# Medical Policy

**Healthcare Services Department**

| Policy Name | Policy Number | Scope |
|---|---|---|
| Tezepelumab-ekko (Tezspire) | MP-RX-FP-90-23 | ☒ MMM MA ☒ MMM Multihealth |

## Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

## Service Description

This document addresses the use of Tezepelumab-ekko (Tezspire) , a drug approved by the Food and Drug Administration (FDA) for the treatment for add-on maintenance treatment of adult and pediatric individuals aged 12 years and older with severe asthma

**Background Information**

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 FEV1 <80% predicted.

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The safety and effectiveness of Tezspire for the treatment of severe asthma was established in two randomized, double-blind, placebocontrolled 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 2022 Global Initiative for Asthma (GINA) guidelines include Tezspire as a treatment option in Step 5 of their asthma management algorithm. Add-on targeted biologic therapy should be considered for individuals with exacerbations or poor symptom control despite taking at least high-dose inhaled corticosteroid/long acting beta2–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**<br>40 or 80 mcg/actuation | 80-160 mcg | >160-320 mcg | >320-640 mcg |
| **Budesonide**<br>90 or 180 mcg/actuation | 180-360 mcg | >360–720 mcg | >720-1440 mcg |
| **Ciclesonide**<br>80 or 160 mcg/actuation | 160 mcg | 320 mcg | 640 mcg |
| **Fluticasone propionate**<br>MDI: 44, 110 or 220 mcg/actuation<br>DPI: 50, 100 or 250 mcg/dose | 176–220 mcg<br>100-250 mcg | >220–440 mcg<br>>250–500 mcg | >440-1760 mcg<br>>500-2000 mcg |
| **Fluticasone furoate**<br>50, 100 or 200 mcg/dose | 50 mcg | 100 mcg | 200 mcg |
| **Mometasone**<br>MDI: 50, 100 or 200 mcg/actuation<br>DPI: 110 or 220 mcg/actuation | 200 mcg<br>220 mcg | >200-400 mcg<br>>220-440 mcg | >400-800 mcg<br>>440-880 mcg |

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

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

| ICD-10 | Description |
|---|---|
| J45.50-J45.52 | Severe persistent asthma |

## Medical Necessity Guidelines

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.

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

***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 (FEV1) less than 80% predicted; **AND**
    B. FEV1 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 beta2–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 rescue medications; **OR**

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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 FEV1 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.

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**

I. Initial Requests: 6 months
II. Continuation Requests: 12 months

## Limits or Restrictions

A. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

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

## Reference Information

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 26, 2023.
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, 2022. Available from: http://ginasthma.org/gina-reports/. Accessed on: February 5, 2023.

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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: February 5, 2023.
9. Wenzel S. Treatment of severe asthma in adolescents and adults. Last updated: October 21, 2022. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: January 27, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.



## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | MPCC Approval Date |
|---|---|---|---|
| Annual Review 03/24/2025 | Validation of information to ensure is up to date. Using GINA 2024 guidelines as reference. | 4/16/2025 | 5/6/2025 |
| Policy Inception | Elevance Health's Medical Policy adoption. | N/A | 11/30/2023 |