/stat/amg162/osteo/20110132/analysis/final_mon24/tables/program/t-aefx-loc-pt.sas Output: t14-06-006-003-clinfx-loc-pt-p.rtf (Date Generated: 14AUG15:05:39:03) Source Data: adam.aslinfo, adam.aaefx

16. ANNEXES

Annex 1. List of Stand-alone Documents

Number	Document Reference Number	Date	Title
1	Number 1	15 October 2015	20110132 Principal Investigator List

The principal investigator list is provided below.

Region	Site #	Account	PI Last Name	PI First Name
Czech Republic	21001	Privamed as, Mestska nemocnice Plzen	Kielbergerova	Klara
Czech Republic	21002	Interni a osteologicka ambulance, Karlovy Vary	Vdoviak	Miroslav
Czech Republic	21003	Osteologicke centrum, Brno	Slesinger	Jan
Czech Republic	21004	Osteocentrum Zlin	Hrdy	Petr
Czech Republic	21005	Osteologicke pracoviste a denzitometrie, Vsetin	Doubravsky	Jaroslav
Czech Republic	21006	Artroscan sro, Ostrava – Trebovice	Smajstrla	Vit
Czech Republic	21007	Nemocnice Havlickuv Brod, Osteologicke centrum	Senk	Frantisek
Czech Republic	21008	Thomayerova nemocnice	Kopsa	Petr
Czech Republic	21009	Revmatologicka ambulance	Vagner	Ivo
Czech Republic	21010	Revmatologicky ustav, Praha	Ruzickova	Olga
Czech Republic	21011	LKN Arthrocentrum sro	Novosad	Libor
Czech Republic	21012	Oblastni nemocnice Trutnov, Interni oddeleni	Tyl	Roman
Czech Republic	21013	MEDISCAN GROUP, s.r.o. Praha	Kasalicky	Petr
Czech Republic	21014	Oblastni nemocnice Kolin as, nemocnice Stredoceskeho kraje, Nemocnice Kutna Hora	Mala	Vaclav
Czech Republic	21015	Nemocnice Ceske Budejovice as	Kucerova	Irena
Czech Republic	21016	Revmatologicka a interni ambulance, Ostrava	Sugarek	Mojmir
Czech Republic	21017	Revmatologie sro, Brno	Nemec	Petr
Czech Republic	21018	Ustredni vojenska nemocnice Praha	Jensovsky	Jiri
Czech Republic	21019	Nuselska poliklinika, Revmatologie,Praha	Stejfova	Zuzana
Czech Republic	21020	Poliklinika ArcelorMittal Ostrava as	Brtnikova	Sylvie
Czech Republic	21021	MEDIPONT sro ambulantni klinika, Rehabilitace, Osteologie, Ceske Budejovice	Tollingerova	Renata
Slovakia	54001	Medcentrum sro, Interna a osteologicka ambulancia, Zilina	Bollova	Dagmar
Slovakia	54002	Fakultna nemocnica s poliklinikou Zilina, Osteologicka ambulancia	Machova	Maria
Slovakia	54003	Rehabilitacno reumatologicke centrum sro, Reumatologicka ambulancia, Martin	Amcha	Emil
Slovakia	54004	Nemocnica Kosice-Saca as, sukromna nemocnica, Reumatologicka a osteologicka ambulancia	Tomkova	Sona
Slovakia	54005	Ergomed poliklinika sro, Ortopedicka ambulancia, Kosice	Abdi	Mirwais
Slovakia	54006	Osteocentrum sro Humenne, Osteologicka ambulancia	Pidanicova	Silvia
Slovakia	54007	Univerzitna Nemocnica Bratislava - Nemocnica Ruzinov, Interna klinika	Killinger	Zdenko
Slovakia	54008	Fidelitas sro, Osteologicka a Reumatologicka ambulancia, Bratislava	Wendl	Juraj
Slovakia	54009	Reumaglobal sro, Reumatologicka ambulancia a osteodenzitometria, Trnava	Dobrovodsky	Pavol
Slovakia	54010	Ortoped sro, Ortopedicka a Osteologicka ambulancia , Presov	Klein	Peter
Slovakia	54011	Ortoped sro	Kleinova-Semancikova	Iveta
Slovakia	54012	Osteocentrum sro, Osteologia a osteodenzitometria vnutorne lekarstvo, Presov	Tomkova	Zlatica
Slovakia	54013	MUDr Drahomir Galbavy sro	Galbavy	Drahomir
Slovakia	54014	Fakultna nemocnica Nitra, Reumatologicka ambulancia	Vano	Ivan
Slovakia	54015	Fakultna nemocnica Nitra, Endokrinologicka ambulancia	Dokupilova	Adriana
Slovakia	54016	Fakultna Nemocnica s Poliklinikou FD Roosevelta, Interna Klinika - Reumatologicka ambulancia, Banska Bystrica	Kmecova	Zlata

Slovakia	54017	Bella sro, Reumatologicka ambulancia, Banska Bystrica	Macejkova	Eva
Slovakia	54018	Jakab Med sro, Lucenec	Jakab	Ernest
Slovakia	54019	Narodny endokrinologicky a diabetologicky ustav n.o. Lubochna	Vanuga	Peter

Annex 2. Study Protocol and Amendments

Title: Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice

Amgen Protocol Number 20110132

AMG 162 - Prolia® (denosumab)

Clinical Study Sponsor:
Amgen Inc.
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Superseding version **14 December 2012**

Confidentiality Notice

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Investigator's Agreement

I have read the attached protocol entitled Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice dated **14 December 2012**, and agree to abide by all provisions set forth therein.

I agree to comply with the International Conference on Harmonisation Tripartite Guideline on Good Clinical Practice (as applicable by local law).

I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of Amgen Inc.

Signature

Name of Principal Investigator

Date (DD Month YYYY)

Approved

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Protocol Synopsis

Title: Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice

Study Phase: Observational

Indication: Treatment of osteoporosis (OP) in postmenopausal women at increased risk of fractures.

Study Objective:

The objective of this prospective, observational study in Czech Republic and Slovakia is to describe per country the characteristics of women treated with Prolia® (denosumab) in routine clinical practice and the clinical management of these patients during the first 2 years of treatment.

Hypotheses: The study is descriptive in nature, and a formal hypothesis will not be tested in this observational, single-arm study.

Study Outcomes:

- Occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia® from the initial prescribing physician's office
- Occurrence (yes/no) of patient receiving an individual prescription and injection of Prolia® from the initial prescribing physician office by injection
- Occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia®, whether or not the injections are given at the initial prescribing physician's office
- Occurrence (yes/no) of patient with a referral by the prescribing physician to other health care providers for continuation or follow up of care by type of physician
- Types of health care providers administering an individual injection of Prolia® inside or outside the initial prescribing office by each individual injection
- Number of Prolia® injections received by each patient during the follow-up period
- Occurrence (yes/no) of patient having radiologic bone assessments pre-treatment with Prolia®, and during the study
- Occurrence (yes/no) of patient having osteoporosis-related laboratory examinations pre-treatment with Prolia®, and during the study
- Incidence (yes/no) of patients with ADR to Prolia®
- Incidence (yes/no) of patients with serious ADR to Prolia®

Approved

Study Design:

This is a multi-center, international, non-interventional, prospective, observational study in PMO (postmenopausal osteoporosis) patients who received at least one injection of Prolia® 60 mg Q6M, SC (subcutaneous) in Czech Republic and Slovakia. This observational study will not alter the routine clinical management of patients and will comply with all applicable local regulations in the countries in which it is being conducted.

Prolia® naive patients will be eligible to enroll within 8 weeks after initiation of Prolia® treatment (ie 8 weeks after receiving the first injection). The decision to treat the patient with Prolia® must be made independent of and prior to their enrollment in the study. However, writing of the prescription for Prolia®, the first Prolia® injection and/or administration of informed consent (as applicable by local country laws and regulations) may happen at the same visit. It is expected that patients will receive their scheduled Prolia® injection every 6 months as part of their routine clinical care.

Approximately 300 patients will be enrolled in Czech Republic and 300 in Slovakia.The estimated duration of enrollment is approximately 12 months. No study drug will be administered as part of the study. The protocol will specify that investigators will offer participation in the study to all patients treated with Prolia® during the enrollment period until they reach their contracted number of patients. Detailed data obtained as part of routine clinical practice will be collected at the initial visit, either directly or from medical record, to characterize the patient population. It is anticipated

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that patients will return to the clinic every 6 months to receive their Prolia® prescription and/or injections. After the initial visit, information regarding Prolia® prescription and administration, procedures pertaining to osteoporosis and Prolia®, concomitant medication use, and non-serious and serious ADRs will be obtained during routine clinical visits and recorded for up to approximately 2 years after entering the study.

The study will describe the profile of patients treated with Prolia® and the clinical management of these patients during the first 2 years of treatment. Patient and site characteristics will be collected at baseline according to the following 4 dimensions:

- Socio-demographic related
- Condition-related (osteoporosis)
- Patient-related
- Physician-related (including geographic region, specialty)

Sample Size: Approximately 300 patients in the Czech Republic and 300 in Slovakia.

Summary of Patient Eligibility Criteria:

Patients will meet the following inclusion criteria at enrollment into the observational study:

- Women with a clinical diagnosis of PMO
- Decision has been made to treat patient with Prolia® 60 mg once every 6 months
- Have received their first injection of Prolia® within 8 weeks prior to enrolling in this study
- Appropriate written informed consent has been obtained (as required per local country regulations)

Patients meeting the following exclusion criteria are not eligible to participate in the observational study:

- Patients who are participating in ongoing or have participated in previous denosumab clinical trials
- Participation in other clinical or device trials in the last 6 months
- Contra-indicated for treatment with Prolia®
- Subject has any kind of disorder that, in the opinion of the investigator, may compromise the ability of the subject to give written informed consent.

Amgen Investigational Product Dosage and Administration: None

Non Amgen Investigational Product Dosage and Administration: None

Non Amgen Non-investigational Product Dosage and Administration: None

Control Group: None

Procedures:

There are no procedures or changes to routine clinical management of PMO patients. It is anticipated that patients will return to the clinic every 6 months to receive their Prolia® prescription and/or injections. Patients will be followed for approximately 2 years after their initial visit. Clinical information obtained for routine clinical practice will be recorded where available, including Prolia® administration, previous and current therapies, medical history (including fracture), ADRs and serious ADRs and co-morbidities (Appendix A). For a full list of study procedures, including the timing of each procedure, please refer to Section 7 and Appendix A (Information Obtained during Routine Clinical Practice).

Statistical Considerations:

This is an observational study for which the analysis will be descriptive in nature; no formal hypothesis will be tested. Frequency distributions will be described for categorical variables. Continuous variables will be summarized by the number of non-missing values, mean, standard deviation, median, lower and upper quartiles and minimum and maximum values. All study outcomes and baseline characteristics will be summarized by country. For selected study outcome related to the clinical management of these patients, point estimate and 95% confidence

interval will be provided as well by country. Summary of the study outcomes by country and selected baseline variables will be provided. Appropriate outcomes specific for a prescription/ injection will be summarized by prescription/injection (1st, 2nd, 3rd and 4th).

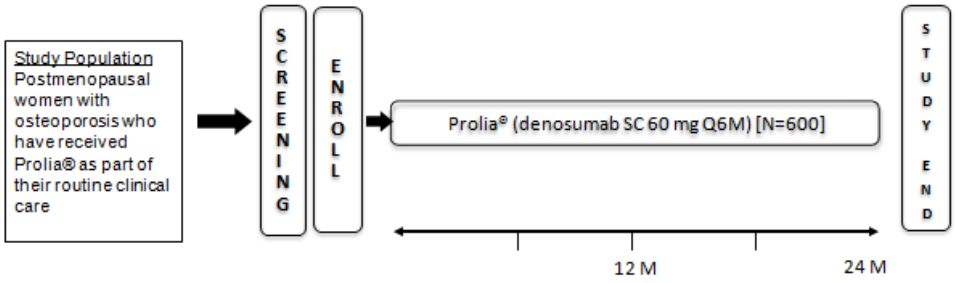
All ADRs and serious ADRs to Prolia® will be coded using the Medical Dictionary for Regulatory Activities (MedDRA). Patient incidence of ADRs and serious ADRs will be tabulated by system organ class and preferred term. Moreover, ADRs and serious ADRs leading to discontinuation of Prolia® or associated with a fatal outcome will be tabulated by system organ class and preferred term.

For a full description of statistical analysis methods, please refer to Section 10.

Sponsor: See Protocol Title Page

Study Design and Treatment Schema

20110132: Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice



The decision to treat the patient with Prolia® 60 mg Q6M SC should occur independent of and prior to their enrollment in the study

Study Glossary

Abbreviation or Term	Definition/Explanation
ADR	Adverse Drug Reaction
AE	Adverse Event
BMD	Bone Mineral Density
BMI	Body Mass Index
BPs	Bisphosphonates
CI	Confidence Interval
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EU	European Union
HCP	Health Care Professional
IEC	Independent Ethics Committee
IVRS	Interactive Voice Response System
IRB	Institutional Review Board
MedDRA	Medical Dictionary for Regulatory Activities
OP	Osteoporosis
OPG	Osteoprotegerin
PMO	Postmenopausal Osteoporosis
Q6M	Once every 6 months
SADR	Serious Adverse Drug Reaction
SAE	Serious Adverse Event
SC	Subcutaneous

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1. OBJECTIVES

The objective of this prospective, observational study is to describe characteristics of postmenopausal women treated with Prolia® (denosumab) in routine clinical practice and to describe the clinical management of these patients during the first 2 years of treatment in Czech Republic and Slovakia.

2. BACKGROUND AND RATIONALE

2.1 Disease

Osteoporosis is a common, systemic skeletal disorder characterized by low bone mass and compromised bone strength predisposing individuals to an increased risk of fracture (NIH Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy, 2000). Osteoporosis is a major public health threat; in a recent review, the prevalence of osteoporosis was reported as an estimated 200 million people worldwide (Reginster and Burlet, 2006).

The morbidity and mortality associated with osteoporosis-related fractures result in significant clinical, human, and economic costs (Cree et al, 2003). About 40 to 50% of women are at risk of having an osteoporotic fracture in their lifetimes (Dennison et al, 2006). In Europe, the number of osteoporotic fractures was estimated at 3.79 million/year of which 0.89 million were hip fractures (Kanis and Johnell, 2005).

Osteoporosis can be treated effectively by antiresorptive agents, such as bisphosphonates, or by anabolic agents, such as parathyroid hormone analogues (Papapoulos and Makras, 2008). Clinical studies have demonstrated the efficacy of the bisphosphonate class of drugs in reducing the risk of osteoporosis-related fractures (Papapoulos, 2005). However, difficult dosing regimens, lack of patient satisfaction and medication side-effects may limit drug adherence (Sambrook and Cooper, 2006).

Denosumab is a fully human monoclonal antibody that inhibits RANKL, an essential regulator of osteoclast differentiation, activation and survival. Administration of denosumab 60 mg SC (subcutaneous) every 6 months (Q6M) (Prolia®) has been shown to decrease bone remodeling with consequent increases in bone mineral density (BMD) and decreased risk for new vertebral, nonvertebral, and hip fractures (Cummings et al. 2009).

2.2 Prolia® Background

Prolia® (denosumab) is a fully human monoclonal antibody that inhibits RANKL, an essential regulator of osteoclast differentiation, activation and survival. It can bind and neutralize the activity of human RANKL similar to the action of endogenous osteoprotegerin (OPG). Denosumab (Prolia®) has been studied for the prevention and treatment of OP in postmenopausal women. Administration of denosumab 60 mg SC Q6M (Prolia®) has been shown to decrease bone remodeling with consequent increases in bone mineral density (BMD) and decreased risk for new vertebral, nonvertebral, and hip fractures (Cummings et al. 2009).

Denosumab 60 mg SC Q6M (Prolia®) has been approved in all 27 European Union (EU) member states plus Iceland, Liechtenstein, Norway and Switzerland for the treatment of osteoporosis in postmenopausal women at increased risk of fracture

2.3 Rationale

After regulatory approval is granted for pharmaceutical products, many countries request data regarding patient demographics to ensure that each drug is being used in the population for which it was intended. Moreover for injectable drugs like Prolia®, countries seek information on the manner of administration to ensure proper use.

In Czech Republic, Prolia® was approved on 26 May 2010 and is the only injectable product available in retail pharmacies (all other injectables are hospital products). Prolia® also was approved in Slovakia on 26 May 2010. In both countries, Prolia® is prescribed predominantly by specialists and reimbursed for PMO patients with a T-score ≤ -2.5 or prior fracture and / or limited by other reimbursement restrictions, as applicable by local country regulations.

By collecting information on patient characteristics including demographics, comorbid conditions and use of concomitant medications, study findings will help describe women receiving Prolia® for osteoporosis in the Czech Republic and Slovakia. Special attention will be given to collecting data enabling description of factors determining therapeutic choice and the patient's fracture risk; comorbid conditions influencing bone health (including systemic, metabolic, rheumatic, thyroid, parathyroid, renal and lung); clinical factors related to osteoporosis (prior fracture, age, ambulatory status, bone turnover markers, BMD T-score, body mass index, Ca (calcium) and vitamin D intake); lifestyle factors (smoking, alcohol and drug use/abuse); socioeconomic status (employed, retired); and physician/healthcare professional related information. Data from this study

will provide information about management practice patterns in patients for whom, in the opinion of the prescribing physician, Prolia® was deemed to be appropriate.

2.4 Clinical Hypotheses

The study is descriptive and no formal hypothesis testing will be performed in this prospective, observational study. However demographic and clinical characteristics of postmenopausal patients who received at least one injection of Prolia® (denosumab 60 mg) will be described.

3. EXPERIMENTAL PLAN

3.1 Study Design

This is a multi-center, international, non-interventional, prospective, observational study in PMO patients who received at least one injection of Prolia® 60 mg Q6M, SC in Czech Republic and Slovakia. This observational study will not alter the routine clinical management of patients and will comply with all applicable local regulations in the countries in which it is being conducted.

Patients will be eligible to enroll within 8 weeks after receiving their first Prolia® injection. The decision to treat the patient with Prolia® must be made independent of and prior to their enrollment in the study. However, the writing of the prescription for Prolia®, the first Prolia® injection and/or administration of informed consent (as applicable by local country laws and regulations) may happen at the same visit. It is expected that patients will receive their scheduled Prolia® injection every 6 months as part of their routine clinical care.

Approximately 300 patients will be enrolled in Czech Republic and 300 in Slovakia. The estimated duration of enrollment is approximately 12 months. No study drug will be administered as part of the study. Investigators may offer participation in the study to all women treated with Prolia® during the enrollment period until they reach their contracted number of patients. Detailed data obtained as part of routine clinical practice will be collected at the initial visit, either directly or from medical record, to characterize the patient population. It is anticipated that patients will return to the clinic every 6 months to receive their Prolia® prescription and/or injections. After the initial visit, information regarding Prolia® prescription and administration, procedures pertaining to Prolia® administration and osteoporosis, concomitant medication use, and non-serious and serious ADRs will be obtained during routine clinical visits and recorded for up to approximately 2 years after entering the study.

The study will describe the profile of patients treated with Prolia® and the clinical management of these patients during the first 2 years of treatment. Patient and site characteristics will be collected at baseline according to the following 4 dimensions, when available:

- Socio-demographic related
- Condition-related (osteoporosis)
- Patient-related
- Physician-related (including geographic region, specialty)

In this observational study, ADRs and serious ADRs related to Prolia® will be collected and reported. ADRs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA).

Additional information as outlined in **Appendix B** will be collected during routine clinical visits over a period of approximately 2 years. Given that the frequency of Prolia® administration is every 6 months, a 2-year observation period is thought appropriate to ascertain treatment practices and document ADRs and serious ADRs.

The overall study design is described by the study schema at the end of the protocol synopsis section.

The study outcomes are defined in Section 10.1.

3.2 Number of Centers

The study will be conducted in approximately 30 representative (country specific) sites (15 each in Czech Republic and Slovakia). Additional sites may be added or removed as deemed necessary to ensure enrollment of the target number of patients. After feasibility assessment, sites selected will represent those providing PMO care in each country and region, with regards to type and location of site. Sites that do not enroll patients within 2 months after site initiation may be closed. Sites will be selected from the available list of potential sites in the country, following feasibility checks.

3.3 Number of Patients

Participants in this clinical investigation shall be referred to as “patients”.

Approximately 600 patients (about 300 each in Czech Republic and Slovakia) will be enrolled into the study. The justification for the sample size is provided in Section 10.2.

3.4 Estimated Study Duration

3.4.1 Study Duration for Participants

The enrollment period is expected to last approximately 12 months. Patients providing appropriate written informed consent and fulfilling inclusion and exclusion criteria will be eligible to enroll in the observational study. Enrolled patients will have a follow-up period of approximately 24 months after enrollment in the study.

3.4.2 End of Study

End of study is defined as the date that the last patient enrolled completes 24 months of observation or when the last patient ends her participation in the study.

4. PATIENT ELIGIBILITY

Postmenopausal women with OP who receive an injection of Prolia® and meet the inclusion/exclusion criteria will be eligible to participate in the study.

Investigators will be expected to maintain a screening log with limited information on all potential study candidates (eg, date of screening). Before entering the study, an appropriate written informed consent must be obtained as applicable by local country regulations (see Section 11.1).

4.1 Inclusion Criteria

4.1.1 Women with a clinical diagnosis of postmenopausal osteoporosis

4.1.2 Decision has been made to treat with Prolia® 60 mg once every 6 months

4.1.3 Have received their first injection of Prolia® within 8 weeks prior to enrolling in this study

4.1.4 Appropriate written informed consent has been obtained (as required per local country regulations)

4.2 Exclusion Criteria

4.2.1 Participating in ongoing or have participated in previous denosumab clinical trials

4.2.2 Participation in other clinical or device trials in the last 6 months

4.2.3 Contra-indicated for treatment with Prolia® according to the approved applicable local product label.

4.2.4 Subject has any kind of disorder that, in the opinion of the investigator, may compromise the ability of the subject to give written informed consent

5. PATIENT ENROLLMENT

Before patients may be entered into the study, Amgen requires a copy of the site's written Independent Ethics Committee (IEC) or Independent Review Board (IRB) approval of the protocol as applicable, informed consent form (as required by local

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country requirements) and all other patient information and/or recruitment material (see Section 11.2).

All patients or their legally acceptable representatives must personally sign and date an appropriate consent form (as required per local country regulations) before being enrolled into this study.

Enrollment is defined as the date the patient is enrolled in the study via an Interactive Voice Response System (IVRS). All patients who are enrolled will be assigned a unique 11-digit patient identification number before the observation period commences. Patient identification numbers will be assigned in sequential order within a site beginning with 132XXXXX001, with 'XXXXX'=site number. This number will be used to identify the patient throughout the observational study and must be used on all study documentation related to that patient. The patient identification number must remain constant throughout the entire observational study.

Each site should maintain a confidential patient list that enables site study staff to link an assigned patient identification number to that patient's medical records.

6. TREATMENT PROCEDURES

This study is designed to follow and observe patients who have recently (within 8 weeks) initiated treatment with Prolia® in routine clinical practice. No study-specific treatment will be provided and no additional clinical procedures or assessments will be required as part of this observational study.

Patients will be observed for a period of up to 2 years after their entry in the study unless patients discontinue the study or are lost to follow up. Information regarding the clinical management of the patients receiving Prolia® may be collected whenever available, even after treatment discontinuation.

There are no procedures or changes to routine clinical management of patients. It is anticipated that patients will return to the clinic every 6 months to receive their Prolia® prescription and/or injections. Patients will be followed for approximately 2 years after their initial visit. Available clinical information obtained for routine clinical practice (including those already recorded on the patient medical records ie, baseline characteristics) will be recorded, including Prolia® administration, previous and current therapies, medical history (including fracture history), ADRs and serious ADRs and co-morbidities (Appendix A).

6.1 Concomitant Therapy

Throughout the study, investigators may prescribe any concomitant medications or treatments deemed necessary to provide adequate routine clinical care including calcium and vitamin D supplementation.

7. STUDY PROCEDURES

There are no procedures or changes to routine clinical management of patients. It is anticipated that patients will return to the clinic every 6 months to receive their Prolia® prescription and/or injections. Patients will be followed for approximately 2 years after their initial visit. Available clinical information obtained for routine clinical practice (including those already recorded on the patient medical records for baseline characteristics) will be recorded, including Prolia® administration, previous and current therapies, medical history (including fracture), ADRs and serious ADRs and co - morbidities (Appendix A).

Patients who switch to another therapy or discontinue treatment will not be followed up for more than 6 months after their last Prolia® injection.

8. REMOVAL AND REPLACEMENT OF PATIENTS

8.1 Removal of Patients

Patients have the right to withdraw fully from the study at any time and for any reason without prejudice to her future medical care by the physician or at the institution.

Withdrawal of full consent for a study means that the patient does not wish to or is unable to continue further study participation; patient data up to withdrawal of consent will be included in the analysis of the study. Any patient may withdraw full consent to participate in the study at any time during the study. The investigator will discuss with the patient appropriate procedures for withdrawal from the study.

Should a patient (or a legally acceptable representative) request or decide to withdraw from the study, all efforts will be made to complete and report the observations as thoroughly as possible up to the date of withdrawal. All information should be reported on the applicable eCRFs.

8.2 Replacement of Patients

Participants who withdraw from the study or lost to follow-up will not be replaced.

9. SAFETY DATA COLLECTION, RECORDING, AND REPORTING

In this observational study, only adverse drug reactions (ADRs) and serious adverse drug reactions (SADRs) will be collected and reported.

General information regarding reporting of ADRs:

- **Report only ADRs, other safety findings, or product complaints involving Amgen products**
- **Do not report ADRs that occurred prior to a subject/patient taking an Amgen product**

9.1 Adverse Events

9.1.1 Definition of Adverse Events

An adverse event (AE) is any untoward medical occurrence in a patient administered a pharmaceutical product(s) and which does not necessarily have to have a causal relationship with this treatment.

An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a product(s), whether or not considered related to the product(s). The definition of an AE includes:

- **Worsening of a pre-existing condition**
- **Events occurring from a medication error or overdose of a product(s), whether accidental or intentional**
- **Events occurring from abuse of a product(s)**
- **Events associated with the discontinuation of the use of a product(s), (eg, appearance of new symptoms)**
- **Any lack or loss of intended effect of the product(s)**

9.1.1.1 Adverse Drug Reactions (ADRs)

AEs that are considered related to the Amgen product(s) are classified as adverse drug reactions (ADRs).

It is the Investigator's responsibility to evaluate if an event is related to an Amgen product prior to reporting the event to Amgen.

9.1.2 Definition of Serious Adverse Events

A serious adverse event (SAE) is any AE as defined above that also:

- **is fatal**
- **is life threatening (places the patient at immediate risk of death)**
- **requires in-patient hospitalization or prolongation of existing hospitalization**

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- **results in persistent or significant disability/incapacity**
- **is a congenital anomaly/birth defect**
- **is an "other significant medical hazard" that does not meet any of the above criteria**

A hospitalization meeting the regulatory definition for "serious" is any in-patient hospital admission that includes a minimum of an overnight stay in a healthcare facility.

"Other significant medical hazards" refer to important medical events that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. Examples of such events could include allergic bronchospasm, convulsions, and blood dyscrasias, drug-induced liver injury, events that necessitate an emergency room visit, outpatient surgery, or other events that require other urgent intervention.

9.1.2.1 Serious Adverse Drug Reactions (SADRs)

SAEs that are considered related to the Amgen product(s) are classified as serious adverse drug reactions (SADRs).

It is the Investigator's responsibility to evaluate if an event is related to an Amgen product prior to reporting the event to Amgen

9.1.3 Definition of Other Safety Findings

Other Safety Findings include:

- **Medication errors, overdose, misuse, or abuse, whether accidental or intentional, involving an Amgen product, regardless of whether associated with an ADR and/or SADR**
- **Pregnancy and lactation exposure regardless of whether associated with an ADR and/or SADR**
- **Transmission of infectious agents regardless of whether associated with an ADR and/or SADR**
- **Reports of uses outside the terms for authorized use of the product including off label use when associated with an ADR and/or SADR**

9.1.4 Definition of Product Complaints

Product Complaints include any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product or device after it is released for distribution. This includes all components distributed with the product(s) such as packaging, product containers, delivery system, labeling, inserts, etc.

Product Complaints may include but are not limited to issues related to:

- **Appearance (eg, broken, cracks, color, particles, odor)**
- **Labeling (eg, missing, torn, smudged)**
- **Durability (eg, stability issues)**
- **Open packaging**
- **Device damage (eg, pre-filled syringe with bent needle)**
- **Inability of customer to understand product labeling**
- **Inability of customer to deliver the product successfully, including partial or incomplete delivery (eg, defective delivery system [syringe])**

9.2 Reportable Events and Reporting Timeframes

The Investigator is responsible for ensuring that all ADRs, SADRs, product complaints and other safety findings for Amgen product(s) observed by the Investigator or reported by the patient that occur after the first dose of Prolia® through the final study visit are recorded in the patient's medical record and are submitted to Amgen via the supplied Amgen Safety Reporting Forms. See Appendix B for a sample Adverse Drug Reaction Report Form and Appendix C for sample Pregnancy and Lactation Notification Worksheets. Refer to Table 1 for the reporting timeframes for reportable events.

Table 1. Reporting Timeframes for Reportable Events

Report Type	Description	Reporting Timeframe
SADR	Initial or follow-up for SADRs	Within 1 business day of awareness
Product complaints	Initial or follow-up of all product complaints	Within 1 business day of awareness
Pregnancy and/or Lactation	Initial or follow-up for all pregnancies or lactation occurring in females while taking Amgen product(s) and/or Initial or follow-up for all pregnancies or lactation occurring in female partners of males taking Amgen product(s)	Within 1 business day of awareness
Other ADR	Initial or follow-up for ADR not meeting serious criteria	Within 60 calendar days of the Investigator's knowledge

The Investigator may be asked to provide additional information for any event submitted, which may include a discharge summary or extracts from the medical record. Information provided about the event must be consistent with information recorded on study Case Report Forms (CRFs) where safety data may also be recorded (eg, Adverse Event Summary CRF).

The Investigator is responsible for medical management of patients who experience adverse events from the date of awareness to resolution or stabilization.

Amgen will report ADRs and unlisted SADRs as required to regulatory authorities, Investigators/institutions, and IRBs/IECs or other relevant ethical review board in accordance with Pharmacovigilance guidelines and in compliance with local regulations.

The Investigator is to notify the appropriate Institutional Review Board/Independent Ethics Committee IRB/IEC or other relevant ethical review board of SADRs occurring at the site and other AE reports received from Amgen, in accordance with local procedures and statutes.

The AE severity grading scale used will be the Amgen adverse event standard grading score. The severity grading scale used in this study is described in Appendix D.

10. STATISTICAL CONSIDERATIONS

10.1 Study Outcomes, Subsets, and Covariates

10.1.1 Study Outcomes

The following outcomes are to characterize the clinical management of the patients during the first 2 years of treatment with Prolia®:

- Occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia® from the initial prescribing physician's office
- Occurrence (yes/no) of patient receiving an individual prescription and injection of Prolia® from the initial prescribing physician office by each individual injection
- Occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia®, whether or not the injections are given at the initial prescribing physician's office
- Occurrence (yes/no) of patient with a referral by the prescribing physician to other health care providers for continuation or follow up of care by type of physician
- Types of health care providers administering an individual injection of Prolia® inside or outside the initial prescribing office by injection
- Number of Prolia® injections received by each patient during the follow-up period

- Occurrence (yes/no) of patient having radiologic bone assessments pre-treatment with Prolia®, and during the study
- Occurrence (yes/no) of patient having osteoporosis related laboratory examinations pre-treatment with Prolia®, and during the study.

The following outcomes are to characterize the safety of patients during the first 2 years of treatment with Prolia®:

- Incidence (yes/no) of patients with ADR to Prolia®.
- Incidence (yes/no) of patients with serious ADR to Prolia®.

PMO patients treated with Prolia® will be characterized according to the 4 dimensions of patient and site characteristics when available, as specified in Section 10.1.3

10.1.2 Analysis Set

The Full Analysis Set will consist of all enrolled patients satisfying the inclusion/exclusion criteria that receive at least one Prolia® injection and have a non-missing enrollment date. All analyses will be performed on this analysis set.

10.1.3 Subsets and/or Covariates

The following 4 dimensions of variables will be collected at baseline, either directly as part of routine clinical practice, or from medical records when available:

Socio-demographic related

- Educational level (no formal education, elementary education, secondary education, university)
- Patient living situation (at home with spouse/family, at home with care/support, at home alone, nursing home)
- Patient employment status (unemployed, retired, employed, self employed)
- Country: Czech Republic or Slovakia

Condition-related (osteoporosis)

- Body mass index (≤ 25 or > 25 kg/m^2)
- Age at menopause (years)
- Cause of menopause (natural onset, clinically/surgically induced)
- Height loss since maximal height (yes, no)
- Height loss in centimeters (cm)
- Previous fracture (yes, no)
  - Previous hip fracture (yes, no)
  - Previous vertebral fracture (yes, no)
  - Other previous fractures (yes, no)

- Time since the most recent previous fracture to first injection (< 12 months or ≥ 12 months)
- Previous hospitalization for osteoporotic fracture and/or surgical osteoporotic fracture treatment (yes, no)
- One or more falls experienced during the past 12 months (yes, no)
- One or more episodes of immobility experienced during the past 12 months (yes, no)
- Parent fractured hip (yes, no)
- Current smoker (yes, no)
- Former smoker (yes, no)
- Systemic glucocorticoid use (yes, no)
- Secondary osteoporosis (yes, no)
- Alcohol 3 or more units per day (yes, no)
- Femoral neck BMD T-score
- Lumbar spine BMD T-score
- Total hip BMD T-score

Patient-related:

- Age (years)
- Age group (< 65, ≥ 65 to <75, ≥ 75 years)
- Time since PMO diagnosis
- Number of prescription medications taken at baseline
- Number of comorbidities
- Any chronic medical condition (yes, no)
- Type of chronic medical condition (diabetes/osteoporosis/hypertension/other)
- Ever exposed to prior PMO therapy (yes, no)
- Exposed to prior PMO therapy during the 12 months prior to enrollment (yes, no)
- Calcium and/or Vitamin D supplementation at baseline (yes, no)
- History of discontinuation of prescription osteoporosis therapy (yes, no)

Physician-related:

- Type of prescribing HCP (Physician specialty: Orthopedist, Traumatologist, Rheumatologist, Internist, Endocrinologist, Gynecologist)
- Physician years of practice (1 to 4, 5 to 9, ≥ 10)
- Physician practice reminder (yes, no)
- Type of reminder
- Centre hospital or non-hospital based (hospital, non-hospital)
- Centre academic or non-academic (academic, non-academic)

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- Reason for prescribing Prolia® (low BMD T-score, history of osteoporotic fracture, multiple risk factors for fracture, failed other available osteoporosis therapy, intolerant to other osteoporosis therapy, other)
- Size of the clinic (small [≤ 2 doctors], medium [between 3 and 5 doctors] or large [≥ 6 doctors])
- Sole physician or group of them
- Geographic region (rural, urban)

10.2 Sample Size Considerations

This is an observational study for which the analysis will be descriptive in nature. Country commitments require that patients and management of patients receiving Prolia® be characterized and described, and safety (Prolia® -related ADRs and serious ADRs as defined in Section 9.1) be reported.

To characterize this Prolia® population, a sample size of approximately 300 patients per country is proposed. For Slovakia and Czech Republic, a sample of the population will be selected from the different regions (districts). There are 17 regions in Czech Republic and 8 regions in Slovakia, and an attempt will be made to recruit sites from as many different regions as possible. For Czech Republic, about 15 sites distributed around the 17 regions will enroll approximately 20 patients per site to provide about 300 patients. In Slovakia, approximately 15 sites distributed around the 8 regions will enroll approximately 20 patients per site or about 300 patients total.

Rationale for the country sample size

The sample size of approximately 300 patients per country is proposed based on the chances of capturing any patient-related characteristics that has a prevalence of approximately 1% or more in the population. As shown in the table below, the chances of observing at least one event with a prevalence rate of 1% or more is equal to or greater than 90% when the sample size is at least 250.

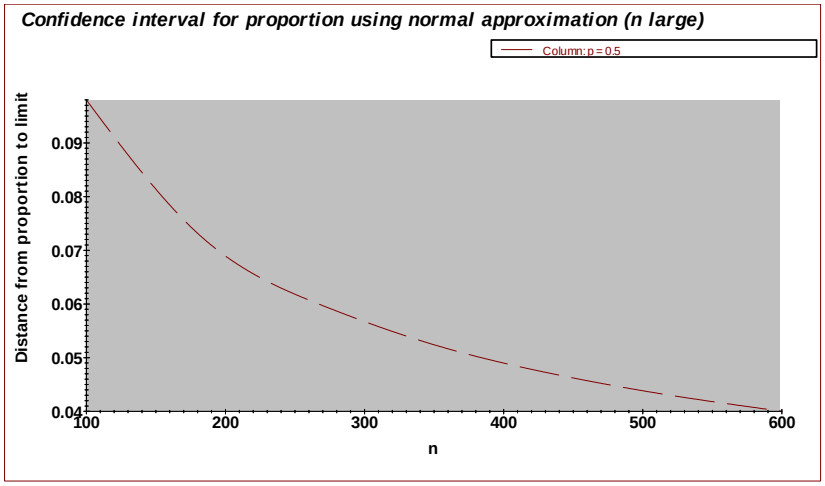
Table 2. Probability of Detecting at Least One Event by Size of Group and Prevalent Rate

True prevalent rate (p)	Group size (N)					
	15	20	100	200	250	300
0.01%	< 0.01	< 0.01	0.01	0.02	0.02	0.03
0.5%	0.07	0.10	0.39	0.63	0.71	0.78
1%	0.14	0.18	0.63	0.87	0.92	0.95
5%	0.54	0.64	0.99	> 0.99	> 0.99	> 0.99
6%	0.60	0.71	> 0.99	> 0.99	> 0.99	> 0.99
8%	0.71	0.81	> 0.99	> 0.99	> 0.99	> 0.99
10%	0.79	0.88	> 0.99	> 0.99	> 0.99	> 0.99
15%	0.91	0.96	> 0.99	> 0.99	> 0.99	> 0.99

Note: The probability of detecting at least one event was calculated by assuming that the number of events has a binomial distribution with parameters (N, p).

Moreover, 95% CI may be provided around selected percentage point estimates, and a sample size of approximately 300 patients is suggested based on the precision of these estimates. The sample size of approximately 300 patients per country will provide a maximum half width (based on an estimate of prevalent rate of 50%) for the 95% CIs around the percentage point estimates of approximately 6%, as shown below.

Figure 1. Half-width of the 95% Confidence Interval – Country Sample Size



10.3 Interim Analysis and Early Stopping Guidelines

An interim analysis is planned to be performed in each country to describe patient characteristics and provide information on the clinical management of PMO patients. This analysis will include data up to 12 months after the initial administration of Prolia® in all participants.

The design of the study will not be changed based on the interim analysis results. No stopping rules will be applied due to the observational nature of this study.

10.4 Planned Methods of Analysis

10.4.1 General Approach/Considerations

This is an observational study for which the analysis will be descriptive in nature and no formal hypothesis will be tested.

Frequency distributions will be described for categorical variables. Continuous variables will be summarized by the number of non-missing values, mean, standard deviation, median, lower and upper quartiles and minimum and maximum values.

10.4.2 Analysis of Key Study Outcomes

10.4.2.1 Outcomes

All study outcomes and baseline characteristics will be summarized by country. For selected study outcome related to the clinical management of these patients, point estimate and 95% confidence intervals will be provided as well by country.

Summary of the study outcomes by country and selected baseline variables also will be provided.

Appropriate outcomes, specific for a prescription/ injection will be summarized by country and prescription/injection (1^{st}, 2^{nd}, 3^{rd} and 4^{th}).

10.4.2.2 Safety Outcomes

All ADRs and serious ADRs to Prolia® will be coded using the Medical Dictionary for Regulatory Activities (MedDRA).

Patient incidence of ADRs and serious ADRs will be tabulated by system organ class and preferred term. Moreover, ADRs and serious ADRs leading to study discontinuation, discontinuation of Prolia® or associated with a fatal outcome will be tabulated by system organ class and preferred term.

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11. REGULATORY OBLIGATIONS

11.1 Informed Consent

This observational study will comply with all relevant national requirements on a country-by-country basis. The following section is applicable per local governing law and/or regulations.

An initial generic informed consent form is provided for the investigator to prepare the informed consent document to be used at his or her site. Updates to the template will be communicated by letter from the Amgen study manager to the investigator. The written informed consent document should be prepared in the language(s) of the potential patient population.

Before a patient's participation in the observational non-interventional study, the investigator is responsible for obtaining written informed consent from the patient or legally acceptable representative after adequate explanation of the aims, methods, anticipated benefits, and potential hazards of the study.

A legally acceptable representative is an individual or other body authorized under applicable law to consent, on behalf of a prospective patient, to the patient's participation in the clinical study.

The investigator is also responsible for asking the patient if the patient has a primary care physician and if the patient agrees to have his/her primary care physician informed of the patient's participation in the clinical study. If the patient agrees to such notification, the investigator shall inform the patient's primary care physician of the patient's participation in the clinical study. If the patient does not have a primary care physician and the investigator will be acting in that capacity, the investigator should document such in the patient's medical record. The acquisition of informed consent and the patient's agreement or refusal of his/her notification of the primary care physician should be documented in the patient's medical records, and the informed consent form should be signed and personally dated by the patient or a legally acceptable representative and by the person who conducted the informed consent discussion. The original signed informed consent form should be retained in accordance with institutional policy, and a copy of the signed consent form should be provided to the patient or legally acceptable representative.

If a potential patient is illiterate or visually impaired and does not have a legally acceptable representative, the investigator must provide an impartial witness to read the

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informed consent form to the patient and must allow for questions. Thereafter, both the patient and the witness must sign the informed consent form to attest that informed consent was freely given and understood.

11.2 Independent Ethics Committee/Institutional Review Board

Where applicable per local governing law and/or regulations a copy of the protocol, proposed informed consent form, other written patient information, and any proposed advertising material must be submitted to the Independent Ethics Committee (IEC)/Institutional Review Board (IRB) for written approval. A copy of the written approval of the protocol and informed consent form must be received by Amgen before recruitment of participants into the study.

The investigator must submit and, where necessary, obtain approval from the IEC/IRB for all subsequent protocol amendments and changes to the informed consent document. The investigator should notify the IEC/IRB of deviations from the protocol or serious adverse events occurring at the site and other adverse event reports received from Amgen, in accordance with local procedures.

The investigator will be responsible for obtaining annual IEC/IRB approval /renewal throughout the duration of the study. Copies of the investigator's reports and the IEC/IRB continuance of approval must be sent to Amgen.

11.3 Patient Confidentiality

The investigator must ensure that the patient's confidentiality is maintained:

- On the CRFs or other documents submitted to Amgen patients should be identified by a patient identification number only, with a complete and accurate date of birth on the demographics eCRF.
- For Serious Adverse Drug Reaction Events reported to Amgen, patients should be identified by their initials, date of birth, and a patient identification number.
- Documents that are not for submission to Amgen (eg, signed informed consent forms) should be kept in strict confidence by the investigator.

Where applicable per local governing law and/or regulations, it is required that the investigator and institution permit authorized representatives of the company, of the regulatory agency(s), and the IEC/IRB direct access to review the patient's original medical records for verification of study-related procedures and data. Direct access includes examining, analyzing, verifying, and reproducing any records and reports that are important to the evaluation of the study. The investigator is obligated to inform and obtain the consent of the patient to permit named representatives to have access to her

study-related records, including personal information, without violating the confidentiality of the patient.

11.4 Investigator Signatory Obligations

Each clinical study report should be signed by the investigator or, in the case of multicenter studies, the coordinating investigator.

The coordinating investigator, identified by Amgen, will either be:

- a recognized expert in the therapeutic area
- an investigator who provided significant contributions to either the design or interpretation of the study
- an investigator contributing a high number of eligible patients

12. ADMINISTRATIVE AND LEGAL OBLIGATIONS

12.1 Protocol Amendments and Study Termination

Where applicable per local governing law and/or regulations if Amgen amends the protocol, agreement from the investigator must be obtained. The IEC/IRB must be informed of all amendments and give approval. The investigator **must** send a copy of the approval letter from the IEC/IRB to Amgen.

Amgen reserves the right to terminate the study at any time. Both Amgen and the investigator reserve the right to terminate the investigator's participation in the study according to the study contract. The investigator should notify the IEC/IRB in writing of the study's completion or early termination and send a copy of the notification to Amgen.

12.2 Study Documentation and Archive

The investigator should maintain a list of appropriately qualified persons to whom he/she has delegated study duties. All persons authorized to make entries and/or corrections on CRFs will be included on the Amgen Delegation of Authority Form.

Source documents are original documents, data, and records from which the patient's CRF data are obtained. These include but are not limited to hospital records, clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence.

In this study, an electronic system (eg, IVRS) will be used for tracking patient enrollment and withdrawal. The site study team will be required to enter site and patient identifiers and some patient demographics, including the most recent date of Prolia® administration into this system in order to enroll a patient into the study.

The investigator and study staff are responsible for maintaining a comprehensive and centralized filing system of all study-related (essential) documentation, suitable for inspection at any time by representatives from Amgen and/or applicable regulatory authorities where applicable per local governing law and/or regulations. Elements should include:

- Patient files containing completed eCRF, informed consent forms, and patient identification list
- Study files containing the protocol with all amendments, investigator's brochure, copies of pre-study documentation, and all correspondence to and from the IEC/IRB and Amgen

In addition, all original source documents supporting entries in the CRFs must be maintained and be readily available.

Retention of study documents will be governed by the Clinical Trial Agreement.

12.3 Study Monitoring and Data Collection

The Amgen representative and regulatory authority inspectors are responsible for contacting and visiting the investigator for the purpose of inspecting the facilities and, upon request, inspecting the various records of the clinical study (eg, eCRFs and other pertinent data) provided that patient confidentiality is respected.

The Amgen monitor is responsible for verifying the eCRFs at regular intervals throughout the study to verify adherence to the protocol; completeness, accuracy, and consistency of the data; and adherence to local regulations on the conduct of clinical research. The monitor should have access to patient medical records and other study-related records needed to verify the entries on the eCRFs where applicable per local governing law and/or regulations.

The investigator agrees to cooperate with the monitor to ensure that any problems detected in the course of these monitoring visits, including delays in completing eCRFs, are resolved.

In accordance with ICH GCP (as applicable by local law) and the sponsor's audit plans, this study may be selected for audit by representatives from Amgen's Global Compliance Auditing function (or designees). Review of study-related records will occur to evaluate the study conduct and compliance with the protocol, ICH GCP (as applicable by local law), and applicable regulatory requirements.

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Data capture for this study is planned to be electronic:

- All source documentation supporting entries into the electronic CRFs must be maintained and readily available.
- Updates to electronic CRFs will be automatically documented through the software's "audit trail".
- To ensure the quality of clinical data across all patients and sites, a clinical data management review will be performed on patient data received at Amgen. During this review, patient data will be checked for consistency, omissions, and any apparent discrepancies. In addition, the data will be reviewed for adherence to the protocol and GCP (as applicable by local law). To resolve any questions arising from the clinical data management review process, data queries and/or site notifications will be created in the electronic data capture (EDC) system database for site resolution and closed by Amgen reviewer.
- The principal investigator signs only the Investigator Verification Form for this electronic data capture study. This signature will indicate that the principal investigator inspected or reviewed the data on the eCRF, the data queries, and the site notifications, and agrees with the content.

Amgen (or designee) will perform self-evident corrections to obvious data errors in the clinical trial database, as documented in the Study Specific Self Evident Corrections Plan. Examples of obvious data errors that may be corrected by Amgen (or designee) include deletion of obvious duplicate data (eg, same results sent twice with the same date with different visit—week 4 and early termination) and clarifying "other, specify" if data are provided (eg, race, physical examination). Each investigative site will be provided a list of the types of corrections applied to study data at the initiation of the trial and at study closeout.

12.4 Language

All written information and other material to be used by patients and investigative staff must use vocabulary and language that are clearly understood. Consult the country-specific requirements for language requirements.

12.5 Publication Policy

To coordinate dissemination of data from this study, Amgen encourages the formation of a publication committee consisting of several principal investigators and appropriate Amgen staff, the governance and responsibilities of which are set forth in a Publication Charter. The committee is expected to solicit input and assistance from other investigators and to collaborate with authors and Amgen staff as appropriate as defined in the Publication Charter. Membership on the committee (both for investigators and Amgen staff) does not guarantee authorship—the criteria described below should be met for every publication.

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Authorship of any publications resulting from this study will be determined on the basis of the Uniform Requirement for Manuscripts Submitted to Biomedical Journals (International Committee of Medical Journal Editors), which states:

- Authorship credit should be based on (1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above.
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

All publications (eg, manuscripts, abstracts, oral/slide presentations, book chapters) based on this study must be submitted to Amgen for corporate review. The Clinical Study Agreement among the institution, principal investigator, and Amgen will detail the procedures for, and timing of, Amgen's review of publications.

Approved

AMGEN®

13. REFERENCES

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14. APPENDICES

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Appendix A. Information Obtained During Routine Clinical Practice

(To be recorded as available and if allowed per local country regulations)

Data (as available and or applicable)	Enrollment	Follow up data	End of Study (24 months) or Early Termination
Informed consent	X		
Type of prescribing health care professional	X	X	
Patient socio-demographics	X		
Menopause history	X		
Postmenopausal osteoporosis and fracture history	X	X	X
Previous osteoporosis medication	X		
Medical history	X		
Clinical risk factors	X	X	X
Behavioral risk factors	X	X	X
Calcium and Vitamin D supplementation	X	X	X
Current medication use	X	X	X
Prolia® administration[1]	X	X	X
Management practice of patient		X	X
Adverse drug reaction (collection)	X	X	X
Discontinuation and reasons for discontinuation from Prolia®		X	X
End of study/Early termination date			X

[1]Part of routine clinical care of the patient.

Appendix B . Sample Serious Adverse Drug Reaction Report Form

AMGEN 20110132

Adverse Drug Reaction Report
Notify Amgen of SADRs and Product Complaints Within One Working Day
UK: +44 20 7136 1046

❑New ❑Follow-up

Indicate event type: ☐ AE/Other safety finding ☐ AE/Other safety finding with Product Complaint ☐ Product Complaint only

1. SITE INFORMATION

Site Number	Investigator/Study Doctor	Country

Reporter	Phone Number	Fax Number
	( )	( )

2. SUBJECT INFORMATION

Subject ID Number	Initials	Date of Birth Day Month Year OR Age	Sex ❑F ❑M	Race

3. ADVERSE DRUG REACTION, Other Safety Finding or Product Complaint

Adverse Drug Reaction Diagnosis or Syndrome If diagnosis is unknown, enter Signs / Symptoms When Final Diagnosis is known, enter as Adverse Drug Reaction *List one event per line. If event is fatal, enter the Cause of Death. Entry of "Death" is not acceptable, as this is an outcome.*	Date Started Day Month Year	Date Ended Day Month Year	Is the event serious? No✓	 Yes✓	Serious, enter Serious Criteria code (see codes below)	Relationship Is there a reasonable possibility that the event may have been caused by Amgen drug? See section 10 No✓	 Yes✓	Outcome of Event 01 Resolved 02 Resolving 03 Not resolved 04 Fatal
							✓	
							✓	
							✓	
							✓	
							✓	

Serious Criteria: 01 Fatal; 02 Immediately life-threatening; 03 Required hospitalization; 04 Prolonged hospitalization; 05 Persistent or significant disability /incapacity; 06 Congenital anomaly / birth defect; 07 Other significant medical hazard

4. HOSPITALIZATION

	Date Admitted Day Month Year	Date Discharged Day Month Year
Was subject/patient hospitalized? ❑No ❑Yes, If yes, provide date(s) →		

5. SUSPECT AMGEN PRODUCT

	Initial Start Date Day Month Year	Prior to, or at time of Event: Date of Dose Day Month Year	Dose	Route	Frequency	Action Taken with Product 01 Still being Administered 02 Permanently discontinued 03 Withheld
Amgen Product: _____ Lot # _____						
Amgen Product: _____ Lot # _____						
Amgen Product: _____ Lot # _____						

6. RELEVANT CONCOMITANT MEDICATIONS (e.g. chemotherapy) If none check here: ☐

Medication Name(s)	Start Date Day Month Year	Stop Date Day Month Year	Co-suspect No✓	 Yes✓	Continuing No✓	 Yes✓	Dose	Route	Freq.	Treatment Med No✓	 Yes✓

FORM-015478 Adverse Drug Reaction Report Form v5.0 Effective date: 17-Aug-2012 *ADR Report Form Created: 05-Dec-2012*
Page 1 of 2

AMGEN®

AMGEN 20110132	Adverse Drug Reaction Report *Notify Amgen of SADRs and Product Complaints Within One Working Day*	❑New ❑Follow-up
	Site Number | Subject ID Number	

7. RELEVANT MEDICAL HISTORY *(include dates, allergies and any relevant prior therapy)*

8. RELEVANT LABORATORY VALUES *(include baseline values)* If none check here: ❑

Date (Day Month Year)	Test										
	Unit										

9. OTHER RELEVANT TESTS *(diagnostics and procedures)* If none check here: ❑

Date (Day Month Year)	Additional Tests	Results	Units

10. CASE DESCRIPTION *(Provide narrative details of findings listed in section 3)*
*For each event in section 3, where relationship=Yes, please provide rationale.

Signature of Investigator or Designee	Title	Date

FORM-015478 Adverse Drug Reaction Report Form v5.0 Effective date: 17-Aug-2012 *ADR Report Form Created: 05-Dec-2012*
Page 2 of 2

Appendix C. Pregnancy and Lactation Notification Worksheets

AMGEN™ Pregnancy Notification Worksheet

Fax Completed Form to the Country-respective Safety Fax Line

SELECT OR TYPE IN A FAX#

1. Case Administrative Information

Protocol/Study Number: _____

Study Design: ☐ Interventional ☐ Observational (If Observational: ☐ Prospective ☐ Retrospective)

2. Contact Information

Investigator Name _____ Site # _____

Phone (____) _____ Fax (____) _____ Email _____

Institution _____

Address _____

3. Subject Information

Subject ID # _____ Subject Gender: ☐ Female ☐ Male Subject DOB: mm ▼ / dd ▼ / yyyy ____

4. Amgen Product Exposure

Amgen Product	Dose at time of conception	Frequency	Route	Start Date
				mm ▼ /dd ▼ /yyyy ____

Was the Amgen product (or study drug) discontinued? ☐ Yes ☐ No

If yes, provide product (or study drug) stop date: mm ▼ /dd ▼ /yyyy ____

Did the subject withdraw from the study? ☐ Yes ☐ No

5. Pregnancy Information

Pregnant female's LMP mm ▼ / dd ▼ / yyyy ____ ☐ Unknown

Estimated date of delivery mm ▼ / dd ▼ / yyyy ____ ☐ Unknown ☐ N/A

If N/A, date of termination (actual or planned) mm ▼ / dd ▼ / yyyy ____

Has the pregnant female already delivered? ☐ Yes ☐ No ☐ Unknown ☐ N/A

If yes, provide date of delivery: mm ▼ / dd ▼ / yyyy ____

Was the infant healthy? ☐ Yes ☐ No ☐ Unknown ☐ N/A

If any Adverse Event was experienced by the infant, provide brief details: _____

Form Completed by:

Print Name: _____ Title: _____

Signature: _____ Date: _____

Amgen maintains a Pregnancy Surveillance Program that collects data about pregnancy of women who have been exposed to an Amgen product directly or via male sexual partner. Information from this program and from other sources of information, will contribute to knowledge that ultimately could help patients and their doctors in the future make more informed decisions about taking an Amgen medication during pregnancy.

Effective Date: March 27, 2011 Page 1 of 1

AMGEN Lactation Notification Worksheet

Fax Completed Form to the Country-respective Safety Fax Line
SELECT OR TYPE IN A FAX# enter fax number

1. Case Administrative Information

Protocol/Study Number: _____

Study Design: ☐ Interventional ☐ Observational (If Observational: ☐ Prospective ☐ Retrospective)

2. Contact Information

Investigator Name _____ Site # _____

Phone (____) _____ Fax (____) _____ Email _____

Institution _____

Address _____

3. Subject Information

Subject ID # _____ Subject Date of Birth: mm____/ dd____/ yyyy____

4. Amgen Product Exposure

Amgen Product	Dose at time of breast feeding	Frequency	Route	Start Date
				mm____/dd____/yyyy____

Was the Amgen product (or study drug) discontinued? ☐ Yes ☐ No

If yes, provide product (or study drug) stop date: mm____/dd____/yyyy____

Did the subject withdraw from the study? ☐ Yes ☐ No

5. Breast Feeding Information

Did the mother breastfeed or provide the infant with pumped breast milk while actively taking an Amgen product? ☐ Yes ☐ No

If No, provide stop date: mm_____/dd_____/yyyy_____

Infant date of birth: mm_____/dd_____/yyyy_____

Infant gender: ☐ Female ☐ Male

Is the infant healthy? ☐ Yes ☐ No ☐ Unknown ☐ N/A

If any Adverse Event was experienced by the mother or the infant, provide brief details: _____

Form Completed by:

Print Name: _____ Title: _____

Signature: _____ Date: _____

Amgen maintains a Lactation Surveillance Program that collects data about women who have been exposed to an Amgen product while breastfeeding. Information from this program and from other sources of information will contribute to knowledge that ultimately could help patients and their doctors in the future make more informed decisions about taking an Amgen medication during lactation.

Effective Date: 03 April 2012, version 2. Page 1 of 1

Appendix D. Additional Safety Assessment Information

Adverse Event Severity Grading Scale

Grade	Amgen Standard Adverse Event Toxicity Grading Scale
1	MILD: Aware of sign or symptom, but easily tolerated
2	MODERATE: Discomfort enough to cause interference with usual activity
3	SEVERE: Incapacitating with inability to work or do usual activity
4	LIFE-THREATENING: Refers to an event in which the patient was, in the view of the investigator, at risk of death at the time of the event. (This category is not to be used for an event that hypothetically might have caused death if it were more severe.)
5	FATAL

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Superseding Version

Protocol Title: Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice

AMG 162 - Prolia® (Denosumab)

Amgen Protocol Number 20110132

Superseding Version Date: **14 December 2012**

Rationale:

The protocol is being superseded to make the safety reporting requirements consistent with new European Union pharmacovigilance directive for non-interventional studies. Typographic and editorial changes were made where necessary.

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Description of Changes

Section: Global

Replace:

28 February 2012

With:

14 December 2012

Section: Title page

Add:

Superseding version: **14 December 2012**.

Section: Title Page

Replace

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240 Cambridge Science Park
Milton Road
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With:

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Middlesex, UB8 1DH
Tel: +44 1895 525377

Section: 3.1, Study Design, paragraph 5, line 1

Replace:

Appendix A

With:

Appendix B

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Section: 9, Safety Data Collection Recording And Reporting

Replace:

In this observational study, only adverse drug reactions (ADRs) and serious adverse drug reactions (SADRs) will be collected and reported.

9.1 Adverse Drug Reaction

9.1.1 Definition of Adverse Drug Reaction

An Adverse Drug Reaction (ADR) is defined as an adverse event associated with a given medication at normal dosage.

The definition of adverse events includes worsening of a pre-existing medical condition. Worsening indicates the pre-existing medical condition (eg, diabetes, migraine headaches, gout) has increased in severity, frequency, and/or duration, and/or has an association with a significantly worse outcome. A pre-existing condition that has not worsened during the study, and involves an intervention such as elective cosmetic surgery or a medical procedure while on study is not considered an adverse event.

9.1.2 Reporting Procedures for Adverse Drug Reactions

The investigator is responsible for ensuring that all ADRs to Prolia® observed by the investigator or reported by the patient that occur after the first injection of Prolia® through the end of study are captured. Moreover, these events will also be captured using the applicable eCRF (electronic Case Report Form) (eg, Adverse Drug Reaction Summary eCRF).

The investigator must assess whether any adverse event is possibly related to Prolia®. This relationship is indicated by a “yes” or “no” response to the question: Is there a reasonable possibility that the event may have been caused by Prolia®? If indicated yes, the investigator must record the ADR and assign the following ADR attributes:

- ADR diagnosis or syndrome(s), if known (if not known, signs or symptoms),
- Date(s) of onset and resolution,
- Severity, and
- Action taken.

The AE severity grading scale used will be the Amgen adverse event standard grading score. The severity grading scale used in this study is described in Appendix B.

9.2 Serious Adverse Drug Reaction

9.2.1 Definition of Serious Adverse Drug Reaction

A SADR is a SAE (serious adverse event) that is considered related to the medicinal product.

A serious adverse event is defined as an adverse event that meets at least 1 of the following serious criteria:

- fatal
- life threatening (places the patient at immediate risk of death)
- requires in-patient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- congenital anomaly/birth defect
- other medically important serious event

An adverse event would meet the criterion of "requires hospitalization", if the event necessitated an admission to a health care facility (eg, overnight stay).

If an investigator considers an event to be clinically important, but it does not meet any of the serious criteria, the event could be classified as a serious adverse event under the criterion of "other medically important serious event". Examples of such events could include allergic bronchospasm, convulsions, blood dyscrasias, drug-induced liver injury, or events that necessitate an emergency room visit, outpatient surgery, or urgent intervention.

9.2.2 Reporting Procedures for Serious Adverse Drug Reaction

The investigator is responsible for ensuring that all SADRs related to Prolia® from the first injection of Prolia® until the end of study are recorded in the patient's medical record and are reported to Amgen via a SADR report form. The SADR form must be submitted/faxed to Amgen within 1 working day of discovery or notification of the event to the designated safety fax number – 800 900 625 for Czech Republic, 0800 044 033 for Slovakia.

New information relating to a previously reported SADR must be recorded on an SADR form. All changes to SADR forms must be sent to Amgen within 1 working day of receipt of the new information. The investigator may be asked to provide additional follow up information, which may include a discharge summary or extracts from the medical record. Information provided on the SADR form must be consistent with that recorded on the applicable eCRF (eg, Adverse Drug Reaction Summary eCRF).

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Amgen will report SADRs as required to regulatory authorities, in compliance with all reporting requirements according to local regulations for observational studies.

9.3 Pregnancy Reporting

Any confirmed pregnancy should be reported to Amgen within 1 working day of discovery or notification of the pregnancy. Initial information should be provided using the pregnancy notification worksheet (Appendix D). Women who become pregnant during Prolia® treatment are encouraged to enrol in Amgen's Pregnancy Surveillance program. Follow-up information on the pregnancy outcome should be communicated by the investigator to Amgen Global Safety as soon as available.

With:

In this observational study, only adverse drug reactions (ADRs) and serious adverse drug reactions (SADRs) will be collected and reported.

General information regarding reporting of ADRs:

- **Report only ADRs, other safety findings, or product complaints involving Amgen products**
- **Do not report ADRs that occurred prior to a subject/patient taking an Amgen product**

9.1 Adverse Events

9.1.1 Definition of Adverse Events

An adverse event (AE) is any untoward medical occurrence in a patient administered a pharmaceutical product(s) and which does not necessarily have to have a causal relationship with this treatment.

An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a product(s), whether or not considered related to the product(s). The definition of an AE includes:

- **Worsening of a pre-existing condition**
- **Events occurring from a medication error or overdose of a product(s), whether accidental or intentional**
- **Events occurring from abuse of a product(s)**
- **Events associated with the discontinuation of the use of a product(s), (eg, appearance of new symptoms)**
- **Any lack or loss of intended effect of the product(s)**

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9.1.1.1 Adverse Drug Reactions (ADRs)

AEs that are considered related to the Amgen product(s) are classified as adverse drug reactions (ADRs).

It is the Investigator's responsibility to evaluate if an event is related to an Amgen product prior to reporting the event to Amgen.

9.1.2 Definition of Serious Adverse Events

A serious adverse event (SAE) is any AE as defined above that also:

- **is fatal**
- **is life threatening (places the patient at immediate risk of death)**
- **requires in-patient hospitalization or prolongation of existing hospitalization**
- **results in persistent or significant disability/incapacity**
- **is a congenital anomaly/birth defect**
- **is an "other significant medical hazard" that does not meet any of the above criteria**

A hospitalization meeting the regulatory definition for "serious" is any in-patient hospital admission that includes a minimum of an overnight stay in a healthcare facility.

"Other significant medical hazards" refer to important medical events that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. Examples of such events could include allergic bronchospasm, convulsions, and blood dyscrasias, drug-induced liver injury, events that necessitate an emergency room visit, outpatient surgery, or other events that require other urgent intervention.

9.1.2.1 Serious Adverse Drug Reactions (SADRs)

SAEs that are considered related to the Amgen product(s) are classified as serious adverse drug reactions (SADRs).

- **It is the Investigator's responsibility to evaluate if an event is related to an Amgen product prior to reporting the event to Amgen**

9.1.3 Definition of Other Safety Findings

Other Safety Findings include:

- **Medication errors, overdose, misuse, or abuse, whether accidental or intentional, involving an Amgen product, regardless of whether associated with an ADR and/or SADR**

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- **Pregnancy and lactation exposure regardless of whether associated with an ADR and/or SADR**
- **Transmission of infectious agents regardless of whether associated with an ADR and/or SADR**
- **Reports of uses outside the terms for authorized use of the product including off label use when associated with an ADR and/or SADR**

9.1.4 Definition of Product Complaints

Product Complaints include any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product or device after it is released for distribution. This includes all components distributed with the product(s) such as packaging, product containers, delivery system, labeling, inserts, etc.

Product Complaints may include but are not limited to issues related to:

- **Appearance (eg, broken, cracks, color, particles, odor)**
- **Labeling (eg, missing, torn, smudged)**
- **Durability (eg, stability issues)**
- **Open packaging**
- **Device damage (eg, pre-filled syringe with bent needle)**
- **Inability of customer to understand product labeling**
- **Inability of customer to deliver the product successfully, including partial or incomplete delivery (eg, defective delivery system [syringe])**

9.2 Reportable Events and Reporting Timeframes

The Investigator is responsible for ensuring that all ADRs, SADRs, product complaints and other safety findings for Amgen product(s) observed by the Investigator or reported by the patient that occur after the first dose of Prolia® through the final study visit are recorded in the patient's medical record and are submitted to Amgen via the supplied Amgen Safety Reporting Forms.
See Appendix B for a sample Adverse Drug Reaction Report Form and Appendix C for sample Pregnancy and Lactation Notification Worksheets. Refer to Table 1 for the reporting timeframes for reportable events.

Table 1. Reporting Timeframes for Reportable Events

Report Type	Description	Reporting Timeframe
SADR	**Initial or follow-up for SADRs**	**Within 1 business day of awareness**
Product complaints	**Initial or follow-up of all product complaints**	**Within 1 business day of awareness**
Pregnancy and/or Lactation	**Initial or follow-up for all pregnancies or lactation occurring in females while taking Amgen product(s) and/or** **Initial or follow-up for all pregnancies or lactation occurring in female partners of males taking Amgen product(s)**	**Within 1 business day of awareness**
Other ADR	**Initial or follow-up for ADR not meeting serious criteria**	**Within 60 calendar days of the Investigator's knowledge**

The Investigator may be asked to provide additional information for any event submitted, which may include a discharge summary or extracts from the medical record. Information provided about the event must be consistent with information recorded on study Case Report Forms (CRFs) where safety data may also be recorded (eg, Adverse Event Summary CRF).

The Investigator is responsible for medical management of patients who experience adverse events from the date of awareness to resolution or stabilization.

Amgen will report ADRs and unlisted SADRs as required to regulatory authorities, Investigators/institutions, and IRBs/IECs or other relevant ethical review board in accordance with Pharmacovigilance guidelines and in compliance with local regulations.

The Investigator is to notify the appropriate Institutional Review Board/Independent Ethics Committee IRB/IEC or other relevant ethical review board of SADRs occurring at the site and other AE reports received from Amgen, in accordance with local procedures and statutes.

The AE severity grading scale used will be the Amgen adverse event standard grading score. The severity grading scale used in this study is described in Appendix D.

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Section: 10.2, Sample Size Considerations

Replace:

Table 1

With:

Table 2

Section: Appendix B, Sample Serious Adverse Drug Reaction Report Form

Replace:

Existing form

With:

Updated form

Section: Appendix C: Pregnancy Notification Worksheet

Replace:

Existing Worksheet

With:

Pregnancy and Lactation Notification Worksheets.

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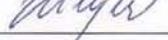
Annex 3. Signature of Coordinating Investigator

Investigator Signature

STUDY NUMBER:Prolia 20110132

STUDY REPORT TITLE:Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice

I have read the above named Observational Research Study Report and signify my agreement with the overall conclusions.

Name of Coordinating Investigator:	Prof.ZdenkoKillinger
Institution:	UniverzitnaNemocnica Bratislava - NemocnicaRuzinov,Ruzinovska 6, UNB a LF UK BratislavaNemocnicaRuzinov, Bratislava 82606, Slovakia
Signature of Investigator:	
Date:	04. DEC. 2015

Annex 4. Additional Information

The statistical analysis plan for this study is provided below.

STATISTICAL ANALYSIS PLAN FOR OBSERVATIONAL STUDIES

Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice

Protocol Number:	**20110132**
Version:	**2.0 (Amendment 01)**
Date:	**11 June 2015**
Author:	**Lisa Hamilton**

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Table of Abbreviations

Abbreviation/Acronym	Definition
ADR	Adverse Drug Reaction
BMD	Bone **Mineral** Density
CI	Confidence interval
DMP	Data Management Plan
DXA	**Dual-energy X-ray Absorptiometry**
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EOS	End of study
EOT	End of treatment
ETO	Electronic Trial Operations
FAS	Full Analysis Set
MedDRA	Medical Dictionary for Regulatory Activities
MI	Myocardial infarction
MWCI	**Modified-Wolfe Comorbidity Index**
OP	Osteoporosis
PMO	Postmenopausal Osteoporosis
PT	Preferred Term
PTH	Parathyroid hormone
Q6M	Every 6 Months
SAP	Statistical Analysis Plan
SC	Subcutaneously
SERM	Selective estrogen receptor modulator
SmPC	Summary of Product Characteristics
SOC	System Organ Class

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1. Introduction

The purpose of this statistical analysis plan (SAP) is to provide details of the statistical analyses that have been outlined within the **superseded version of the** protocol for denosumab Study 20110132 dated **14 December 2012**, entitled Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice.

2. Objectives

The objective of this prospective, observational study in Czech Republic and Slovakia is to describe per country the characteristics of women treated with Prolia® (denosumab) in routine clinical practice and the clinical management of these patients during the first 2 years of treatment.

3. Study Overview

3.1 Study Design

This is a multi-center, international, non-interventional, prospective, observational study in postmenopausal osteoporosis (PMO) patients who received at least one injection of Prolia® 60 mg subcutaneously (SC) every 6 months (Q6M), in Czech Republic and Slovakia. This observational study will not alter the routine clinical management of patients and will comply with all applicable local regulations in the countries in which it is being conducted.

Prolia® naive patients will be eligible to enroll within 8 weeks after initiation of Prolia® treatment (i.e., 8 weeks after receiving the first injection). The decision to treat the patients with Prolia® must be made independent of and prior to their enrollment in the study. However, writing of the prescription for Prolia®, the first Prolia® injection and/or administration of informed consent (as applicable by local country laws and regulations) may happen at the same visit. It is expected that patients will receive their scheduled Prolia® injection Q6M as part of their routine clinical care.

Approximately 300 patients will be enrolled in Czech Republic and 300 in Slovakia. The estimated duration of enrollment is approximately 12 months. No study drug will be administered as part of the study. The protocol specifies that investigators will offer participation in the study to all patients treated with Prolia® during the enrollment period until they reach their contracted number of patients. Detailed data obtained as part of routine clinical practice will be collected at the initial visit, either directly or from medical record, to characterize the patient population. It is anticipated that patients will return to

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the clinic Q6M to receive their subsequent Prolia® prescriptions and/or injections. After the initial visit, information regarding Prolia® prescription and administration, procedures pertaining to osteoporosis and Prolia®, concomitant medication use, and non-serious and serious adverse drug reactions (ADRs) will be obtained during routine clinical visits and recorded for up to approximately 2 years after entering the study.

The study will describe the profile of patients treated with Prolia® and the clinical management of these patients during the first 2 years of treatment. Patient and site characteristics will be collected at baseline according to the following 4 dimensions:

- Socio-demographic related
- Condition-related (osteoporosis)
- Patient-related
- Physician-related (including geographic region and specialty)

3.2 Data Source

3.2.1 Selection of Participants

Postmenopausal women with osteoporosis (OP) who receive an injection of Prolia® according to the approved regional Prescribing Information (eg, EU Summary of Product Characteristics [SmPC]) and meet the inclusion/exclusion criteria will be eligible to participate in the study.

Investigators will be expected to maintain a screening log with limited information on all potential study candidates (eg, date of screening). The following inclusion and exclusion criteria will be used to select study participants:

Inclusion Criteria

- Women with a clinical diagnosis of postmenopausal osteoporosis
- Decision has been made to treat with Prolia® 60 mg once every 6 months
- Have received their first injection of Prolia® within 8 weeks prior to enrolling in this study
- Appropriate written informed consent has been obtained (as required per local country regulations)

Exclusion Criteria

- Participating in ongoing or have participated in previous denosumab clinical trials
- Participation in other clinical or device trials in the last 6 months
- Contra-indicated for treatment with Prolia® according to the approved applicable local product label.
- Patient has any kind of disorder that, in the opinion of the investigator, may compromise the ability of the patient to give written informed consent

3.2.2 Selection of Sites

The study will be conducted in approximately 30 representative (country specific) sites (15 each in Czech Republic and Slovakia). Additional sites may be added or removed as deemed necessary to ensure enrollment of the target number of patients. After feasibility assessment, sites selected will represent those providing PMO care in each country and region, with regards to type (eg hospital, non-hospital) and location of site. Sites that do not enroll patients within 2 months after site initiation may be closed.

3.2.3 Data Collection

This study is designed to follow and observe patients who have recently (within 8 weeks) initiated treatment with Prolia® in routine clinical practice. No study-specific treatment will be provided and no additional clinical procedures or assessments will be required as part of this observational study.

Patients will be observed for a period of up to 2 years after their entry in the study unless patients discontinue the study or are lost to follow up. Information regarding the clinical management of the patients receiving Prolia® may be collected whenever available, even after treatment discontinuation.

There are no procedures or changes to routine clinical management of patients. It is anticipated that patients will return to the clinic every 6 months to receive their Prolia® prescription and/or injections. Patients will be followed for approximately 2 years after their initial visit. Available clinical information obtained for routine clinical practice (including those already recorded on the patient medical records i.e., baseline characteristics) will be recorded, including Prolia® administration, previous and current therapies, medical history (including fracture history), ADRs and serious ADRs and co-morbidities. See Appendix A for the list of previous therapies and co-morbidities collected in this study.

3.3 Sample Size

This is an observational study for which the analysis will be descriptive in nature. Country commitments require that patients and management of patients receiving Prolia® be characterized and described, and safety (Prolia® - related ADRs and serious ADRs) be reported.

To characterize this Prolia® population, a sample size of approximately 300 patients per country is proposed. For Slovakia and Czech Republic, a sample of the population will be selected from the different regions (districts). There are 17 regions in Czech

Republic and 8 regions in Slovakia, and an attempt will be made to recruit sites from as many different regions as possible. For Czech Republic, about 15 sites distributed around the 17 regions will enroll approximately 20 patients per site to provide about 300 patients. In Slovakia, approximately 15 sites distributed around the 8 regions will enroll approximately 20 patients per site or about 300 patients total.

Rationale for the country sample size

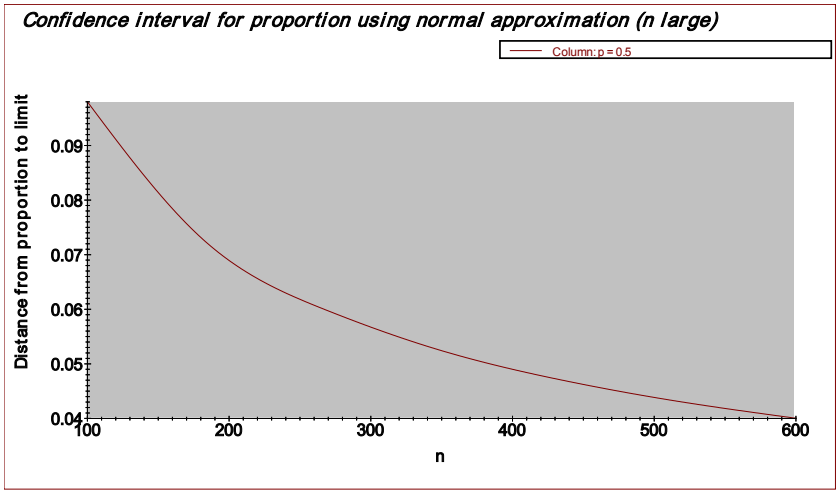
The sample size of approximately 300 patients per country is proposed based on the chances of capturing any patient-related characteristics that has a prevalence of approximately 1% or more in the population. As shown in the table below, the chances of observing at least one event with a prevalence rate of 1% or more is equal to or greater than 90% when the sample size is at least 250.

Table 1. Probability of Detecting at Least One Event by Size of Group and Prevalent Rate

True prevalent rate (p)	Group size (N)					
	15	20	100	200	250	300
0.01%	< 0.01	< 0.01	0.01	0.02	0.02	0.03
0.5%	0.07	0.10	0.39	0.63	0.71	0.78
1%	0.14	0.18	0.63	0.87	0.92	0.95
5%	0.54	0.64	0.99	> 0.99	> 0.99	> 0.99
6%	0.60	0.71	> 0.99	> 0.99	> 0.99	> 0.99
8%	0.71	0.81	> 0.99	> 0.99	> 0.99	> 0.99
10%	0.79	0.88	> 0.99	> 0.99	> 0.99	> 0.99
15%	0.91	0.96	> 0.99	> 0.99	> 0.99	> 0.99

Note: The probability of detecting at least one event was calculated by assuming that the number of events has a binomial distribution with parameters (N, p).

Moreover, 95% confidence interval (CI) may be provided around selected percentage point estimates, and a sample size of approximately 300 patients is suggested based on the precision of these estimates. The sample size of approximately 300 patients per country will provide a maximum half width (based on an estimate of prevalent rate of 50%) for the 95% CIs around the percentage point estimates of approximately 6%, as shown below.



4. Study Outcomes

The following outcomes are to characterize the clinical management of the patients during the first 2 years of treatment with Prolia®:

- Occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia® from the initial prescribing physician's office
- Occurrence (yes/no) of patient receiving an individual prescription and injection of Prolia® from the initial prescribing physician office by each individual injection
- Occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia®, whether or not the injections are given at the initial prescribing physician's office
- Occurrence (yes/no) of patient with a referral by the prescribing physician to other health care providers for continuation or follow up of care by type of physician
- Types of health care **professionals** administering an individual injection of Prolia® inside or outside the initial prescribing office by individual injection
- Number of Prolia® injections received by each patient during the follow-up period
- Occurrence (yes/no) of patient having radiologic bone assessments pre-treatment with Prolia®, and during the study
- Occurrence (yes/no) of patient having osteoporosis related laboratory examinations pre-treatment with Prolia®, and during the study.

The following outcomes are to characterize the safety of patients during the first 2 years of treatment with Prolia®:

- Incidence (yes/no) of patients with ADR to Prolia®.
- Incidence (yes/no) of patients with serious ADR to Prolia®.

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PMO patients treated with Prolia® will be characterized according to the 4 dimensions of patient and site characteristics when available, as specified in Section 6.6.

5. Hypotheses or Estimation

The study is descriptive in nature, and a formal hypothesis will not be tested in this observational study. However, demographic and clinical characteristics of postmenopausal patients who received at least one injection of Prolia® (denosumab 60 mg) will be described.

6. Definitions

6.1 Patient Disposition

Enrolled

Patients are considered enrolled once they have fulfilled and successfully completed the inclusion and exclusion criteria and the patient or their legally acceptable representative (as required per local country regulations) has signed the informed consent, and the patient has been enrolled in the Electronic Trial Operations (ETO) system.

6.2 Study Dates

Informed Consent Date

The informed consent date is the date on which a patient or her legally acceptable representative signs the informed consent (or equivalent as required by the local regulations) for this study.

Enrollment Date

Enrollment is defined as the date the patient is enrolled in the study via an ETO system.

Visits to the Clinic

It is anticipated that patients will return to the clinic every 6 months to receive their Prolia® injections. The injection visits will be recorded consecutively after the initial, pre-enrollment injection, into the 6-, 12- , 18-, and 24-month Prolia® administration eCRFs (Electronic Case Report Forms).

End of Treatment Date

End of treatment (EOT) date is the date for patients who did not complete the treatment, which is when a decision is made by the investigator and/or patients to stop treatment as recorded on the Prolia® administration eCRF.

End of Study Date

End of study (EOS) date is the patient's last study visit date as recorded on the Study Completion eCRF. For those patients that completed study treatment, the end of study

visit is expected to occur approximately 6 months from the 3rd Prolia® injection but no later than 24 months from the first injection. For patients lost to follow-up, the EOS date is defined according to the investigator discretion.

6.3 Study Time Period

Enrollment Period

The enrollment period covers the period between the first patient enrolled in the study until the last patient is enrolled in the study. The enrollment period is expected to last approximately 12 months **for each country**.

Follow-up Period

The follow-up period is from patient's enrollment date until the patient's end-of-study date.

End of Study

End of study is defined as the date that the last eligible patient completes the last visit.

Study Period

The study starts with the first patient enrolled in the study (the beginning of the enrollment period) and ends when the last patient in the study has an end-of-study eCRF page completed (end of follow-up period).

6.4 Study Points of Reference

Study Day 1

The date the patient took the first Prolia® injection.

Study Day

The number of days from Study Day 1 to the date of interest, inclusive:

If date of interest ≥ date of Study Day 1 then

Study Day = (date of interest – date of Study Day 1) + 1

If date of interest < date of Study Day 1 then

Study Day = (date of interest – date of Study Day 1)

6.5 Derived Variables

Baseline assessment

All baseline assessments are to be performed at most **91 days** following the administration of the first pre-enrollment Prolia® (denosumab 60 mg) injection, i.e., at most **91 days** from the date of the first Prolia® (denosumab 60 mg) injection. For baseline assessment performed prior to the first injection, the closest assessment to the

injection date will be used. **For Dual-energy X-ray Absorptiometry (DXA) BMD baseline assessments, please see Section 9.4 for details.**

Modified-Wolfe Comorbidity Index (MWCI)

The Wolfe Comorbidity Index evaluates comorbidities in patients with rheumatic diseases (Wolfe et al, 2010). It is a composite derived comorbidity index (range 0-9) composed of 11 present or past comorbid conditions including pulmonary disorders; myocardial infarction (MI); stroke; other cardiovascular (CV) disorders; hypertension; diabetes; spine, hip, and leg fractures; depression; gastrointestinal disorders; gastrointestinal ulcer; and cancer. Certain conditions were grouped together such that a total of 8 conditions were evaluated.

A comorbidity index adopting the Wolfe comorbidity index algorithm (modified-Wolfe comorbidity index) will be calculated based on the responses related to the known history of comorbidities. Implementation details are defined in Appendix A.

Patient Age at Study Entry

Only the year of patients' birth will be collected due to country restrictions. The full date will be imputed as per usual clinical data management rule to 15 June for all patients, and the age will be calculated as the number of whole years from a patient's imputed birth date to the enrollment date.

6.6 Covariates

Collection of the covariates will not be mandatory. They will be collected where information can be obtained during routine clinical practice and wherever local country regulations allow and data are available. As the analyses will be done by country (eg Czech Republic or Slovakia), the impact of differential reasons for missing variables across countries should be minimal at a country level.

The baseline covariates are classified according to the following 4 dimensions:

- Socio-demographic related
- Condition-related (osteoporosis)
- Patient-related
- Physician-related (including geographic region, specialty)

Summary statistics will be provided for each of the covariates per country as long as the covariate has non-missing information in at least 10% of the country sample.

The list of all covariates for each dimension is provided below. Reference groups are provided in bold below and in general they should represent the healthier group and/or the group more likely to receive all prescriptions and injections. Continuous variables will be dichotomized based on its median. If a dichotomized continuous covariate is found to predict an outcome then the continuous covariate may be considered in its continuous format.

Socio-demographic related

- Educational level (no formal education, elementary education, secondary education, **university**)
- Patient living situation (**at home with spouse/family**, at home with care/support, at home alone, nursing home)
- Patient employment status (unemployed, **retired,** employed, self employed)

Condition-related (osteoporosis)

- Body mass index (**≤ 25** or > 25 kg/m^2)
- Age at menopause (years) (**≤ median**, > median**)**
- Years since menopause (years) (**≤ median,** > median**)**
- Cause of menopause (**natural onset**, clinically/surgically induced)
- Height loss since maximal height (yes, **no**)
- Height loss in centimeters (cm) (**≤ median**, > median**)**
- Previous fracture (yes, **no**)
    - Previous hip fracture (yes, **no**)
    - Previous vertebral fracture (yes, **no**)
    - Other previous fractures (yes, **no**)
- Time since the most recent previous fracture to first injection (< 12 months or **≥ 12 months**)
- Previous hospitalization for osteoporotic fracture and/or surgical osteoporotic fracture treatment (yes, **no**)
- One or more falls experienced during the past 12 months (yes, **no**)
- One or more episodes of immobility experienced during the past 12 months (yes, **no**)
- Parent fractured hip (yes, **no**)
- Current smoker (yes, **no**)
- Former smoker (yes, **no**)
- Systemic glucocorticoid use (yes, **no**)
- Secondary osteoporosis (yes, **no**)
- Alcohol 3 or more units per day (yes, **no**)
- Femoral neck BMD (Bone **Mineral** Density) T-score (≤-2.5 or **>-2.5**)
- Lumbar spine BMD T-score (≤-2.5 or **>-2.5**)

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- Total hip BMD T-score (≤-2.5 or **>-2.5**)

Patient-related:

- Age (years) (**≤ median**, > median**)**
- Age group (**< 65**, ≥ 65 to <75, ≥ 75 years)
- Time since PMO diagnosis (years) (**≤ median**, > median**)**
- Number of prescription medications taken at baseline (**≤ median**, > median)
- Number of co-morbidities (see Appendix A for the list of the comorbidities to be collected) (**≤ median**, > median**)**
- Any chronic medical condition (yes, **no**)
- Type of chronic medical condition (diabetes/**osteoporosis**/hypertension/other)
- Ever exposed to prior PMO therapy (**yes**, no)
- Exposed to prior PMO therapy during the 12 months prior to enrollment (**yes**, no)
- Calcium and/or Vitamin D supplementation at baseline (**yes**, no)
- History of discontinuation of prescription osteoporosis therapy (yes, **no**)

Physician-related:

- Type of prescribing health care professional (Physician specialty: Orthopedist, Traumatologist, Rheumatologist, Internist, Endocrinologist, **Gynecologist**)
- Physician years of practice (1 to 4, 5 to 9, **≥ 10**)
- Physician practice reminder (**yes**, no)
- Type of reminder (**telephone call**, mailing (eg Postcard), email/SMS, appointment card, sticker from drug package, magazine, other)
- Centre hospital or non-hospital based (**hospital**, non-hospital)
- Centre academic or non-academic (**academic**, non-academic)
- Reason for prescribing Prolia® (**low BMD T-score**, history of osteoporotic fracture, multiple risk factors for fracture, failed other available osteoporosis therapy, intolerant to other osteoporosis therapy, other)
- Size of the clinic (**small [≤ 2 doctors]**, medium [between 3 and 5 doctors] or large [≥ 6 doctors])
- Sole physician or group of physicians (**sole**, group)
- Geographic region (rural, **urban**)

7. Analysis Subsets

7.1 Full Analysis Set

The Full Analysis Set (FAS) will consist of all enrolled patients **(providing informed consent and enrolled in the ETO system)** satisfying the inclusion/exclusion criteria that receive at least one Prolia® injection. All analyses will be performed on this analysis set.

8. Interim Analysis

A baseline analysis is planned once the last patient is enrolled. Only baseline outputs will be produced for each country.

An interim analysis is planned to be performed in each country to describe patient characteristics and provide information on the clinical management of PMO patients. The interim analysis will include data from each patient up to 12 months, after all enrolled patients have had the opportunity to be followed for a least 12 months after their initial administration of Prolia®. All outcomes will be summarized at the interim analysis for each country and selected covariates which may include the following; type of prescribing health care professional and type of center.

The design of the study will not be changed based on the interim analysis results. No stopping rules will be applied due to the observational nature of this study.

9. Data Screening and Acceptance

9.1 General Principles

The objective of the data screening is to assess the quantity, quality and statistical characteristics of the data relative to the requirements of the planned analyses.

All edit checks for the study will be described in a separate Data Management Plan (DMP).

9.2 Data Handling and Electronic Transfer of Data

Amgen's Clinical Data Management department will provide all data to be used in the planned analyses. This study will use the Medidata RAVE EDC (Electronic Data Capture) database.

Data extractions will be provided for the planned analyses.

9.3 Handling of Missing and Incomplete Data

Missing data, **except for ADR start dates,** will be maintained as missing.

Partial start date for serious and non-serious ADRs will be imputed as follows:

- **Missing day will be set to "01" unless an event started the same month and year as first dose date then set to first dose date;**
- **Missing day/month will be set to "01 Jan" unless an event started the same year as first dose date then set to first dose date.**

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9.4 DXA Assessment Visits

DXA BMD will be collected at every visit whenever possible. These assessments will be assigned to a visit as per the following criteria:

- **Baseline DXA assessments taken closest to the baseline injection and not more than 1 years (or 365 days) prior to the baseline injection will be selected as the baseline assessment. If that is not available then the DXA assessment taken closest to the baseline injection and no more than 91 days after the baseline injection will be selected as the baseline visit;**
- **DXA assessments taken between 92 to 274 study days will be assigned to the 6-month visit; if more than one assessment are reported, the one closest to the 6-month visit (study day 183) will be selected. If more than one assessment are at the same distance from study day 183, the one taken after study day 183 will be selected as the 6-month assessment;**
- **DXA assessments taken between 275 and 457 study days will be assigned to the 12-month visit; if more than one assessment are reported, the one closest to the 12-month visit (study day 366) will be selected. If more than one assessment are at the same distance from study day 366, the one taken after study day 366 will be selected as the 12-month assessment;**
- **DXA assessments taken between 458 to 640 study days will be assigned to the 18-month visit; if more than one assessment are reported, the one closest to the 18-month visit (study day 549) will be selected. If more than one assessment are at the same distance from study day 549, the one taken after study day 549 will be selected as the 18-month assessment;**
- **DXA assessments taken after or on study day 641 day will be assigned to the 24-month visit; if more than one assessment are reported, the one closest to the 24-month visit (study day 732) will be selected. If more than one assessment is at the same distance from study day 732, the one taken after study day 732 will be selected as the 24-month assessment.**

9.5 Detection of Bias

The prospective observational nature of the study may impact the investigator and patient's subjective response to treatment. There are no mandated study procedures, so the study is as close to a patient's routine clinical setting as possible. Moreover, patients will only be asked to enroll into the study after they have agreed to receive Prolia® and have already received Prolia®.

Descriptive summaries of endpoints from this study may be informally compared to estimates for similar endpoints reported in the literature for similar patient populations.

9.5.1 Selection Bias

The study will not be able to verify the representativeness of the population due to the limited information on the patients that refuse to participate in the study and the lack of

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information on the characteristics of patients receiving Prolia® in Czech Republic and Slovakia. The conclusion from this study should take this in account.

9.5.2 Observational Bias

It has been documented that patients taking part in a study may alter their behavior as a result of knowing they are being observed (Hawthorne effect) (McCarney et al, 2007).

We consider this bias to be unavoidable and the proposed type of study the best option to achieve the proposed objectives with acceptable levels of precision.

9.6 Outliers

Descriptive statistics will be examined to identify potential outliers in any of the continuous variables analyzed. Potential outliers identified after database lock may be excluded from the analyses as appropriate. Prior to any data exclusion, sensitivity analyses may be performed to evaluate the robustness of the results obtained once the confirmed outliers are excluded from the analyses.

9.7 Validation of Statistical Analyses

Programs will be developed and maintained, and output will be verified in accordance with current risk-based quality control procedures.

Tables, figures and listings will be produced with validated standard macro programs where standard macros can produce the specified outputs.

The production environment for statistical analyses consists of Amgen-supported versions of statistical analysis software, for example the SAS System and S-plus.

10. Statistical Methods of Analysis

10.1 General Principles

This is an observational study for which the analysis will be descriptive in nature and no formal hypothesis will be tested.

Frequency distributions will be described for categorical variables. Continuous variables will be summarized by the number of non-missing values, mean, standard deviation, median, lower and upper quartiles and minimum and maximum values.

All study outcomes and baseline characteristics will be summarized by country. For selected study outcomes related to the clinical management of these patients, point estimate and 95% confidence intervals will be provided as well by country.

Summary of the study outcomes by country and by selected covariates also will be provided. Continuous covariates will be dichotomized based on its median.

Appropriate outcomes, specific for a prescription/ injection will be summarized by country and prescription/injection (**baseline and** 1st, 2nd, 3rd and 4th **injection post baseline**).

10.2 Patient Accountability

Patient accountability data will be summarized by country. The number and percentage of enrolled patients will be tabulated. The number and percentage of enrolled patients completing and discontinuing from the study and the reasons for discontinuation (death, lost to follow-up, full consent withdrawn or other) will be tabulated. If available, the data collected for patients eligible but not participant will be tabulated by country.

10.3 Demographic and Baseline Characteristics

Demographic and baseline characteristics will be summarized by country to identify possible differences. No formal comparison of baseline characteristics/covariates will be made between countries. There are a large number of covariates and it is unlikely that a meaningful difference would be detected.

10.3.1 Dimensions

A summary of the profile of patients treated with Prolia® and the clinical management of these patients during the first 2 years of treatment will include factors within the following 4 dimensions: Socio-demographic related, Condition-related (osteoporosis), Patient-related, Physician-related (including geographic region, specialty). For details on each dimension see Section 6.6.

Covariates will be investigated for empty cells or allocation imbalances across categories, and a re-categorization may be proposed prior to the interim or final analysis.

10.3.1.1 Predictors of Outcomes

For each country, if data permits the following exploratory analyses may be conducted to determine if any of the covariates are important in explaining the different outcomes being analyzed. Logistic regression will be used to explore the univariate association of each covariate with selected outcomes at 24 months. For each covariate entered individually in the model, point estimates of the odds ratio, and 95% confidence intervals will be provided for each pairwise comparison relative to the reference group. For example, for age groups (<65, 65-75, ≤75), the odds ratio (95%CI) will be given for each category using the < 65 subgroup as the reference group. Reference groups are provided in bold in Section 6.6 and in general they should represent the group most likely to receive all prescriptions and injections. Factors that are statistically significant at

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the 25% level on the univariate analysis may be added to the list of covariates of interest for the multivariate analysis.

A multivariate logistic regression including selected covariates that showed possible association with selected outcomes from the univariate analyses at 24 months will also be performed to identify predictors of selected outcomes at 24 months. Factors that are statistically significant at the 25% level (as suggested in Bendel and Afifi, 1977) on the univariate analysis will be of interest. Given the relatively large sample size per country the proposed significance level of 25% should be able to identify the important variables without over fitting or including those that are of questionable importance.

The next step will be to build the model based on the stepwise selection which will be implemented using the SAS® LOGISTIC procedure. A Wald chi-square test significance level of 0.25 is required to allow a variable to enter the model (slentry=0.25), and a significance level of 0.30 is required for a variable to stay in the model (slstay=0.30). The Hosmer and Lemeshow goodness-of-fit test for the final selected model will be inspected (lackfit option). Once the model with main effects has been refined, interactions among the variables in the model will be explored using the stepwise selection as above.

The selected outcomes are:

- Occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia® from the initial prescribing physician's office
- Occurrence (yes/no) of patient receiving an individual prescription and injection of Prolia® from the initial prescribing physician office by each individual injection
- Occurrence (yes/no) of patient receiving all prescriptions and injections of Prolia®, whether or not the injections are given at the initial prescribing physician's office

10.4 DXA BMD Data

DXA BMD T-score will be summarized in descriptive statistics by location and visit. Percent change from baseline in BMD T-score by location and visit will be summarized when a patient provides a baseline and a post baseline measurement at the same location. However, percentage change from baseline in BMD (Lumbar Spine/Femoral Neck/Total Hip) will not be tabulated since DXA machine type is not collected. BMD values will be collected only when BMD is assessed by DXA during the study as per local clinical practice and or guidelines. DXA BMD assessments will be assigned to a study visit as detailed in Section 9.4.

10.5 Analyses of Outcomes of Clinical Management

All outcomes related to the clinical management of the patients as specified in Section 4 will be summarized by country and by the baseline variables at 12 and 24 months. For each outcome, the point estimate and 95% CI (based on binomial distribution) will be provided by country as well.

10.6 Safety Analyses

Safety data will be summarized by country.

All serious and non-serious ADRs to Prolia® will be coded using the Medical Dictionary for Regulatory Activities (MedDRA). Patient incidence of ADRs, serious ADRs, serious ADRs leading to discontinuation of Prolia®, and serious ADRs associated with fatal outcomes will be tabulated by system organ class (SOC) and preferred term (PT).

All serious and non-serious clinical fractures will be coded using the Medical Dictionary for Regulatory Activities (MedDRA). Patient incidence of clinical fractures and serious clinical fractures will be tabulated by system organ class (SOC) and preferred term (PT).

The Medical Dictionary for Regulatory Activities (MedDRA) version 14.1 or later will be used to code all adverse events to a system organ class and a preferred term.

11. Changes from Protocol or RPP Specified Analyses

There are no changes to the pre-specified analyses. An additional analysis of the baseline data is planned once the last patient is enrolled. Only baseline outputs will be produced for each country.

Full analysis set has been re-defined:

All enrolled patients (provided informed consent and enrolled in the ETO system) will be included into the full analysis set (FAS).

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12. Literature Citations / References

McCarney R, Warner J, Iliffe S, van Haselen R, Griffin M, Fisher P. The Hawthorne Effect: a randomized, controlled trial. BMC Medical Research Methodology 2007 7:30

Hosmer,DW and Lemeshow,S. Applied Logistic Regression. Wiley Inter-Science. Second Edition. 2000

Bendel, R.B., and Afifi, A.A. Comparison of Stopping Rules in Forward Regression. Journal of the American Statistical Association 1977 72: 46-53

13. Appendices

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Appendix A. Co-Morbidities and Prior Prescription Osteoporosis Therapies

List of Co-morbidities

Co-morbidities collected include:

- Anemia or other blood disease
- Back pain
- Cancer (not considered cured)
- Depression
- Mental illness
- Diabetes (Type 1 or 2)
- Endocrine disease (such as thyroid, adrenal, or pituitary)
- Hearing Impairment (very hard of hearing, even with hearing aids)
- Hypertension
- Myocardial infarction (MI)
- Stroke
- Peripheral vascular disease
- Heart disease (excluding hypertension, myocardial infarction, stroke, and peripheral vascular disease)
- Historical spine/hip/leg fracture
- Kidney disease
- Liver disease including gall bladder conditions
- Lung disease
- Neurological disease (such as multiple sclerosis or Parkinson's)
- Obesity (body mass index > 30 kg/m^2)
- Osteoarthritis, degenerative arthritis
- Rheumatoid arthritis
- Other rheumatologic diseases (excluding osteoarthritis, degenerative arthritis, and rheumatoid arthritis)
- Gastrointestinal disorders (such as ulcers or gastritis)
- Visual impairment (such as cataracts, glaucoma or macular degeneration)
- Genito-urinary disease (such as problems with uterus or ovaries)

List of prior prescription osteoporosis therapies

Prior prescription osteoporosis therapies collected include:

- Alendronate
- Risedronate
- Ibandronate

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- Zoledronate
- Etidronate
- Other Bisphosphonate
- Parathyroid hormone (PTH)/Teriparatide
- Strontium ranelate
- Selective estrogen receptor modulators (SERMs)
- Calcitonin
- Calcium supplements
- Vitamin D supplements
- Hormone Replacement Therapy
- Other (non-bisphosphonate)

Code Fragment for Multivariable Logistic Regression Model

The following is an example of the SAS® PROC LOGISTIC code to be used in the multivariable analysis:

```
proc logistic data=data_set;
   class cov1 cov2 cov3;
   model outcome = cov1 cov2 cov3 / selection=stepwise slentry=0.25 slstay=0.30
                                    details lackfit;
run;
```


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Modified-Wolfe Comorbidity Index (MWCI)

The modified-Wolfe comorbidity index is defined as the sum of points from the comorbid conditions presented in the table below.

Comorbid Conditions Considered in Wolfe Comorbidity Index Algorithm	Comorbid Condition Collected in the Study	Number of Points
Pulmonary disorders	• Lung disease	2
Cardiovascular disorders	• Myocardial infarction	2
	• Stroke	
	• Peripheral vascular disease	
	• Heart disease (excluding hypertension, myocardial infarction, stroke, and peripheral vascular disease)	
Hypertension	• Hypertension	1[a]
Diabetes	• Diabetes (Type 1 or 2)	1
Depression	• Depression	1
GI ulcer or disorders	• Gastrointestinal disorders (such as ulcers or gastritis)	1
Cancer	• Cancer (not considered cured)	1
Spine/hip/leg fracture	• This condition will be excluded from the modified-Wolfe comorbidity index calculation because prior fracture is evaluated separately in this study	N/A

[a]Only when no other cardiovascular disorder is identified

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