



## PRIOR AUTHORIZATION POLICY

- POLICY:** Immunologicals – Tezspire Prior Authorization Policy
- Tezspire® (tezepelumab-ekko subcutaneous injection – AstraZeneca/Amgen)

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

### INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

### CIGNA NATIONAL FORMULARY COVERAGE:

#### OVERVIEW

Tezspire, a thymic stromal lymphopoietin (TSLP) blocker, is indicated for the following uses:<sup>1</sup>

- **Severe asthma** as add-on maintenance treatment in patients  $\geq 12$  years of age.
- **Chronic rhinosinusitis with nasal polyps (CRSwNP)**, as an add-on maintenance treatment in patients  $\geq 12$  years of age with inadequately controlled disease.

#### Clinical Efficacy

##### Asthma

Tezspire has been studied in patients  $\geq 12$  years of age with severe asthma.<sup>2</sup> 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<sub>2</sub>-agonist [LABA], leukotriene antagonist).<sup>2,3</sup> 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.<sup>1,10</sup> 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.<sup>4</sup> Tezspire is listed as an option for add-on therapy in patients  $\geq 12$  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.<sup>5,6</sup> 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  $\geq 1.5$  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<sub>1</sub>)  $< 80\%$  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.<sup>13</sup> 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.<sup>14-17</sup> 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.<sup>14,15,17</sup>

## **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of Tezspire. 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.

- **Tezspire® (tezepelumab-ekko subcutaneous injection - AstraZeneca/Amgen)**

**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### **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  $\geq$  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<sub>2</sub>-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<sub>1</sub>) < 80% predicted; OR
    - d) Patient has an FEV<sub>1</sub>/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.

**2. 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  $\geq 12$  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  $\geq 3$  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.

## CONDITIONS NOT COVERED

- **Tezspire® (tezepelumab-ekko subcutaneous injection - AstraZeneca/Amgen)**

**is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

- 1. Atopic Dermatitis.** Tezspire is not indicated for the treatment of atopic dermatitis.<sup>1</sup> 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.<sup>7</sup> 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.<sup>8</sup>
- 2. Chronic Obstructive Pulmonary Disease (COPD).** Tezspire is not indicated for the treatment of COPD.<sup>1</sup> 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).<sup>8</sup> 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.<sup>9</sup>
- 3. Chronic Spontaneous Urticaria.** Tezspire is not indicated for the treatment of chronic spontaneous urticaria.<sup>1</sup> One Phase II, randomized, double-blind, placebo-controlled trial, INCEPTION, evaluated the efficacy of Tezspire in patients with chronic spontaneous urticaria.<sup>8,12</sup> 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 UAS7 compared with placebo, but these improvements were not significant.
- 4. 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<sup>®</sup> (tralokinumab-ldrm subcutaneous [SC] injection), Cinqair<sup>®</sup> (reslizumab intravenous infusion), Dupixent<sup>®</sup> (dupilumab SC injection), Ebglyss<sup>™</sup> (lebrikizumab-lbkz SC injection), Fasentra<sup>®</sup> (benralizumab SC injection), Nemluvio<sup>®</sup> (nemolizumab-ilto SC injection), Nucala<sup>®</sup> (mepolizumab SC injection), or Xolair<sup>®</sup> (omalizumab SC injection).

## REFERENCES

1. Tezspire<sup>®</sup> subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; October 2025.
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. Lipworth BJ, Han JK, Desrosiers M, et al. Tezepelumab in adults with severe chronic rhinosinusitis with nasal polyps. *N Engl J Med*. 2025;392(12):1178-1188.
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. McLaren J, Chon Y, Gorski KS, et al. Tezepelumab for the treatment of chronic spontaneous urticaria: results of the phase 2b INCEPTION study. *J Allergy Clin Immunol*. 2025;155(6):1945-1956.
13. Rank MA, Chu DK, Bognanni A, et al. Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol*. 2023;151(2):386-398.
14. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol*. 2014:347-385.
15. Dykewicz MS, Wallace DV, Baroody F, et al. Treatment of seasonal allergic rhinitis: an evidenced-based focused 2017 guideline update. *Ann Allergy Asthma Immunol*. 2017;119(6):489-511.
16. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg*. 2015;152(2S):S1-S39.
17. Joint Task Force on Practice Parameters: American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology. Rhinitis 2020: a practice parameter update. *J Allergy Clin Immunol*. 2020;146:721-767.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<b>Conditions Not Covered:</b> 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.  <b>Asthma:</b> Leukotriene receptor antagonists were removed as an example of additional asthma controller or asthma maintenance medications.	NA
Early Annual Revision	<b>Chronic Rhinosinusitis with Nasal Polyps:</b> This new indication was added to the policy. <b>Conditions Not Covered:</b> "Chronic Rhinosinusitis with Nasal Polyps" was removed as a Condition Not Recommended for Approval.	10/29/2025
Selected Revision	<b>Chronic Rhinosinusitis with Nasal Polyps:</b> 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.

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2025 The Cigna Group.