

# Comparative Effectiveness of Osteoporosis Medications Among Female Medicare Fee-For-Service (FFS) Beneficiaries in the United States (20210028)

**First published:** 02/10/2022

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS49101

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### Study ID

49180

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study status

Finalised

## Research institutions and networks

# Institutions

## Amgen

 United States

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 22/02/2022

Actual: 21/02/2022

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**Study start date**

Planned: 30/09/2022

Actual: 03/10/2022

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**Data analysis start date**

Planned: 30/09/2022

Actual: 03/10/2022

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**Date of final study report**

Planned: 01/12/2023

Actual: 24/01/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Other study registration identification numbers and links

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

A retrospective cohort study.

**Main study objective:**

The main objective of this study is to evaluate the comparative effectiveness of osteoporosis treatments on the incidence of major osteoporotic fractures, non-vertebral fractures, vertebral fracture, and hip fractures among post-menopausal women.

## Study Design

## Non-interventional study design

Cohort

Other

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## Non-interventional study design, other

Retrospective, observational cohort study

# Study drug and medical condition

## Medicinal product name

PROLIA

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## Study drug International non-proprietary name (INN) or common name

DENOSUMAB

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## Anatomical Therapeutic Chemical (ATC) code

(M05BX04) denosumab

denosumab

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## Medical condition to be studied

Osteoporosis postmenopausal

# Population studied

## Short description of the study population

We included female patients in this study if they met all of the following criteria:

- Use of denosumab, an oral BP (alendronate, ibandronate, risedronate) or ZA with at least one outpatient pharmacy claim for one of these medications

- o Date of prescription between January 1, 2012 through December 31, 2018
- 66 years + 90 days (3 mo.) of age or older on the date of treatment initiation
- At least 15 months (455 days) of continuous health plan enrollment preceding the date

of treatment initiation

We excluded patients from the study if they had a history of the following criteria during the 455-day baseline period:

- Paget's disease of bone,
  - Cancer (excluding non-melanoma skin cancer),
  - Treatment with chemotherapy,
  - Treatment with hormonal therapy for cancer,
  - Treatment with radiation therapy for cancer,
  - Exposed to > 1 OP drug (including any combination of study medications, teriparatide, abaloparatide, raloxifene, calcitonin, pamidronate, and etidronate) at treatment initiation (index date)
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### **Age groups**

- Elderly ( $\geq 65$  years)
    - o Adults (65 to < 75 years)
    - o Adults (75 to < 85 years)
    - o Adults (85 years and over)
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### **Estimated number of subjects**

585334

## Study design details

### **Setting**

The database was extracted from the US Centers for Medicare and Medicaid Services' Chronic Condition Warehouse database from January 1, 2012 through December 31, 2019.

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### **Comparators**

Pairwise treatment comparisons for the three treatment cohorts listed above will include: denosumab vs. alendronate, denosumab vs. oral BP (alendronate, ibandronate, risedronate), denosumab vs. IV ZA

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### **Outcomes**

- Major osteoporotic fracture is defined as non-vertebral fractures or clinical vertebral fractures
  - Non-vertebral fracture sites include: pelvis, humerus, radius/ulna, hip, other femur
  - Clinical vertebral fracture
  - Hip Fracture
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### **Data analysis plan**

Cumulative incidence of the outcomes of interest will be described for all the treatment cohorts of interest and measures of effect (i.e. relative risk and risk difference) will be assessed for the pairwise comparisons. Summary statistics will be computed on demographics, clinical factors, and treatment history in each treatment cohort of interest.

## **Documents**

### **Study results**

[20210028\\_ORSR\\_abstract\\_Redacted\\_.pdf](#) (203.84 KB)

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Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data source(s), other**

Medicare Administrative Claims, United States

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### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Other](#)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No