STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Tezspire (tezepelumab-ekko)
PAM–080

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	07/01/2022
Revision Number:	1	**Last Rev Date:**	07/19/2024
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	07/18/2025
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 o Vial and pre-filled syringe are intended for administration by a healthcare provider. o 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

A 2020 report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group presents focused updates to the previous 2007 asthma management guidelines on six priority topics (seventeen topics were suggested initially for updating, and six topics were found to have sufficient new information to warrant an update).

The Expert Panel 3 of the National Asthma Education and Prevention Program defines asthma as "a common chronic disorder of the airways that is complex and characterized by variable and recurring symptoms, airflow obstruction, bronchial hyperresponsiveness, and an underlying inflammation. The interaction of these features of asthma determines the clinical manifestations and severity of asthma and the response to treatment." [2]

Severe asthma affects 5 to 10 percent of the asthma population but drives the majority of the morbidity and costs of the disease. It is defined as requiring high-dose inhaled glucocorticoid, or continuous or near continuous oral glucocorticoid treatment to maintain asthma control, or never achieving control despite that treatment.[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 a 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. Tezspire® will not be used as monotherapy, i.e., member will continue treatment with 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**
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 this 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 at: www.tezspirehcp.com. Accessed May 24, 2024.

[2] Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol. 2020 Dec;146(6):1217-1270. PMID 33280709. Available online: www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines.

[3] Wenzel S. Evaluation of severe asthma in adolescents and adults. Dieffenbach P, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed June 4, 2024.

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
07/19/2024	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee