POLICY: Immunologicals – Tezspire Utilization Management Medical Policy

- Tezspire™ (tezepelumab-ekko subcutaneous injection – AstraZeneca/Amgen)

EFFECTIVE DATE: 6/1/2022
LAST REVISION DATE: 02/19/2025

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Tezspire, a thymic stromal lymphopoietin (TSLP) blocker, is indicated as add-on maintenance treatment of **severe asthma** in patients ≥ 12 years of age.[1]

Clinical Efficacy

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).

Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention (2024) 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.

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

---

1. 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.

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]

2. **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]

3. **Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP).** Tezspire is not indicated for the treatment of CRSwNP.[1] One Phase III, randomized, double-blind, placebo-controlled trial, WAYPOINT, evaluated the efficacy of Tezspire in adults with severe CRSwNP.[10] Following 52 weeks of therapy, Tezspire significantly improved the total Nasal Polyp Score and the mean Nasal Congestion Score compared with placebo. A post-hoc analysis of one of the Tezspire pivotal asthma studies also showed an improvement in sino-nasal symptoms with Tezspire in patients with concomitant asthma and CRSwNP.[11] Additional data are needed.

4. **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] Results are available from a subgroup of anti-immunoglobulin E-naïve patients. In this subgroup, there was numeric improvement in the Urticaria Activity Score over 7 days (UAS7) at Week 16 compared with placebo; these improvements were not significant compared with placebo.

5. **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).

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

REFERENCES

1. Tezspire® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; May 2023.
2. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in adults and adolescents with severe, uncontrolled asthma. *N Engl J Med*. 2021;384(19):1800-1809.
3. Corren J, Parnes JR, Wang L, et al. Tezepelumab in adults with uncontrolled asthma. *N Engl J Med*. 2017;377(10):936-946.
4. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2024. Available at: http://www.ginasthma.org. Accessed on February 7, 2025.
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;43:343-373.
6. Holguin F, Cardet JC, Chung KF, *et al*. Management of severe asthma: a European Respiratory Society/American Thoracic Society Guideline. *Eur Respir J*. 2020;55:1900588.
7. Simpson EL, Parnes JR, She D, et al. Tezepelumab, an anti-thymic stromal lymphopoietin monoclonal antibody, in the treatment of moderate to severe atopic dermatitis: a randomized phase 2A clinical trial. *J Am Acad Dermatol*. 2019;80(4):1013-1021.
8. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2025 Feb 7]. Available from: https://www.clinicaltrials.gov/ct2/results?cond=&term=tezepelumab&cntry=&state=&city=&dist=. Search term: tezepelumab.
9. Singh D, Brightling CE, Rabe KF, et al. Efficacy and safety of Tezepelumab versus placebo in adults with moderate to very severe chronic obstructive pulmonary disease (COURSE): a randomized, placebo-controlled, phase 2a trial. *Lancet Respir Med*. 2025;13(1):47-58.
10. Han J, Lipworth B, Desrosiers M, et al. Efficacy and safety of tezepelumab in adults with severe chronic rhinosinusitis with nasal polyps: results from the Phase 3 WAYPOINT study [abstract L44]. Presented at: the American Academy of Allergy, Asthma, and Immunology/World Allergy Organization Joint Congress; San Diego, CA; February 28 – March 3, 2025.
11. Laidlaw TM, Menzies-Gow A, Caveney S, et al. Tezepelumab efficacy in patients with severe, uncontrolled asthma with comorbid nasal polyps in NAVIGATOR. *J Asthma Allergy*. 2023;16:915-932.
12. Maurer M, McLaren J, Chon Y, et al. Sustained improvement in UAS7 after 16-week treatment with tezepelumab in biologic-naïve adults with CSU: results of the phase 2b INCEPTION study [abstract L39]. Presented at: the American Academy of Allergy, Asthma, and Immunology Annual Meeting; Washington D.C.; February 23-26, 2024.

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
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	02/19/2025
DEU Update	**Asthma:** Leukotriene receptor antagonists were removed as an example of additional asthma controller or asthma maintenance medications.	03/05/2025

DEU – Drug evaluation unit.