Tezspire (tezepelumab-ekko)
PAM – 080

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/01/2022
Revision Number	2	**Last Reviewed**	07/18/2025
Reviewed By	Medicaid Medical Director	**Next Review**	07/17/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	07/19/2024

Overview

Medication: [1]	tezepelumab-ekko
Brand Name:	Tezspire®
Pharmacologic Category:	Respiratory Tract/Pulmonary Agent; thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2 λ)
FDA-Approved Indication(s):	Indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. ➢ Limitations of Use: Not for relief of acute bronchospasm or status asthmaticus.
How Supplied:	• Single-dose vial: 210 mg/1.91 mL (110 mg/mL) • Single-dose prefilled syringe: 210 mg/1.91 mL (110 mg/mL) • Single-dose prefilled pen: 210 mg/1.91 mL (110 mg/mL)
Dosage and Administration:	• 210 mg once every 4 weeks • Administer by subcutaneous injection ○ Vial and prefilled syringe are intended for administration by a healthcare provider. ○ Pre-filled pen can be administered by patients/caregivers or healthcare providers. Patients/caregivers may administer pre-filled pen after proper training in SC injection technique and after the healthcare provider determines it is appropriate.
Benefit Category:	Medical

Descriptive Narrative

Asthma is a serious global health problem, affecting approximately 300 million people worldwide and causing around 1,000 deaths per day (most of these deaths occur in low- and middle-income countries, and most of them are preventable). Asthma interferes with people's work, education, and family life, especially when children have asthma.

The Global Initiative for Asthma (GINA) was established to increase awareness about asthma among healthcare providers, public health authorities, and communities, to improve management of asthma, and to help prevent asthma.

- *"Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms, such as wheeze, shortness of breath, chest tightness, and cough, that vary over time and in intensity, together with variable expiratory flow."*

This definition of asthma, from the GINA Annual Strategy Report, is based on consideration of the characteristics that are typical of asthma before inhaled corticosteroid (ICS)-containing treatment is started, and that distinguish it from other respiratory conditions.

Asthma is usually associated with airway hyperresponsiveness and airway inflammation, but these are not necessary or sufficient to make the diagnosis. The diagnosis of asthma is based on the history of characteristic symptom patterns and evidence of variable expiratory flow.

Uncontrolled asthma includes one or both of the following:

- Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma);
- Frequent exacerbations (2 or more per year) requiring oral corticosteroids (OCS), or severe exacerbations (1 or more per year) requiring hospitalization.

Difficult-to-treat asthma is asthma that is uncontrolled despite prescribing of medium or high-dose treatment with the combination of ICS and long-acting beta$_2$-agonist (LABA), or that requires high-dose ICS-LABA treatment to maintain good symptom control and reduce exacerbations.

Severe asthma is asthma that is uncontrolled despite adherence to optimized high-dose ICS/LABA therapy and treatment of contributory factors, or that worsens when high-dose treatment is decreased. Severe asthma places a large physical, mental, emotional, social, and economic burden on patients. Asthma is not classified as severe if it markedly improves when contributory factors such as inhaler technique and adherence are addressed. Severe asthma affects 5 to 10 percent of the asthma population but drives the majority of the morbidity and costs of the disease.[2]

Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention (2025) proposes a step-wise approach to asthma treatment. Tezspire® (tezepelumab) is included in the list of recommendations for add-on biologic therapy in patients 12 years of age and older with uncontrolled severe asthma despite optimized maximal therapy.[3]

Criteria

Prior authorization is required.

Tezspire® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of severe asthma; **AND**
2. Member has an inadequate response after, or a documented intolerance to, a minimum of 3 months of adherent treatment with appropriate controller therapy, i.e., medium-to-high dose inhaled corticosteroid (ICS) in combination with either a long-acting $beta_2$ agonist (LABA) or a leukotriene modifying agent (LTMA; if LABA is contraindicated or patient is intolerant to LABA therapy); **AND**
3. Documentation that member's asthma is not well-controlled, as indicated by **AT LEAST ONE** of the following:
    a. Asthma symptoms experienced more than 2 days per week despite adherent use of controller therapy (i.e., ICS-LABA or ICS-LTMA); and/or
    b. Spirometry measurement of FEV_1 (forced expiratory volume in one second) less than or equal to 80 percent predicted; and/or
    c. In the past 12 months, member has had two or more asthma exacerbations requiring oral or systemic corticosteroid treatment (or an increase in patient's current maintenance dose of oral corticosteroids), and/or an emergency office visit with specialist, an urgent care visit, or a hospital admission; **AND**
4. Member is 12 years of age or older; **AND**
5. Member does **NOT** have acute bronchospasm or status asthmaticus; **AND**
6. Tezspire® will not be used as monotherapy (i.e., member will continue treatment with ICS-LABA or ICS-LTMA); **AND**
7. Tezspire® will not be used in combination with Cinqair®, Dupixent®, Fasenra®, Nucala®, or Xolair®; **AND**
8. Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist; **AND**
9. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 210 mg every 4 weeks; or
    b. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Tezspire® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, [e.g., increase in FEV_1 (forced expiratory volume in one second) from baseline, decrease in the frequency of exacerbations, reduction in oral corticosteroid dosage if applicable, reduction in the use of rescue therapy]; **AND**
3. Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist; **AND**
4. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 210 mg every 4 weeks; or
    b. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	210 mg every 4 weeks	210 mg every 4 weeks

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J2356	Injection, tezepelumab-ekko, 1 mg

ICD-10	Description
J45.5	Severe persistent asthma
J45.50	Severe persistent asthma, uncomplicated

NDC	Dosage Form and Strength	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
55513-0100-01	210 mg/1.91 mL single-dose vial	Amgen Inc. (55513)	1 mg	1	EA	210
55513-0112-01	210 mg/1.91 mL single-dose prefilled syringe	Amgen Inc. (55513)	1 mg	1	EA	210
55513-0123-01	210 mg/1.91 mL single-dose prefilled pen	Amgen Inc. (55513)	1 mg	1	EA	210

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Tezspire® prescribing information (05/2023). Amgen Inc.: Thousand Oaks, CA. Available online: www.tezspirehcp.com. Accessed June 9, 2025.

[2] Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2025. Updated May 2025. Available from: www.ginasthma.org.

[3] Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2025. Updated May 2025. Available from: www.ginasthma.org.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
07/18/2025	CAC	Annual review. Updated Descriptive Narrative with information from the 2025 GINA Strategy Report. Added Guidelines section to policy.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/19/2024	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee