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

Study ID

1000000475

DARWIN EU® study

No

Study countries

United States

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.

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.

medinfo@amgen.com

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: 22/08/2024

Actual: 22/08/2024

Study start date

Planned: 17/02/2025

Actual: 17/02/2025

Data analysis start date

Planned: 17/02/2025

Actual: 17/02/2025

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

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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Study drug and medical condition

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

PEGLOTICASE

Anatomical Therapeutic Chemical (ATC) code

(M04AX02) pegloticase

pegloticase

Medical condition to be studied

Gout

Documents

Study results

20240302_ORSR_17SEP2025.pdf (1.8 MB)

Data management

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

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes