Pharmacy Medical Necessity Guidelines:
Tezspire® (tezepelumab-ekko) pre-filled pen

Effective: March 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Tezspire (tezepelumab-ekko) is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ) indicated for:

- **Asthma**
  The add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. Not for relief of acute bronchospasm or status asthmaticus.
- **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**
  The add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps

COVERAGE GUIDELINES

The plan may authorize coverage of Tezspire (tezepelumab-ekko) prefilled-pen pen for Members, when **ALL** of the following criteria are met:

Asthma

Initial Authorization Criteria

1. Documented diagnosis of severe asthma

AND

2. Patient is at least 12 years of age or older

AND

3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

AND

4. Documentation of **one (1)** of the following within the past 12 months:
   a. History of two (2) or more asthma exacerbations requiring oral or injectable corticosteroid treatment
   b. One (1) asthma exacerbation resulting in hospitalization

AND

5. Documentation the patient is currently maintained on a maximally tolerated inhaled corticosteroid plus at least one other asthma maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist)

AND

6. Documentation the Member will not be concurrently treated with an alternative biologic for asthma

Reauthorization Criteria

1. Documented diagnosis of severe asthma

AND

2. Member is 12 years of age or older or older

AND

3. Prescribed by or in consultation with an allergist, immunologist or pulmonologist

AND

4. Documentation the Member has experienced a therapeutic response as defined by at least on (1) of the following:
   a. Increase in percent Forced Expiratory Volume (FEV1) from pretreatment baseline
   b. Reduction in the dose of inhaled corticosteroids required to control asthma

c. Reduction in asthma exacerbations (e.g., decreased frequency of use of unscheduled emergency department/urgent care visits/hospitalizations)
d. Reduction in asthma symptoms (e.g., chest tightness, coughing, shortness of breath, or nocturnal awakenings)
e. Reduction in the use of oral corticosteroids to treat and/or prevent asthma exacerbations

AND

5. Documentation the Member will not be concurrently treated with an alternative biologic for asthma

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Initial Authorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps as evidenced by both of the following:
    a. Symptoms of chronic rhinosinusitis for at least 12 weeks (e.g., decreased sense of smell; facial pressure, pain, fullness; mucopurulent drainage; mucosal inflammation; nasal obstruction)
    b. Presence of nasal polyps

AND

2. Patient is at least 12 years of age or older

AND

3. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist

AND

4. Documentation of **one (1)** of the following:
    a. Member is concurrently treated with intranasal corticosteroids
    b. Contraindication to intranasal corticosteroids

AND

5. The patient will not be concurrently treated with an alternative biologic for nasal polyps

Reauthorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Patient is at least 12 years of age or older

AND

3. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist

AND

4. Documented of **one (1)** of the following:
    a. Patient is concurrently treated with intranasal corticosteroids
    b. Contraindication to intranasal corticosteroids

AND

5. Documentation the patient has experienced a therapeutic response as defined by at least **one (1)** of the following:
    a. Adequate sinus ventilation and drainage
    b. Control of mucosal inflammation and edema
    c. Reduction in exacerbations

AND

6. The patient will not be concurrently treated with an alternative biologic for nasal polyps

LIMITATIONS

1. Initial coverage of Tezspire (tezepelumab-ekko) will be authorized for 6 months. Reauthorization will be granted for 12 months.
2. Members new to the plan and stable on Tezspire (tezepelumab-ekko) should be reviewed against Reauthorization Criteria.

CODES

None

REFERENCES

1. Tezspire (tezepelumab-ekko) [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; October 2025.
2. National Heart, Lung, and Blood Institute (NHLBI) & National Asthma Education and Prevention Program (NAEPP). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group (EPR-4). 2020. Accessed April 17, 2024.
3. National Heart, Lung, and Blood Institute (NHLBI) & National Asthma Education and Prevention Program (NAEPP). Guidelines for the Diagnosis and Management of Asthma (EPR-3). 2007. Accessed April 17, 2024.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention - GINA Report Updated 2023. 2023. Accessed April 17, 2024
5. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014 Feb; 43(2):343-373.
6. Chun EJ, Zhang HP, Lv Yan, et al. The Asthma Control Test and Asthma Control Questionnaire for assessing asthma control: systemic review and meta -analysis. J Allergy Clin Immunol. 2013 Mar;131(3):695-703.

APPROVAL HISTORY

May 9, 2023: Reviewed by Pharmacy & Therapeutics Committee.

- May 14, 2024: Removed documentation the underlying condition or triggers for asthma or pulmonary disease are being maximally managed. Added documentation of one of the following within the previous 12 months: history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or one asthma exacerbation resulting in hospitalization. Updated prerequisite requirements. Minor wording updates (eff 8/1/24).
- May 13, 2025: No changes (eff 5/13/25).
- February 10, 2026: Added coverage criteria for chronic rhinosinusitis with nasal polyps (eff 3/1/2026).

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services