Medical Policy:

Tezspire (tezepelumab-ekko) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.356	January 2, 2024	May 12, 2022

Definitions:

TEZSPIRE is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. 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

Length of Authorization

Initial coverage will be provided for 6 months; Renewal coverage: 12 months

Dosing Limits [Medical Benefit]

- Approve 210 mg given subcutaneously once every 4 weeks. (210 billable units (210 mg) every 4 weeks)

Guideline

INITIAL APPROVAL CRITERIA

1. **Asthma** Approve for 6 months if the patient meets the following criteria (A, B, C, **AND** D)
   A. Patient is ≥ 12 years of age; **AND**
   B. 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 beta$_2$-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, anti-interleukin-5 therapies (e.g., Cinqair [reslizumab intravenous infusion], Fasenra [benralizumab subcutaneous injection], Nucala [mepolizumab subcutaneous injection]), Dupixent (dupilumab subcutaneous injection), Xolair (omalizumab subcutaneous injection), and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta$_2$-agonist would fulfill the requirement for both criteria i and ii.
   C. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by **ONE** of the following (i, ii, iii, iv, **OR** v)
      Note: "Baseline" is defined as prior to receiving any Tezspire, anti-interleukin-5 therapies (ie. Cinqair, Fasenra, or Nucala), Dupixent, or Xolair.
      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 (FEV_1) < 80% predicted; **OR**
      iv. Patient has an FEV_1/forced vital capacity (FVC) < 0.8; **OR**
      v. The patient has asthma that worsens upon tapering of oral corticosteroid therapy; **AND**
   D. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

RENEWAL CRITERIA:

A. **Patient is Currently Receiving Tezspire**. Approve for 1 year if the patient meets the following criteria (i, ii, **and** iii):
   i. Patient has already received at least 6 months of therapy with Tezspire; **AND**
   Note: A patient who has received < 6 months of therapy or who is restarting therapy with Tezspire should be considered under initial criterion
   ii. Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**
   iii. 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 clinic visits due to asthma; improved lung function parameters; and/or a decreased requirement for oral corticosteroid therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tezspire is not recommended in the following situations:

1. Concurrent use of Tezspire with another Monoclonal Antibody Therapy (i.e., Cinqair, Fasenra, Nucala, Dupixent, Xolair, or Adbry); **AND**
2. Concurrent use with live vaccines

Dosing/Administration:

The recommended dosage of Tezspire is 210 mg administered subcutaneously once every 4 weeks. Tezspire is intended for administration by a healthcare provider.

Applicable Procedure Codes

Code	Description
J2356	Injection, tezepelumab-ekko, 1 mg

Applicable NDCs

Code	Description
55513-0112-01	Tezspire 210mg/1.91mL single-dose prefilled syringe
55513-0100-xx	Tezspire 210 mg/1.91 mL single-dose vial

ICD-10 Diagnoses

Code	Description
J45.50	Severe persistent asthma, uncomplicated

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Added NDC 5513-0100-xx, no criteria changes
EmblemHealth & ConnectiCare	5/02/2023	Annual Review: added "Conditions not recommended for approval: 1.Concurrent use of Tezspire with another Monoclonal Antibody Therapy (i.e., Cinqair, Fasenra, Nucala, Dupixent, Xolair, or Adbry); AND 2.Concurrent use with live vaccines"
EmblemHealth & ConnectiCare	5/12/2022	New Policy

References

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