Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Tezspire (tezepelumab-ekko)

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

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

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) 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 in 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 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. Prior asthma-related 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 contraindicated

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 at least **one (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 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

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 eight (8) 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 or older

AND

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

AND

4. Documentation 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 **one (1)** of the following:
    a. Adequate sinus ventilation and drainage
    b. Control of mucosal inflammation and edema
    c. Reduction in exacerbations

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)

Limitations

- Initial approval of Tezspire will be authorized for six (6) months. Reauthorization of Tezspire will be provided in 12-month intervals.
- Patients new to the plan and stable on Tezspire 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 approval criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2356	Injection, tezepelumab-ekko, 1 mg

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

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- October 10, 2023: Minor wording changes. Administrative update to clarify use of Reauthorization Criteria for Members new to the plan stable on Tezspire (effective 11/1/2023).
- May 14, 2024: Removed documentation the underlying condition or triggers for asthma or pulmonary disease are being maximally managed. Added "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. Modified language to "Documentation the patient is currently maintained on a maximally tolerated corticosteroid plus at least one other asthma maintenance medication (e.g., long-acting inhaled beta-2 agonist (LABA), long-acting muscarinic antagonist, leukotriene receptor antagonist). Added "The patient will not be concurrently treated with an alternative biologic for asthma" Removed the Limitation Coverage will not be authorized if the Member is also receiving another biologic medication for the treatment of asthma (e.g., Dupixent, Xolair, Cinqair, Fasenra, Nucala) (eff 8/1/2024).

- May 13, 2025: Updated diagnosis requirements for the Initial Authorization Criteria to also include “Current treatment with an alternative biologic indicated for moderate to severe asthma.” Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template. (eff 6/1/25).
- February 10, 2026: Added coverage criteria for chronic rhinosinusitis with nasal polyps. Administrative update: removed Carelink from template (eff 3/1/26).
- June 9, 2026: Removed Tufts Health RITogether from the Medical Necessity Guideline. 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. 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). (eff 9/1/26). Administrative update to template to remove CareLink from the Medical Necessity Guideline template. Administrative update: updated template to read: “Tufts Health Together- MassHealth Accountable Care Partnership Plans; Fax 617-673-0939”, to reflect change.
- 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

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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