

# Effectiveness, Efficacy, and Safety of XGEVA (denosumab) in Chinese Patients With Giant Cell Tumor of Bone (GCTB): A Systematic Literature Review (20220044)

**First published:** 28/09/2022

**Last updated:** 05/12/2023

Study

Finalised

## Administrative details

### EU PAS number

EUPAS49061

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### Study ID

50352

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### DARWIN EU® study

No

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### Study countries

 China

 Taiwan

 United States

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## Study status

Finalised

# Research institutions and networks

## Institutions

**Amgen**

 United States

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

**Last updated:** 27/03/2026

**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: 22/08/2022

Actual: 22/08/2022

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### **Study start date**

Planned: 11/11/2022

Actual: 04/11/2022

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### **Data analysis start date**

Planned: 12/12/2022

Actual: 19/12/2022

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### **Date of final study report**

Planned: 01/04/2023

Actual: 01/12/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Protocol-Published Original denosumab 20220044.pdf](#) (489.33 KB)

## 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

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

#### **Main study objective:**

The objective of this systematic review is to evaluate published evidence on the safety and clinical effectiveness of XGEVA among mainland Chinese and Chinese patients in Taiwan, Hong Kong, and Macau with GCTB, and to characterize the benefit-risk profile associated with use of this drug in these Chinese GCTB patients, in context of the global body of evidence of XGEVA treated GCTB patients.

## Study Design

## **Non-interventional study design**

Other

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### **Non-interventional study design, other**

This systematic literature review will include randomized clinical trials (RCTs), case reports, observational studies published in peer reviewed journals, as well as RCTs and observational studies published as abstracts and/or posters at conferences

## Study drug and medical condition

### **Medicinal product name**

XGEVA

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

DENOSUMAB

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

Bone giant cell tumour

## Population studied

### **Age groups**

- 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**

0

## Study design details

### **Data analysis plan**

A qualitative synthesis of results will be performed, and a narrative summary provided in the text of the final report.

## Documents

### **Study results**

[20220044\\_ORSR Abstract\\_28MAR2023\\_Redacted.pdf](#) (104.26 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**

PubMed (MEDLINE) United States, Embase United States, Google Scholar United States, Cochrane Library United States, Clarivate Analytics United States

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**Data sources (types)**

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

[Other](#)

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**Data sources (types), other**

Systematic review of all published studies of XGEVA among mainland Chinese and Chinese patients in Taiwan, Hong Kong, and Macau with GCTB.

## 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