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Coverage Policy Number **IP0412**

Tezepelumab-ekko

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Related Coverage Resources

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. 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.

Overview

This policy supports medical necessity review for tezepelumab-ekko (**Tezspire**™).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Tezepelumab-ekko (Tezspire) is considered medically necessary when the following are met:

Asthma. Individual meets **ALL** of the following criteria:
- A. Age 12 years or older
- B. Documented diagnosis of asthma is confirmed by **BOTH** of the following:
  - i. Pre-bronchodilator FEV1 below the lower limits of normal for age in the setting of reduced FEV1/FVC (usually less than 80% in adults and 90% in children)
  - ii. Variable expiratory airflow obstruction as documented by **ONE** of the following:

a. Increase of at least 12% **AND** 200 mL in FEV1 after the administration of 200 to 400 mcg albuterol or levalbuterol
b. Increase of at least 12% **AND** 200 mL in FEV1 from baseline between visits or after 4 weeks of treatment
c. Positive exercise or bronchial challenge testing

C. Asthma that is uncontrolled or was uncontrolled at baseline as defined by **ONE** of the following:
   i. Poor symptom control as defined by Asthma Control Questionnaire consistently greater than 1.5 or Asthma Control Test less than 20
   ii. Two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year
   iii. One or more asthma exacerbation(s) requiring hospitalization, an Emergency Department visit or an urgent care visit in the previous year
   iv. Daily or every other day oral corticosteroids are required to prevent asthma exacerbations

D. Has received at least three consecutive months of combination therapy with BOTH of the following:
   i. An inhaled corticosteroid
   ii. At least one additional asthma controller or asthma maintenance medication

E. Medication is prescribed by, or in consultation with, an allergist, immunologist or pulmonologist

Dosing. 210 mg given subcutaneously once every 4 weeks

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of tezepelumab-ekko (Tezspire) is considered medically necessary for asthma when the above medical necessity criteria are met, there is documentation of beneficial response, and the individual continues to receive therapy with one inhaled corticosteroid OR one inhaled corticosteroid-containing combination.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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, 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.[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 Antibody Therapy.** The efficacy and safety of Tezspire used in combination with other monoclonal antibody therapies have not been established.

6. **Treatment of Eosinophilic Gastroenteritis (EG), Eosinophilic Esophagitis (EE) or Eosinophilic Colitis.**

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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

Background

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 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 (2022) 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 difficult-to-treat, severe asthma (i.e., asthma that cannot be managed by therapy with an inhaled corticosteroid [ICS]/LABA combination with or without an additional controller). Higher blood eosinophil levels and higher fractional exhaled nitric oxide may predict a good asthma response to Tezspire.

The European Respiratory Society/American Thoracic Society 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;

Airflow limitation: forced expiratory volume in 1 second (FEV_1) < 80% predicted after appropriate bronchodilator withholding.

References

1. Tezspire subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; December 2021.
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 2021. Available at: http://www.ginasthma.org. Accessed on: March 2, 2022.
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: tezepelumab.