Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Tezspire® (tezepelumab-ekko) Pre-filled Pen**

Effective: September 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Tezspire (tezepelumab-ekko) Pre-filled Pen 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 indicated 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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Tezspire pre-filled pen for Members when **ALL** of the following criteria are met:

Asthma

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of severe asthma

AND

2. Patient is 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 systemic corticosteroids
   b. One (1) asthma exacerbation resulting in hospitalization

AND

5. Documentation of history of failure to a minimum three (3) month trial with 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), unless contraindicated

AND

6. Documentation the requested medication will be used as add-on maintenance therapy with 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), unless contraindicate)

AND

7. Documentation the patient is not receiving the requested medication in combination with any of the following:

a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
b. Anti-IgE therapy (e.g., omalizumab)
c. Anti-interleukin 4 therapy (e.g., dupilumab)

Reauthorization Criteria

1. Documented diagnosis of severe asthma

AND

2. Patient is 12 years of age or older

AND

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

AND

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:
   a. Increase in percent predicted 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)
   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 requested medication will be used as add-on maintenance therapy with 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), unless contraindicated

AND

6. Documentation the patient is not receiving the requested medication in combination with any of the following:
   a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
   b. Anti-IgE therapy (e.g., omalizumab)
   c. Anti-interleukin 4 therapy (e.g., dupilumab)

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Patient is 12 years of age or older

AND

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

AND

4. Documentation of history of failure to a minimum four (4) week trial of intranasal corticosteroids, unless contraindicated

AND

5. Documentation the requested medication will be used as add-on maintenance therapy with intranasal corticosteroids, unless contraindicated

AND

6. Documentation the patient is not receiving the requested medication in combination with any of the following:
   a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
   b. Anti-IgE therapy (e.g., omalizumab)
   c. Anti-interleukin 4 therapy (e.g. dupilumab)

Reauthorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Patient is 12 years of age

AND

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

AND

4. Documented the requested medication will be used as add-on maintenance therapy with intranasal corticosteroids, unless contraindicated

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. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
    b. Anti-IgE therapy (e.g., omalizumab)
    c. Anti-interleukin 4 therapy (e.g. dupilumab)

Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
2. Initial approval of Tezspire pre-filled pen will be authorized for six (6) months. Reauthorization of Tezspire pre-filled pen will be provided in 12-month intervals.
3. Patients new to the plan stable on Tezspire pre-filled pen should be reviewed against Reauthorization Criteria. Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against Initial Authorization 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 And Revision History

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

- May 14, 2024: Updated diagnosis requirements to include current treatment with another biologic for moderate to severe asthma. Removed a documented trial and failure or intolerance to other respiratory biologics (Dupixent, Fasenra, Nucala, Xolair) based on the requested use of the medication, respectively. Clarified that either two exacerbations requiring steroids or resulting in hospitalization have to be within the previous 12 months (eff 06/1/2024).
- May 13, 2025: No changes (eff 5/13/25).
- February 10, 2026: Added coverage criteria for chronic rhinosinusitis with nasal polyps (eff 3/1/26).
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template
- June 9, 2026: For Asthma added submission of medical charts confirming diagnosis (Initial), removed current treatment with an alternative respiratory biologic as confirmation of diagnosis (Initial), added severity requirements (history of exacerbations or hospitalization), separated confirmation of history of failure of inhaler prerequisites and requested use as add-on therapy to inhalers (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), enhanced concurrent therapy language (Initial and Reauthorization), added confirmation treatment will be used as add-on therapy (Reauthorization), and added submission of medical charts confirming objective reauthorization criteria (Reauthorization). For Chronic Rhinosinusitis with Nasal Polyps added additional objective responses to therapy in objective reauthorization criteria (Reauthorization), separated confirmation of history of failure of inhaler prerequisites and requested use as add-on therapy to inhalers (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), enhanced concurrent therapy language (Initial and Reauthorization), and submission of medical charts confirming objective reauthorization criteria (Reauthorization). Added limitation statement that members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against initial approval criteria. (eff 9/1/26).
- August 11, 2026: Removed submission of medical records requirements for response to therapy in Reauthorization Criteria

(eff 9/1/26).

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.