

Tezspire® (tezepelumab-ekko)

When requesting Tezspire® (tezepelumab-ekko), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Tezspire is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Coverage Guidelines

Severe Asthma

Initial authorization:

The individual must meet **all** of the following criteria:

- Has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and one additional asthma controller/maintenance medication (e.g., monoclonal antibody therapies, inhaled long-acting beta₂-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, a combination inhaler containing both an inhaled corticosteroid and a long acting beta₂-agonist);
- Asthma is/was uncontrolled prior to starting Tezspire or another monoclonal antibody therapy (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair) defined by ONE of the following:
 - Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - Has experienced one or more asthma exacerbations requiring hospitalizations, emergency room visits, or urgent care visits in the previous year; OR
 - Has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - Has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - Asthma worsens upon tapering of oral corticosteroids therapy;
- Is 12 years of age or older;
- Tezspire is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

Reauthorization:

The individual must meet **all** of the following criteria:

- Has already received at least 6 months of Tezspire therapy (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Tezspire should be considered under initial criteria*);
- Continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler (i.e., Flovent Diskus/HFA, ArmonAir RespiClick, Arnuity);
- Has responded to Tezspire therapy (i.e., decreased asthma symptoms or exacerbations; decreased hospitalizations, emergency room visits, urgent care visits)

or medical clinic visits due to asthma; decreased requirement for oral corticosteroids; improved lung function parameters).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendation

The recommended dose of Tezspire is 210 mg administered subcutaneously once every 4 weeks.

References

1. Tezspire™ subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; May 2023. .
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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 2022.. Available at: <http://www.ginasthma.org>. Accessed on: January 17, 2023.
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 2023 Jan 17]. Available from: <https://www.clinicaltrials.gov/ct2/results?cond=&term=tezepelumab&cntry=&state=&city=&dist=>. Search term: tezepelumab.