Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Tezepelumab-ekko (Tezspire®)	MP-RX-FP-90-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	2/22/2026
			Last Review Date:	Frequently Revision:
			2/22/2026	2/22/2027

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 add-on maintenance treatment of adult and pediatric individuals aged 12 years and older with severe asthma and for inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

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 and for inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

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.

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- 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, 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 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) (Sharma 2025)

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.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Tezspire is approved by the FDA as add-on maintenance treatment of adults and pediatric individuals aged 12 and older with chronic rhinosinusitis with nasal polyps (CRSwNP). FDA approval was based on the results of a randomized, double-blind, placebo-controlled trial where nasal polyp score (NPS) and nasal congestion score (NCS) were the principal outcome. The trial enrolled individuals with symptomatic CRSwNP despite treatment with nasal corticosteroids and who had history of systemic corticosteroids or sinonasal surgery. Participants received Tezspire or placebo in addition to

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background nasal corticosteroid therapy. The Tezspire group had a statistically significant greater improvement at week 52 in NPS and NCS compared to the placebo group.

In 2014, the Joint Task Force on Practice Parameters (JTFPP) representing the American Academy of Allergy, Asthma & Immunology (AAAAI), the American College of Allergy, Asthma & Immunology (ACAAI) and the Joint Council of Allergy, Asthma & Immunology published a practice parameter on the diagnosis and management of rhinosinusitis. In 2025, the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNS) published a clinical practice guideline on adult sinusitis. Both publications recommend confirming a clinical diagnosis of nasal polyps with imaging using anterior rhinoscopy, nasal endoscopy or computed tomography (CT). Intranasal corticosteroids are recommended for long-term treatment of nasal polyps. A short course of oral corticosteroids is included as a reasonable option to decrease polyp size and alleviate symptoms. Sinonasal surgery is another treatment option.

In 2022, the JTFPP published guidelines for the medical management of CRSwNP. The guidelines focus on select interventions for treatment of CRSwNP including intranasal corticosteroids, biologics and aspirin therapy after desensitization. The guidelines recommend intranasal corticosteroids over no intranasal corticosteroids in individuals with CRSwNP. The guidelines also recommend biologics over no biologics but note it is a conditional recommendation as other treatment options should be considered or used together with biologics (including inhaled corticosteroids and surgery).

Approved Indications

A. For the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
B. For the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

Other Uses

A. N/A

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Codes Information

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
J32.0-J32.9	Chronic sinusitis
J33.0-J33.9	Nasal polyp
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)

A. Criteria For Initial Approval

a. Initial requests for Tezspire (tezepelumab-ekko) for *severe asthma* 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**

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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).

b. Initial requests for Tezspire (tezepelumab-ekko) for chronic rhinosinusitis with nasal polyps (CRSwNP) 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 chronic rhinosinusitis with nasal polyps (CRSwNP); **AND**

iii. Documentation is provided of presence of nasal polyps demonstrated on one of the following (AAO-HNS 2025):

A. Anterior rhinoscopy;
OR

B. Nasal endoscopy;
OR

C. Computed tomography (CT); **AND**

iv. Individual has had a trial and inadequate response to maintenance intranasal corticosteroids; **AND**

v. Individual is refractory to or is ineligible or intolerant to the following (AAAAI/ACAAI 2014, JTFPP 2022):

A. Systemic corticosteroids;
OR

B. Sinonasal surgery; **AND**

vi. Individual is requesting Tezspire (tezepelumab-ekko) as add-on therapy to maintenance intranasal corticosteroids.

B. Criteria For Continuation of Therapy

a. MMM considers continuation of Syfovre (pegcetacoplan) therapy medically necessary in members requesting reauthorization for *severe asthma* 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

B. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids);
OR

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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.

b. MMM considers continuation of Syfovre (pegcetacoplan) therapy medically necessary in members requesting reauthorization for *chronic rhinosinusitis with nasal polyps (CRSwNP)* if the following criteria are met:

i. Treatment with Tezspire (tezepelumab-ekko) has resulted in clinically significant improvement in clinical signs and symptoms of disease (including but not limited to improvement in nasal congestion or reduced nasal polyp size); AND

ii. Individual continues to use Tezspire (tezepelumab-ekko) in combination with maintenance intranasal corticosteroids.

C. Authorization Duration

a. Initial Approval Duration: 6 months
b. Reauthorization Approval Duration: Up to 12 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

i. For the relief of acute bronchospasm or status asthmaticus;
OR

ii. In combination with Cinqair, Dupixent, Fasenra, Nucala or Xolair;
OR

iii. May not be approved when the above criteria are not met and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

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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 pen/syringe/vial per 28 days
Dosage	
• 210 mg subcutaneous every 4 weeks * TEZSPIRE vial and pre-filled syringe are intended for administration by a healthcare provider. TEZSPIRE pre-filled pen can be administered by patients/caregivers or healthcare providers. Patients/caregivers may administer TEZSPIRE pre-filled pen after proper training in subcutaneous injection technique and after the healthcare provider determines it is appropriate.	

Reference Information

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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.

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Policy History

Type of Revision	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Background Information updated to include the new indication for chronic rhinosinusitis with nasal polyps (CRSwNP) and to update the comparative doses for inhaled corticosteroids (Sharma, 2025). Clinical criteria added (initial and continuation) for the new indication of chronic rhinosinusitis with nasal polyps (CRSwNP). Limitations of use updated to specify that treatment for the relief of acute bronchospasm or status asthmaticus is not covered. Coding reviewed and updated, including the addition of ICD-10-CM codes J32.0–J32.9 and J33.0–J33.9. Recommended dosage added. References list updated. Wording and formatting updates made throughout the document.	2/13/2026	2/22/2026
Annual Review	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