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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Respiratory Agents	**Original Policy Date:**	January 28, 2022
Subject:	Tezspire	**Page:**	1 of 5

Last Review Date: December 8, 2023

Tezspire

Description

Tezspire (tezepelumab-ekko)

Background
Tezspire (tezepelumab-ekko) is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody IgG2λ that binds to human TSLP and blocks its interaction with the heterodimeric TSLP receptor. TSLP is a cytokine mainly derived from epithelial cells and occupies an upstream position in the asthma inflammatory cascade. Blocking TSLP reduces biomarkers and cytokines associated with inflammation. Airway inflammation is an important component in the pathogenesis of asthma (1).

Regulatory Status
FDA-approved indication: Tezspire is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma (1).

Limitations of Use: (1)
- Not for relief of acute bronchospasm or status asthmaticus.

Tezspire contains warnings regarding the following: hypersensitivity reactions; acute asthma symptoms or deteriorating disease; risk associated with abrupt reduction of corticosteroid dosage; parasitic (helminth) infection; and live attenuated vaccines (1).

FEP adherence is defined as ≥50% utilization within the last 180 days.

The safety and effectiveness of Tezspire in pediatric patients less than 12 years of age have not been established (1).

Related policies
Cinqair, Dupixent, IL-5 Antagonist, Xolair

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tezspire may be considered **medically necessary** if the conditions indicated below are met.

Tezspire may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following **AND** submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Severe asthma
    a. Inadequate control of asthma symptoms after a minimum of 3 months of compliant use with greater than or equal to 50% adherence with **ONE** of the following within the past 6 months:
        i. Inhaled corticosteroids & long acting $beta_2$ agonist
        ii. Inhaled corticosteroids & long acting muscarinic antagonist
    b. Used as add-on maintenance treatment and patient will be receiving **ALL** of the following:
        i. Medium or high-dose inhaled corticosteroid
        ii. An additional controller medication (e.g., long acting $beta_2$ agonist, leukotriene modifier)
    c. **NOT** used for the relief of acute bronchospasm or status asthmaticus
    d. **NO** dual therapy with another monoclonal antibody for the treatment of

asthma
e. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following **AND** submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Asthma
    a. Decreased exacerbations **OR** improvement in symptoms
    b. Decreased utilization of rescue medications
    c. Patient has been compliant on Tezspire therapy
    d. Used as add-on maintenance treatment
    e. **NOT** used for the relief of acute bronchospasm or status asthmaticus
    f. **NO** dual therapy with another monoclonal antibody for the treatment of asthma
    g. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength / Dosage Form	Quantity
210 mg / 1.91 mL single-dose vial	3 units per 84 days
210 mg / 1.91 mL single-dose pre-filled syringe	
210 mg / 1.91 mL single-dose pre-filled pen	

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Tezspire (tezepelumab-ekko) is a TSLP blocker and human monoclonal antibody that is used for the add-on maintenance treatment of patients 12 years and older with severe asthma. Tezspire is not used for the relief of acute bronchospasm or status asthmaticus. It is also recommended to avoid the use of live attenuated vaccines with Tezspire. The safety and effectiveness of Tezspire in pediatric patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Tezspire while maintaining optimal therapeutic outcomes.

References

1. Tezspire [package insert]. Thousand Oaks, CA: AstraZeneca AB, Inc.; February 2023.
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2021. Available from www.ginasthma.org.

Policy History

Date	Action
January 2022	Addition to PA
March 2022	Annual review
April 2022	Per FEP, added initiation requirement that patient must be using as add-on maintenance treatment and will be using with a medium or high-dose

	corticosteroid and an additional controller medication and added renewal requirement that patient must be using as add-on maintenance treatment.
June 2022	Annual review
September 2022	Annual review
February 2023	Per PI update, added new dosage form pre-filled pen
June 2023	Annual review
December 2023	Annual review. Per SME, changed renewal requirement to decreased exacerbations or improvement in symptoms

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.