Real-World Analysis of Exacerbations and Exacerbation-Related Costs Among Patients with Asthma Receiving Tezepelumab (CROSSROADS-5) (20240066)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000514

Study ID

1000000514

DARWIN EU® study

No

Study countries

United States

Study description

This non-interventional, retrospective database analysis will describe treatment outcomes including asthma exacerbations and healthcare resource utilization and costs among severe asthma patients initiating tezepelumab and segmented by payer channel (with a special emphasis on the Medicare FFS population) and by prior biologic experience.
Secondary and exploratory analyses will include a description of patterns of tezepelumab utilization and OCS dosing.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.
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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/03/2024

Actual: 21/03/2024

Study start date

Planned: 31/03/2025

Actual: 31/03/2025

Data analysis start date

Planned: 31/03/2025

Date of final study report

Planned: 30/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen 100%

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

20240066

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)

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

Descriptive retrospective cohort study

Main study objective:

To describe asthma exacerbations in the 12-months following initiation of tezepelumab (12-month post-index period) relative to the baseline period (12-month pre-index period) among patients with severe asthma

Study Design

Non-interventional study design

Cohort

Non-interventional study design, other

Non-interventional retrospective database analysis.

Study drug and medical condition

Medicinal product name

TEZSPIRE

Medicinal product name, other

Tezepelumab

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

TEZEPELUMAB

Anatomical Therapeutic Chemical (ATC) code

(R03DX11) tezepelumab

tezepelumab

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Patients with severe asthma with asthma exacerbations in the baseline period.

Age groups

- Adolescents (12 to < 18 years)
- **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)

Estimated number of subjects

1396

Study design details

Setting

The study population consists of asthma patients 12 years of age or older with ≥2 medical claims for tezepelumab during the identification period (December 17, 2021 to 12 months prior to latest available data at the time of data extraction) in the United States.
Patients will be identified in the MORE2 Registry® database and the 100% Medicare Fee-for-Service (FFS) database.

Comparators

NA

Outcomes

Primary outcomes

• Annual asthma exacerbation rate (AAER) in the pre-index period.
• AAER in the post-index period.
• Percentage change in AAER between the pre- and post-index periods.

Secondary outcomes

• Number of tezepelumab claims.
• Time to tezepelumab discontinuation.
• Proportion of days covered (PDC).
• Adherence based on PDC categories (PDC≥0.80; PDC 0.50-0.80, PDC <0.50).
• Exacerbation-related healthcare resource utilization in the pre-index and post-index periods.
• Exacerbation-related costs in the pre-index and post-index periods.
• Ratio of exacerbation-related healthcare resource utilization between the pre-index and post-index periods.
• Ratio of exacerbation-related costs between the pre-index and post-index periods.

• Cumulative oral corticosteroids (OCS) dose in the pre- index and post-index periods.
• Cumulative OCS dose ratio between the pre-index and post-index periods.

Data analysis plan

Categorical study variables will be reported as frequencies (counts and percentages). Continuous variables will be described by means, standard deviation (SD), and medians. Ratios will be reported as a percentage change between the pre-index and post-index periods.

AAER ratios between the post-index period relative to the pre-index period will be estimated using a generalized estimating equation (GEE) model with a Poisson distribution and a log link function.

The ratio between exacerbation-related healthcare resource utilization in the post-index period relative to the pre-index period will be estimated using a GEE model with a negative binomial distribution (as appropriate) and a log link.

The ratio of exacerbation-related costs between the post-index period relative to the pre-index period will be estimated using a GEE model with a gamma distribution and a log link.

These analyses will be descriptive in nature and no hypothesis testing will be conducted.

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

No

Data quality specifications

Check conformance

No

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes