

# Estimation of Off-Label Use of XGEVA® (denosumab) Using Population-Based Databases in Denmark (20101335)

**First published:** 15/02/2014

**Last updated:** 30/03/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/20211>

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### EU PAS number

EUPAS5687

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### Study ID

20211

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### DARWIN EU® study

No

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### Study countries

Denmark

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## Study description

This study aims to evaluate off-label XGEVA use in Denmark using data linked from registries and other sources in Northern Jutland Region of Denmark. This will allow for accurate assessment of prescriptions and diagnoses, especially those related to cancer patients during the first year post the initial market availability of XGEVA.

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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

Actual: 15/11/2012

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### Study start date

Actual: 24/01/2013

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### Date of final study report

Actual: 03/11/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[01.20.01 Protocol Amend 2 2014-07-28 English.pdf\(870.44 KB\)](#)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

**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:**

Other

**If 'other', further details on the scope of the study**

Evaluation of XGEVA off-label use

**Data collection methods:**

Secondary use of data

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**Main study objective:**

This study will evaluate off-label use of XGEVA® (denosumab) in Denmark during the first 1-year post XGEVA market availability, defined as 12 months after RADS opinion on 24th January 2013.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Name of medicine**

XGEVA

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### **Medical condition to be studied**

Off label use

## Population studied

### **Short description of the study population**

Patients with a treatment code for XGEVA in the Northern Jutland Region during the first 1-year period after the initial market availability of XGEVA.

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### **Age groups**

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 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**

108

## Study design details

### **Outcomes**

On or off label individual prescription type. On or off label patient treatment.

Type of off-label use. Off-label use stratified by administering department

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### **Data analysis plan**

Primary statistical analysis will be based on data of off-label use after the initial market availability of XGEVA in Denmark. Stratified analysis will be done for data accumulated during the first year of commercial availability. Additional analyses will stratify 12-month periods into 6-month intervals. Study population will be characterized with regard to demographic factors, diagnoses and treatments using descriptive statistics. Categorical variables will be summarized in frequency tables and numeric variables as the number of observations, mean, standard deviation, quartiles, and median.

## Documents

### **Study results**

## Data management

### Data sources

#### **Data source(s)**

Danish registries (access/analysis)

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

[Electronic healthcare records \(EHR\)](#)

### 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**

Unknown