

tezepelumab-ekko (Tezspire) prefilled syringe and vial

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

Drug Details

USP Category: RESPIRATORY TRACT/PULMONARY AGENTS

Mechanism of Action: a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody IgG2-lambda

HCPCS:

J2356:Injection, tezepelumab-ekko, 1 mg

How Supplied:

- 210 mg/1.91 mL (single-dose pre-filled syringe or single-dose glass vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Severe Asthma

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Tezspire prefilled syringes and vials are managed under the Medical Benefit. Please include medical rationale why the patient cannot use the self-administered Tezspire prefilled pen in the home. The Tezspire prefilled pen can be obtained through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

Members with the following plans: **PPO, Direct Contract HMO (non-direct contract) and when applicable, ASO, Shared Advantage, and HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physicians' office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet

one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG™ Care Guidelines, 19th edition, 2015

ADMINISTRATION OF TEZSPIRE IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE

REQUIRES ONE OF THE FOLLOWING: (Supporting Documentation must be submitted)

1. Patient is receiving their first infusion of Tezspire or is being re-initiated on Tezspire after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Tezspire based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Tezspire based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Severe Asthma

Meets medical necessity if all the following are met:

Initial:

1. Age is consistent with the FDA approved indication (12 years of age and older)
2. Asthma symptoms remain uncontrolled despite 3 months of treatment with a high-dose inhaled corticosteroid in combination with long-acting beta agonist [LABA] or leukotriene receptor antagonists [LTRA]
3. Not used in combination with another biologic medication indicated for asthma treatment
4. Meets ONE of the following within the past year:
 - a. One or more acute asthma attacks requiring emergency care (hospital emergency dept visit)
 - b. One or more acute inpatient visits where asthma was the principal diagnosis
 - c. Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids

Reauthorization:

1. Not being used in combination with another biologic medication indicated for asthma treatment
2. Asthma symptoms have improved and/or controlled while on Tezspire

Covered Doses:

Up to 210 mg given subcutaneously once every 4 weeks

Coverage Period:

Initial: 6 months

Reauthorization: Yearly

ICD-10:

J45.40, J45.41, J45.42, J45.50, J45.51, J45.52

References

1. AHFS. Available by subscription at <http://www.lexi.com>
DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
2. Tezspire (tezepelumab) Prescribing Information. Amgen, Inc; Thousand Oaks, CA: 10/2025
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention (2025 Update). Available from: www.ginasthma.org.

Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- Removed specialist requirement for severe asthma (Rationale: Prescribing patterns consistent with expected specialists)

Blue Shield of California Medication Policy to Determine Medical Necessity

Reviewed by P&T Committee