



UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 01/12/2022

OVERVIEW

Tezspire, a thymic stromal lymphopoietin (TSLP) blocker, is indicated as add-on maintenance treatment of patients ≥ 12 years of age with **severe asthma**.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 beta₂-agonist [LABA], leukotriene antagonist [LTRA], theophylline).^{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

Asthma Guidelines

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention (2021) does not address Tezspire.⁴ However, in general, biologic therapies (i.e., immunologicals) are recommended treatment options for select patients with severe asthma that cannot be managed by maximal, optimized high-dose ICS/LABA therapy and mitigation of other contributing factors.

The European Respiratory Society (ERS)/American Thoracic Society (ATS) guidelines (2014; updated in 2020) define severe asthma as requiring 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 (FEV₁) $< 80\%$ 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

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1. **Asthma.** Approve Tezspire for the duration noted if the patient meets one of the following conditions (A or B):
 - A) **Initial Therapy.** Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, and v):
 - 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 beta₂-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, anti-interleukin-5 therapies (e.g., Cinqair [reslizumab intravenous infusion], Fasentra [benralizumab subcutaneous injection], Nucala [mepolizumab subcutaneous injection]), Dupixent (dupilumab subcutaneous injection), Xolair (omalizumab subcutaneous injection), and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta₂-agonist 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):
 - 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 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 (FEV₁) < 80% predicted; OR
 - d) Patient has an FEV₁/forced vital capacity (FVC) < 0.80; OR
 - e) The patient has asthma that worsens upon tapering of oral corticosteroid therapy; AND
Note: “Baseline” is defined as prior to receiving any Tezspire, anti-interleukin-5 therapies (i.e., Cinqair, Fasentra, or Nucala), Dupixent, or Xolair.
 - iv. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

- B) Patient is Currently Receiving Tezspire.** Approve for 1 year if the patient meets the following criteria (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 (EASI-50) [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, is currently underway evaluating the efficacy of Tezspire in patients with moderate- to very severe-COPD who are continuing to experience exacerbations despite triple inhaled maintenance therapy (i.e., ICS/LABA/long-acting muscarinic antagonist [LAMA]).⁸ Results are not yet available.
- 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, is currently underway evaluating the efficacy of Tezspire in adults with severe CRSwNP.⁸ Results are not yet available.
- 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, is currently underway evaluating the efficacy of Tezspire in patients with chronic spontaneous urticaria.⁸ Results are not yet available.
- 5. Concurrent use of Tezspire with other Monoclonal Antibodies for Asthma.** The efficacy and safety of Tezspire used in combination with other monoclonal antibodies, such as Cinqair[®] (reslizumab intravenous infusion), Fasentra[®] (benralizumab subcutaneous injection), Nucala[®] (mepolizumab subcutaneous injection), Dupixent[®] (dupilumab subcutaneous injection), or Xolair (omalizumab subcutaneous injection), have not been established.
- 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; December 2021.
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4. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2021. Available at: <http://www.ginasthma.org>. Accessed on: December 20, 2021.
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 2021 Dec 20]. Available from: <https://www.clinicaltrials.gov/ct2/results?cond=&term=tezepelumab&cntry=&state=&city=&dist=>. Search term: tezpelumab.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|--------------------|-------------|
| New Policy | | 01/12/2022 |