



Commercial/Healthcare Exchange PA Criteria Effective: March 30, 2023

Prior Authorization: Tezspire

Products Affected: Tezspire (Tezepelumab-ekko) prefilled pens

Medication Description: Tezepelumab-ekko is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody IgG2-lambda that binds to human TSLP and blocks its interaction with the heterodimeric TSLP receptor. TSLP occupies an upstream position in the asthma inflammatory cascade. Blocking TSLP reduces biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, IgE, fractional exhaled nitric oxide (FeNO), interleukin-5, and interleukin-13. However, the mechanism of action in asthma has not been definitively established

Covered Uses: add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis
2. Medical History
3. Current Medication List
4. Medications tried and failed

Prescriber Restriction: The medication is prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist

Age Restriction: 12 years of age and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Asthma** Approve if the patient meets the following criteria (A **AND** B)
 - A. Patient has received at least 3 consecutive months of combination therapy with **BOTH** of the following (i **AND** ii)
 - i. An inhaled corticosteroid; **AND**
 - ii. At least one additional asthma controller or asthma maintenance medication; **AND**
Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta₂-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, anti-interleukin-5 therapies (e.g., Cinqair [reslizumab intravenous infusion], Fasentra [benralizumab subcutaneous injection], Nucala [mepolizumab subcutaneous injection]), Dupixent (dupilumab subcutaneous injection), Xolair (omalizumab

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subcutaneous injection), and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta₂-agonist would fulfill the requirement for both criteria i and ii.

- B.** Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by **ONE** of the following (i, ii, iii, iv, **OR** v)
- i.** Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
 - ii.** Patient experienced one or more asthma exacerbation(s) requiring hospitalization, an Emergency Department visit, or an Urgent care visit in the previous year; **OR**
 - iii.** Patient has a forced expiratory volume in 1 second (FEV₁) < 80% predicted; **OR**
 - iv.** Patient has an FEV₁/forced vital capacity (FVC) < 0.8; **OR**
 - v.** The patient has asthma that worsens upon tapering of oral corticosteroid therapy; **AND**
- Note: "Baseline" is defined as prior to receiving any Tezspire, anti-interleukin-5 therapies (ie. Cinqair, Fasenna, or Nucala), Dupixent, or Xolair.*

Renewal Criteria

- 1. Asthma** Approve if the patient meets the following criteria (A, B, **AND** C)
 - A.** Patient has already received at least of 6 months of therapy with Tezspire; **AND**
Note: A patient who have received less than 6 months of therapy or who is restarting therapy with Tezspire should be considered under Initial therapy.
 - B.** Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**
 - C.** Patient has responded to therapy as determined by the prescriber.
Note: Examples of a response to Tezspire therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department/urgent care or medical clinical visits due to asthma; improved lung function parameters; or a decreased requirement for oral corticosteroid therapy.

References:

1. Tezspire™ [package insert]. Thousand Oakes, CA, Amgen, Inc. Updated December 2021. Accessed March 31st, 2022.

Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|-------|----------------|-------------------|-------------------|------------|
| 1 | New Policy | New Policy | All | 03/30/2023 |