SmartHealth Ascension

Tezepelumab-ekko

(Tezspire®) J2356 (1mg)

Covered with prior authorization

Requests for Tezspire® (tezepelumab-ekko) may be approved if the following criteria are met:

- Individual is 12 years of age or older; **AND**
- Individual has a diagnosis of severe asthma; **AND**
- Evidence of asthma is demonstrated by the following (NAEPP 2008):
    - A pretreatment forced expiratory volume in 1 second (FEV1) less than 80% predicted; **AND**
    - FEV1 reversibility of at least 12% and 200 milliliters after albuterol administration; **AND**
- Documentation is provided that individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting beta2 –agonists, leukotriene modifiers, long-acting muscarinic antagonists or oral corticosteroids) (GINA 2021); **AND**
- Individual has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance dosage of oral corticosteroids (ERS/ATS 2013).

Continuation requests for Tezspire® (tezepelumab-ekko) may be approved if the following criteria are met:

- Treatment with Tezspire® has resulted in clinical improvement as confirmed by one or more of the following:
    - Decreased utilization of rescue medications; **OR**
    - Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
    - Increase in percent predicted FEV1 from pretreatment baseline; **OR**
    - Reduction in reported asthma-related symptoms, including asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance or wheezing.

Requests for Tezspire® (tezepelumab-ekko) may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial authorizations are for up to 6 months.

Renewal authorizations are for up to 12 months.

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.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Tezspire® (tezepelumab-ekko) is supplied as a 210 mg/1.91mL prefilled syringe/vial with usual dosing of 1 prefilled syringe/vial per 28 days.

Exclusion criteria:

- Tezspire® (tezepelumab-ekko) is not considered medically necessary when any of the following selection criteria is met:
    - In combination with Cinqair, Dupixent, Fasenra, Nucala or Xolair.
    - Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
    - Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.). Tezspire® (tezepelumab-ekko) is a thymic stromal lymphopoietin (TSLP) blocker and human monoclonal antibody (IgG2λ) that is approved by the Food and Drug Administration (FDA) for add-on maintenance treatment of adult and pediatric individuals aged 12 years and older with severe asthma. In 2013, the European Respiratory Society/American Thoracic Society (ERS/ATS) released guidance for defining, evaluating and treating severe asthma. The guidelines recommend to start by confirming the asthma diagnosis, including a spirometry assessment, and then differentiating severe asthma from milder asthma. The guidelines define severe asthma as asthma which has required treatment with high dose inhaled corticosteroids and a long-acting beta agonist, leukotriene modifier or theophylline for the previous year in order to prevent asthma symptoms from becoming uncontrolled. Alternatively, severe asthma can be defined as asthma that has required systemic corticosteroid treatment for over 50% of the previous year.

ERS/ATS guidance defines uncontrolled asthma as meeting one of the following:

- Poor symptom control: Asthma Control Questionnaire (ACQ) consistently >1.5, Asthma Control Test (ACT) <20.
- Frequent severe exacerbations: two or more bursts of systemic corticosteroids in the previous year.
- History of serious exacerbation: at least one hospitalization, intensive care unit stay or mechanical ventilation in the previous year.
- Airflow limitation: after appropriate bronchodilator withhold FEV1 <80% predicted.

The safety and effectiveness of Tezspire® for the treatment of severe asthma was established in two randomized, double-blind, placebo controlled trials (PATHWAY, NAVIGATOR). The trials included individuals with severe asthma on medium or high-dose inhaled corticosteroids and at least one additional asthma controller with or without oral corticosteroids. Participants were

required to have a history of asthma exacerbations in the last 12 months. Study data confirms the efficacy of Tezspire® in reducing asthma exacerbations and improving asthma control and quality of life measures. The 2021 Global Initiative for Asthma (GINA) guidelines recommend considering add-on targeted biologic therapy for individuals with exacerbations or poor symptom control despite taking at least high-dose inhaled corticosteroid/long acting beta2 –agonists and who have allergic or eosinophilic biomarkers or need maintenance oral corticosteroids. This guideline update predates the Tezspire® FDA approval.

Key References Accessed 8/2022:

1. Chung KF, Wenzel SE, Brozek JL, et al. International European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014; 43(2):343-373.
2. Cloutier MM, Baptist AP, Blake KV, et. al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program (NAEPP) Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol. 2020 Dec;146(6):1217-1270.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
4. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2021. Available from: http://ginasthma.org/gina-reports/.
5. Holguin F, Cardet JC, Chung KF, et. al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J. 2020 Jan 2;55(1):1900588.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. National Asthma Education and Prevention Program (NAEPP). Expert Panel Report 3: Guidelines for the diagnosis and management of asthma. NIH Publication Number 08-5846. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.