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# 5.45.015

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2025
<b>Subsection:</b>	Respiratory Agents	<b>Original Policy Date:</b>	January 28, 2022
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**Last Review Date:** December 13, 2024

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## Tezspire

### Description

#### Tezspire (tezepelumab-ekko)

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#### Background

Tezspire (tezepelumab-ekko) is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody IgG2 $\lambda$  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 (IgG2 $\lambda$ ), 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).

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FEP adherence is defined as  $\geq 50\%$  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).

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### 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<sub>2</sub> 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<sub>2</sub> 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

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- asthma or COPD (see Appendix 1)
- 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.

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## 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 or COPD (see Appendix 1)
  - 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

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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

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## 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](http://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

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	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
December 2024	Annual editorial review. Added Appendix 1

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.**

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## Appendix 1 - List of Monoclonal Antibodies for Asthma or COPD

Generic Name	Brand Name
benralizumab	Fasenra
dupilumab	Dupixent
mepolizumab	Nucala
omalizumab	Xolair
reslizumab	Cinqair
tezepelumab-ekko	Tezspire