Administration of Elranatamab In the Real-World: Treatment Patterns, Healthcare Resource Utilization, Costs, Effectiveness, anD SafEty (ALTITUDE-2)

First published: 18/10/2024

Last updated: 27/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000293

Study ID

1000000293

DARWIN EU® study

No

Study countries

United States

Study description

This study aims to describe the real-world usage of elranatamab for the treatment of RRMM. To meet these objectives, the Clarify team will partner with Pfizer to create a curated dataset of Medicare FFS beneficiaries to serve as the foundation upon which to generate descriptive data.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Clarify Health

Contact details

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Primary lead investigator

Marco DiBonaventura

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/05/2024

Study start date

Planned: 25/10/2024

Actual: 25/10/2024

Date of final study report

Planned: 08/05/2026

Sources of funding

More details on funding

Pfizer

Study protocol

C1071044 Non Interventional Study Protocol - ALTITUDE-2 Real-world usage of ELREXFIO in Medicare - 20-Sep-2024 _Redacted.pdf (722.38 KB)

C1071044_NON-INTERVENTIONAL STUDY PROTOCOL_Redacted_V2_06AUG2025.pdf (1.14 MB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Other

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

Demographics, clinical history, treatment history

Data collection methods:

Secondary use of data

Study design:

This will be a retrospective, non-interventional descriptive cohort study using de-identified patient data from US-based Medicare FFS beneficiaries. The study will utilize claims data from the Centers for Medicare and Medicaid Services (CMS), spanning from 2016 through 2025.

Main study objective:

The overall research question of this study is to describe the real-world usage of elranatamab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ELREXFIO

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

ELRANATAMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX32) elranatamab

elranatamab

Additional medical condition(s)

Multiple Myeloma

Population studied

Short description of the study population

This study will include adult (≥18 years old) patients with an International Classification of Diseases, tenth revision (ICD-10) code for RRMM (defined as MM ICD-10 codes: C90.0x). The study cohort will include patients with RRMM who initiate elranatamab between August 14, 2023 (US approval date for elranatamab) and most current, available data. The index date for patients in each cohort will be defined as the date of the first prescription or medical claim for elranatamab. Patients will be required to have at least 180 days of continuous closed-claims enrollment before the index date and 30 days after the index date. Select exploratory analyses will also include a teclistamab-exposed cohort.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with multiple myeloma

Study design details

Setting

This study will evaluate adult patients with RRMM who initiate elranatamab or teclistamab. Patients will enter (i.e., index) on the first observed elranatamab or teclistamab claim between August 14, 2023, and the most current, available data. Limited eligibility criteria will be applied.
Study Period: Start of data (Jan 1, 2016) to the most current, available data.
MM diagnosis window: Start of data (Jan 1, 2016) to index date
Index date: First elranatamab or teclistamab claim after initial MM diagnosis
Observability: At least 180 days of continuous closed-claims medical and pharmacy enrollment prior to index (inclusive) and 30 days after the index date
Baseline period for MM-related treatments and MM-related comorbidities: MM diagnosis to one day prior to index date
Charlson Comorbidity Index and baseline HCRU assessment window: 180 days prior to index date to index date
Follow-up: Index date until death, the earliest of end of study period, or end of continuous enrollment (unless otherwise noted). Alternative censoring criteria will be applied for certain outcomes (such as OS, TTD, and TTNT/D).

Comparators

No formal statistical comparisons will be performed between groups.

Outcomes

Primary

• Objective 1: To describe the demographics, clinical history, and treatment history of patients treated with elranatamab

• Objective 2: To describe the administration and treatment management of elranatamab

• Objective 3: To describe all-cause and MM-related HCRU and associated costs among patients treated with elranatamab

Exploratory

• Exploratory Objective 1: To describe the tolerability and real-world safety of elranatamab

• Exploratory Objective 2: To describe the overall effectiveness of elranatamab in terms of time to next treatment or death (TTNT/D) and overall survival (OS)

• Exploratory Objective 3: In a separate cohort, replicate all objectives for patients who initiated teclistamab

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Data analysis plan

This study will be largely descriptive in nature, and no formal statistical comparisons will be performed between groups. All characteristics and outcomes will be reported separately for each cohort. The number of patients who meet study eligibility criteria will be summarized in an attrition table. Inclusion and exclusion criteria will be listed hierarchically and the number of patients remaining at each step will be reported. Patient and treatment characteristics will be summarized using descriptive statistics. Categorical variables will be summarized by the number of available observations, frequency, percentage, and 95% confidence limits. Continuous variables will be

summarized by the number of available observations, mean, standard deviation, 95% confidence limits, median, quartiles, minimum, and maximum, where appropriate. The prevalence and incidence, as well as the associated 95% confidence intervals (CI) for each adverse event, will be estimated. Kaplan-Meier methods will be used to estimate the median time to event, including 95% CIs for TTNT/D and OS.

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

Medicare FFS data from the VRDC

Data sources (types)

Administrative healthcare records (e.g., claims)

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