

# 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

### **PURI**

<https://redirect.ema.europa.eu/resource/49180>

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### **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

**Last updated:** 21/02/2024

**Institution**

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.

**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

20210028

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

#### **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

## **Name of medicine**

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

## **Age groups**

Elderly ( $\geq$  65 years)

Adults (65 to  $<$  75 years)

Adults (75 to  $<$  85 years)

Adults (85 years and over)

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### **Estimated number of subjects**

585334

## Study design details

### **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.

## Data management

### 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