UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Immunologicals – Tezspire Utilization Management Medical Policy
- Tezspire® (tezepelumab-ekko subcutaneous injection – AstraZeneca/Amgen)

REVIEW DATE: 10/29/2025; selected revision 11/05/2025

OVERVIEW

Tezspire, a thymic stromal lymphopoietin (TSLP) blocker, is indicated for the following uses:[1]
- **Severe asthma** as add-on maintenance treatment in patients ≥ 12 years of age.
- **Chronic rhinosinusitis with nasal polyps (CRSwNP)**, as an add-on maintenance treatment in patients ≥ 12 years of age with inadequately controlled disease.

Clinical Efficacy

Asthma

Tezspire has been studied in patients ≥ 12 years of age with severe asthma.[2] The patients enrolled in the Phase III pivotal Tezspire trial had experienced two or more asthma exacerbations in the previous year, despite treatment with a medium- or high-dose inhaled corticosteroid (ICS) and one additional controller medication (e.g., long-acting beta$_2$-agonist [LABA], leukotriene antagonist).[2,3] In one study, 6 months of these previous therapies were required for enrollment, while in another, 12 months of ICS therapy with at least 3 months of additional controller therapy was required. In these trials, asthma exacerbation data was evaluated following 52 weeks of treatment. However, improvements in lung function parameters and symptom scores were reported as early as the first post-baseline assessment (i.e., 2 weeks of therapy).

Chronic Rhinosinusitis with Nasal Polyps

To enroll in the pivotal CRSwNP studies of Tezspire, patients were required to have experienced ongoing nasal symptoms for at least 8 weeks.[1,10] Additionally, prior treatment with a systemic corticosteroid (or a contraindication) within the previous 12 months or prior surgery for nasal polyps were key enrollment requirements. The primary efficacy endpoints were evaluated following 52 weeks of treatment. However, improvements in these endpoints with Tezspire vs. placebo were observed as early as the first 2 to 4 weeks of treatment and were sustained over the 52-week treatment period. Patients continued intranasal corticosteroid background therapy throughout the studies.

Guidelines

Asthma Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention (2025) proposes a stepwise approach to asthma treatment.[4] Tezspire is listed as an option for add-on therapy in patients ≥ 12 years of age with uncontrolled severe asthma. Severe asthma is defined as asthma that is uncontrolled despite adherence to optimized high-dose ICS/LABA therapy or that worsens when high-dose treatment is decreased. Higher blood eosinophil levels and higher fractional exhaled nitric oxide may predict a good asthma response to Tezspire.

According to the European Respiratory Society/American Thoracic Society guidelines (2014; updated in 2020), severe asthma is defined as asthma which requires treatment with a high-dose ICS in addition to a second controller medication (and/or systemic corticosteroids) to prevent it from becoming uncontrolled, or asthma which remains uncontrolled despite this therapy.[5,6] Uncontrolled asthma is defined as asthma that worsens upon tapering of high-dose ICS or systemic corticosteroids or asthma that meets one of the following four criteria:

1) Poor symptom control: Asthma Control Questionnaire consistently ≥ 1.5 or Asthma Control Test < 20;

2) Frequent severe exacerbations: two or more bursts of systemic corticosteroids in the previous year;
3) Serious exacerbations: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year;
4) Airflow limitation: forced expiratory volume in 1 second (FEV_1) < 80% predicted after appropriate bronchodilator withholding.

Chronic Rhinosinusitis with Nasal Polyps Guidelines

The Joint Task Force on Practice Parameters (JTFPP) published a focused guideline update for the medical management of CRSwNP (2023), which updated recommendations regarding intranasal corticosteroids and biologic therapies.[13] Intranasal corticosteroids are recommended for the treatment of CRSwNP. Use of biologics (e.g., Dupixent) is also recommended. However, in patients who derived a sufficient benefit from other therapies such as intranasal corticosteroids, surgery, or aspirin therapy after desensitization, biologics may not be preferred. Conversely, biologics may be preferred over other medical treatment options in patients who continue to have a high burden of disease despite receiving at least 4 weeks of treatment with an intranasal corticosteroid.

The diagnosis of CRSwNP was not addressed in this focused guideline update, but previous guidelines have noted that the presence of two or more signs and symptoms of chronic rhinosinusitis (e.g., rhinorrhea, postnasal drainage, anosmia, nasal congestion, facial pain, headache, fever, cough, and purulent discharge) that persist for an extended period of time makes the diagnosis chronic rhinosinusitis likely.[14-17] However, this requires confirmation of sinonasal inflammation, which can either be done via direct visualization or computed tomography (CT) scan. Oral corticosteroids and surgical intervention were not specifically addressed in this update, but prior guidelines recommend short courses of oral corticosteroid as needed and consideration of surgical removal as an adjunct to medical therapy in patients with CRSwNP that is not responsive or is poorly responsive to medical therapy.[14,15,17]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Tezspire. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tezspire as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Tezspire to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tezspire is recommended in those who meet the following criteria:

FDA-Approved Indication

Asthma. Approve Tezspire for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 12 years of age; AND

ii. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b):

a) An inhaled corticosteroid; AND

b) At least one additional asthma controller or asthma maintenance medication; AND

Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta$_2$-agonists, inhaled long-acting muscarinic antagonists, and monoclonal antibody therapies for asthma (e.g., Tezspire, Cinqair [reslizumab intravenous infusion], Fasenra [benralizumab subcutaneous injection], Nucala [mepolizumab subcutaneous injection]), Dupixent [dupilumab subcutaneous injection], Xolair [omalizumab subcutaneous injection]). Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfill the requirement for both criteria a and b.

iii. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, or e):

Note: "Baseline" is defined as prior to receiving Tezspire or another monoclonal antibody therapy for asthma. Examples of monoclonal antibody therapies for asthma include Cinqair, Dupixent, Fasenra, Nucala, Tezspire, and Xolair.

a) Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR

b) Patient experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year; OR

c) Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; OR

d) Patient has an FEV_1/forced vital capacity (FVC) < 0.80; OR

e) Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy; AND

iv. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; OR

B) Patient is Currently Receiving Tezspire. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has already received at least 6 months of therapy with Tezspire; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Tezspire should be considered under criterion 1A (Asthma, Initial Therapy).

ii. Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; AND

iii. Patient has responded to therapy as determined by the prescriber.

Note: Examples of a response to Tezspire therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department, urgent care, or medical clinic visits due to asthma; improved lung function parameters; and/or a decreased requirement for oral corticosteroid therapy.

Dosing. Approve 210 mg given subcutaneously once every 4 weeks.

Chronic Rhinosinusitis with Nasal Polyps. Approve for the duration noted if the patient meets ONE of the following (A or B):

- **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
  - **i)** Patient is ≥ 12 years of age; AND
  - **ii)** Patient has chronic rhinosinusitis with nasal polyps as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan; AND
  - **iii)** Patient has had the diagnosis of chronic rhinosinusitis with nasal polyps for at least 6 months; AND
  - **iv)** Patient has experienced two or more of the following symptoms for at least 8 weeks: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell; AND
  - **v)** Patient meets BOTH of the following (a and b):
    - **a)** Patient has received at least 4 weeks of therapy with an intranasal corticosteroid; AND
    - **b)** Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Tezspire; AND
  - **vi)** Patient meets ONE of the following (a, b, or c):
    - **a)** Patient has received at least one course of treatment with a systemic corticosteroid within the previous year; OR
      Note: One course of a systemic corticosteroid is ≥ 3 consecutive days of treatment or one long-acting injectable dose.
    - **b)** Patient has a contraindication to systemic corticosteroid therapy; OR
    - **c)** Patient has had prior surgery for nasal polyps; AND
  - **vii)** The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose, and throat [ENT] physician specialist); OR
- **B)** Patient is Currently Receiving Tezspire. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
  - **i)** Patient has already received at least 6 months of therapy with Tezspire; AND
    Note: A patient who has received < 6 months of therapy or who is restarting therapy with Tezspire should be considered under criterion 2A (Chronic Rhinosinusitis with Nasal Polyps, Initial Therapy).
  - **ii)** Patient continues to receive therapy with an intranasal corticosteroid; AND
  - **iii)** Patient has responded to therapy as determined by the prescriber.
    Note: Examples of a response to Tezspire therapy are reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sinonasal symptoms, improved sense of smell.

Dosing. Approve 210 mg given subcutaneously once every 4 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tezspire is not recommended in the following situations:

1. **Atopic Dermatitis.** Tezspire is not indicated for the treatment of atopic dermatitis.[1] One Phase IIa study, ALLEVIAD (published) [n = 113] evaluated the efficacy of Tezspire in combination with topical corticosteroids (TCS) vs. placebo in adults with moderate to severe atopic dermatitis.[7] At Week 12, a larger proportion of patients in the Tezspire + TCS group achieved a 50% reduction in the Eczema Area and Severity Index (primary efficacy endpoint) compared with placebo + TCS. However, this treatment difference was not statistically significant. Another Phase II, dose-ranging study in patients with atopic dermatitis was terminated prior to completion.[8]

Chronic Obstructive Pulmonary Disease (COPD). Tezspire is not indicated for the treatment of COPD.[1] One Phase II, randomized, double-blind, placebo-controlled trial, COURSE, evaluated the efficacy of Tezspire in patients with moderate- to very severe-COPD who continued to experience exacerbations despite triple inhaled maintenance therapy (i.e., ICS/LABA/long-acting muscarinic antagonist).[8] In this patient population, Tezspire did not result in a significant reduction in the annualized rate of moderate or severe COPD exacerbations compared with placebo.[9]

2. **Chronic Spontaneous Urticaria**. Tezspire is not indicated for the treatment of chronic spontaneous urticaria.[1] One Phase II, randomized, double-blind, placebo-controlled trial, INCEPTION, evaluated the efficacy of Tezspire in patients with chronic spontaneous urticaria.[8,12] At Week 16, the primary end point was not met. In the overall population, Tezspire did not significantly improve weekly Urticaria Activity Score (UAS7) versus placebo. In a subgroup of anti-immunoglobulin E-naïve patients, there was numeric improvement in the UAS7compared with placebo, but these improvements were not significant.

3. **Concurrent use of Tezspire with another Monoclonal Antibody Therapy.** The efficacy and safety of Tezspire used in combination with other monoclonal antibody therapies have not been established. Note: Monoclonal antibody therapies are Adbry® (tralokinumab-ldrm subcutaneous [SC] injection), Cinqair® (reslizumab intravenous infusion), Dupixent® (dupilumab SC injection), Ebglyss™ (lebrikizumab-lbkz SC injection), Fasenra® (benralizumab SC injection), Nemluvio® (nemolizumab-ilto SC injection), Nucala® (mepolizumab SC injection), or Xolair® (omalizumab SC injection).

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Conditions Not Recommended for Approval:** For "Concurrent use of Tezspire with another Monoclonal Antibody Therapy", the condition was updated to specify that "other monoclonal antibody therapy" is defined as "Cinqair, Dupixent, Fasenra, Nucala, Xolair, and Adbry". There were no other changes to the criteria.	02/08/2023
Annual Revision	No criteria changes.	02/14/2024
Annual Revision	No criteria changes.	02/19/2025
Update	03/05/2025: No criteria changes. **Asthma:** Leukotriene receptor antagonists were removed as an example of additional asthma controller or asthma maintenance medications.	NA
Early Annual Revision	**Chronic Rhinosinusitis with Nasal Polyps:** This new indication was added to the policy. **Conditions Not Recommended for Approval:** "Chronic Rhinosinusitis with Nasal Polyps" was removed as a Condition Not Recommended for Approval.	10/29/2025
Selected Revision	**Chronic Rhinosinusitis with Nasal Polyps:** A requirement that the patient has had the diagnosis of chronic rhinosinusitis with nasal polyps for at least 6 months was added. In the "Note" describing systemic corticosteroid therapy, the term "depo-injectable" was replaced with "long-acting injectable".	11/05/2025

NA – Not applicable.