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

First published: 02/10/2022

Last updated: 02/05/2024

Study Finalised

Administrative details

PURI

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

EU PAS number

EUPAS49101

Study ID

49180

DARWIN EU® study

No

Study countries

United States

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

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

Study start date
Planned: 30/09/2022

Actual: 03/10/2022

Data analysis start date
Planned: 30/09/2022

Actual: 03/10/2022

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

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

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

Non-interventional study design, other

Retrospective, observational cohort study

Study drug and medical condition

Name of medicine

PROLIA

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

DENOSUMAB

Anatomical Therapeutic Chemical (ATC) code

(M05BX04) denosumab

denosumab

Medical condition to be studied

Osteoporosis postmenopausal

Population studied

Age groups

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No