

# Burden of Illness Among Patients with Gout and Treated with Pegloticase (20240302)

**First published:** 24/02/2025

**Last updated:** 28/01/2026

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000475

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### Study ID

1000000475

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### DARWIN EU® study

No

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### Study countries

United States

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### Study description

This retrospective cohort study will describe patient characteristics and treatment patterns and compare gout flares, laboratory measures, and HCRU and cost between the pre- and post-pegloticase initiation periods among gout

patients in a real-world setting using administrative claims data from the MORE2 Registry® and the 100% Medicare FFS database. The objective of the study are:

1. To describe the patient characteristics of pegloticase initiators.
  2. To examine the treatment patterns pre and post pegloticase initiation.
  3. To assess gout- and flare-related healthcare resource utilization and costs pre- and post-pegloticase initiation.
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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**

[Inovalon \(Vendor\)](#)

### Contact details

### **Study institution contact**

Global Development Leader Amgen Inc.  
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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: 22/08/2024

Actual: 22/08/2024

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### **Study start date**

Planned: 17/02/2025

Actual: 17/02/2025

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### **Data analysis start date**

Planned: 17/02/2025

Actual: 17/02/2025

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

Planned: 31/12/2025

Actual: 17/09/2025

## Sources of funding

- Pharmaceutical company and other private sector

## Study protocol

[Protocol-Published Original pegloticase 20240302 .pdf](#) (328.07 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 topic:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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

## Study drug and medical condition

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

PEGLOTICASE

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### **Anatomical Therapeutic Chemical (ATC) code**

(M04AX02) pegloticase

pegloticase

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

Gout

## Documents

### **Study results**

[20240302\\_ORSR\\_17SEP2025.pdf](#) (1.8 MB)

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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 sources (types)**

Administrative healthcare records (e.g., claims)

## Use of a Common Data Model (CDM)

### **CDM mapping**

Yes

## Data quality specifications

### **Check conformance**

Yes

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### **Check completeness**

Yes

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### **Check stability**

Yes

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### **Check logical consistency**

Yes

## Data characterisation

### **Data characterisation conducted**

Yes