Medical Drug Clinical Criteria

Subject:	Tezspire (tezepelumab-ekko)		
Document #:	CC-0212	**Publish Date**:	04/01/2025
Status:	Revised	**Last Review Date**:	02/21/2025

Table of Contents

Overview

This document addresses the use of Tezspire (tezepelumab-ekko), a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), approved by the Food and Drug Administration (FDA) for add-on maintenance treatment of adult and pediatric individuals aged 12 years and older with severe asthma.

In 2013, the European Respiratory Society/American Thoracic Society (ERS/ATS) released guidance for defining, evaluating and treating severe asthma. The guidelines recommend to start by confirming the asthma diagnosis, including a spirometry assessment, and then differentiating severe asthma from milder asthma. The guidelines define severe asthma as asthma which has required treatment with high dose inhaled corticosteroids and a long-acting beta agonist, leukotriene modifier or theophylline for the previous year in order to prevent asthma symptoms from becoming uncontrolled. Alternatively, severe asthma can be defined as asthma that has required systemic corticosteroid treatment for over 50% of the previous year.

ERS/ATS guidance defines uncontrolled asthma as meeting one of the following:

- Poor symptom control: Asthma Control Questionnaire (ACQ) consistently >1.5, Asthma Control Test (ACT) <20
- Frequent severe exacerbations: two or more bursts of systemic corticosteroids in the previous year
- History of serious exacerbation: at least one hospitalization, intensive care unit stay or mechanical ventilation in the previous year
- Airflow limitation: after appropriate bronchodilator withhold FEV_1 <80% predicted

The safety and effectiveness of Tezspire for the treatment of severe asthma was established in two randomized, double-blind, placebo-controlled trials (PATHWAY, NAVIGATOR). The trials included individuals with severe asthma on medium or high-dose inhaled corticosteroids and at least one additional asthma controller with or without oral corticosteroids. Participants were required to have history of asthma exacerbations in the last 12 months. Study data confirms the efficacy of Tezspire in reducing asthma exacerbations and improving asthma control and quality of life measures.

The 2024 Global Initiative for Asthma (GINA) guidelines list Tezspire as a treatment option in Step 5 of their asthma management algorithm. Add-on targeted biologic therapy should be considered for individuals with severe asthma experiencing exacerbations or poor symptom control despite taking at least high-dose inhaled corticosteroid/long acting $beta_2$ –agonists and who have allergic or eosinophilic biomarkers or need maintenance oral corticosteroids. Tezspire is an option for individuals who do not have evidence of Type 2 airway inflammation.

Comparative Doses for Inhaled Corticosteroids (Adults and Adolescents) (Wenzel 2021)

Drug	Low Daily Dose	Medium Daily Dose	High Daily Dose
Beclomethasone 40 or 80 mcg/actuation	80-160 mcg	>160-320 mcg	>320-640 mcg
Budesonide 90 or 180 mcg/actuation	180-360 mcg	>360–720 mcg	>720-1440 mcg
Ciclesonide 80 or 160 mcg/actuation	160 mcg	320 mcg	640 mcg
Fluticasone propionate MDI: 44, 110 or 220 mcg/actuation DPI: 50, 100 or 250 mcg/dose	176–220 mcg 100-250 mcg	>220–440 mcg >250–500 mcg	>440-1760 mcg >500-2000 mcg

Fluticasone furoate 50, 100 or 200 mcg/dose	50 mcg	100 mcg	200 mcg
Mometasone MDI: 50, 100 or 200 mcg/actuation DPI: 110 or 220 mcg/actuation	200 mcg 220 mcg	>200-400 mcg >220-440 mcg	>400-800 mcg >440-880 mcg

DPI = dry powder inhaler, MDI = metered dose inhaler.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tezspire (tezepelumab-ekko)

Initial requests for Tezspire (tezepelumab-ekko) may be approved if the following criteria are met:

I. Individual is 12 years of age or older; **AND**
II. Individual has a diagnosis of severe asthma; **AND**
III. Evidence of asthma is demonstrated by the following (NAEPP 2008):
    A. A pretreatment forced expiratory volume in 1 second (FEV_1) less than 80% predicted; **AND**
    B. FEV_1 reversibility of at least 12% and 200 milliliters after albuterol administration; **AND**
IV. Documentation is provided that individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting $beta_2$ –agonists, leukotriene modifiers, long-acting muscarinic antagonists or oral corticosteroids) (GINA 2024); **AND**
V. Individual has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance dosage of oral corticosteroids (ERS/ATS 2013).

Continuation requests for Tezspire (tezepelumab-ekko) may be approved if the following criteria are met:

I. Treatment with Tezspire has resulted in clinical improvement in one or more of the following:
    A. Decreased utilization of reliever medications; **OR**
    B. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
    C. Increase in percent predicted FEV_1 from pretreatment baseline; **OR**
    D. Reduction in reported asthma-related symptoms, including asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance or wheezing; **AND**
II. Individual continues to use Tezspire in combination with inhaled corticosteroid-based controller therapy.

Tezspire (tezepelumab-ekko) may not be approved for the following:

I. In combination with Cinqair, Dupixent, Fasenra, Nucala or Xolair; **OR**
II. May not be approved when the above criteria are not met and for all other indications.

Approval Duration
Initial Requests: 6 months
Continuation Requests: 12 months

Quantity Limits

Tezspire (tezepelumab-ekko) Quantity Limit

Drug	Limit
Tezspire (tezepelumab-ekko) 210 mg/1.91 mL prefilled pen/prefilled syringe/vial	1 prefilled syringe/vial per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J2356	Injection, tezepelumab-ekko, 1 mg [Tezspire] (tezepelumab-ekko)

ICD-10 Diagnosis

J45.50-J45.52	Severe persistent asthma

Document History

Revised: 2/21/2025
Document History:

- 2/21/2025 – Annual Review: Update guideline references. Coding Reviewed: No changes. 2/23/2024 – Annual Review: Update continuation criteria. Wording and formatting changes. Update guideline references. Coding Reviewed: No changes.
- 2/24/2023 – Annual Review: Add quantity limit for new Tezspire dosage form. Wording and formatting changes. Update guideline references. Coding Reviewed: No changes.
- 2/25/2022 – Annual Review: Add clinical criteria and quantity limit for Tezspire. Coding Reviewed: Added HCPCS J3590, C9399. All diagnoses pend. Effective 7/1/2022 Added HCPCS J2356. Remove HCPCS J3590, C9399. Added ICD-10-CM J45.50-J45.52. Remove All diagnoses pend.

References

1. Chung KF, Wenzel SE, Brozek JL, et al. International European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014; 43(2):343-373.
2. Cloutier MM, Baptist AP, Blake KV, et. al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program (NAEPP) Coordinating Committee Expert Panel Working Group. *J Allergy Clin Immunol*. 2020 Dec;146(6):1217-1270.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 31, 2025.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from: ginasthma.org/2024-report/. Accessed on: January 31, 2025.
6. Holguin F, Cardet JC, Chung KF, et. al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. *Eur Respir J*. 2020 Jan 2;55(1):1900588.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
8. National Asthma Education and Prevention Program (NAEPP). Expert Panel Report 3: Guidelines for the diagnosis and management of asthma. NIH Publication Number 08-5846. Updated: August 5, 2008. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm. Accessed: January 31, 2025.
9. Sharma S, Carr TF. Treatment of severe asthma in adolescents and adults. Last updated: January 30, 2025. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: January 31, 2025.