

Medical Policy:

Tezspire (tezepelumab-ekko) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.356	February 11, 2025	May 12, 2022

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions:

Tezspire is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. 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 occupies an upstream position in the asthma inflammatory cascade. Blocking TSLP reduces biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, IgE, fractional exhaled nitric oxide (FeNO), interleukin-5, and interleukin-13. However, the mechanism of action in asthma has not been definitively established.

Length of Authorization

Initial coverage will be provided for 6 months; Renewal coverage: 12 months.

Dosing Limits [Medical Benefit]

- Approve 210 mg given subcutaneously once every 4 weeks. (210 billable units (210 mg) every 4 weeks)

Guideline

INITIAL APPROVAL CRITERIA

1. **Asthma** Approve for 6 months if the patient meets the following criteria (A, B, C, **AND** D)
 - A. Patient is ≥ 12 years of age; **AND**
 - B. Patient has received at least 3 consecutive months of combination therapy with **BOTH** of the following (i **AND** ii)
 - i. An inhaled corticosteroid; **AND**
 - ii. At least one additional asthma controller or asthma maintenance medication; **AND**
Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta₂-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, anti-interleukin-5 therapies (e.g., Cinqair [reslizumab intravenous infusion], Fasentra [benralizumab subcutaneous injection], Nucala [mepolizumab subcutaneous injection]), Dupixent (dupilumab subcutaneous injection), Xolair (omalizumab subcutaneous injection), and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta₂-agonist would fulfill the requirement for both criteria i and ii.
 - C. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by **ONE** of the following (i, ii, iii, iv, **OR** v)
Note: "Baseline" is defined as prior to receiving any Tezspire, anti-interleukin-5 therapies (ie. Cinqair, Fasentra, or Nucala), Dupixent, or Xolair.
 - i. Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
 - ii. Patient experienced one or more asthma exacerbation(s) requiring hospitalization, an Emergency Department visit, or an Urgent care visit in the previous year; **OR**
 - iii. Patient has a forced expiratory volume in 1 second (FEV₁) < 80% predicted; **OR**
 - iv. Patient has an FEV₁/forced vital capacity (FVC) < 0.8; **OR**
 - v. The patient has asthma that worsens upon tapering of oral corticosteroid therapy; **AND**
 - D. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

RENEWAL CRITERIA:

- A. **Patient is Currently Receiving Tezspire.** Approve for 1 year if the patient meets the following criteria (i, ii, **and** iii):
 - i. Patient has already received at least 6 months of therapy with Tezspire; **AND**
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Tezspire should be considered under initial criterion
 - ii. Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**
 - iii. Patient has responded to therapy as determined by the prescriber.
Note: Examples of a response to Tezspire therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department/urgent care, or medical clinic visits due to asthma; improved lung function parameters; and/or a decreased requirement for oral corticosteroid therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tezspire is not recommended in the following situations:

1. Concurrent use of Tezspire with another Monoclonal Antibody Therapy (i.e., Cinqair, Fasentra, Nucala, Dupixent, Xolair, or Adbry); **AND**
2. Concurrent use with live vaccines

Dosing/Administration:

The recommended dosage of Tezspire is 210 mg administered subcutaneously once every 4 weeks. Tezspire is

intended for administration by a healthcare provider.

Applicable Procedure Codes

Code	Description
J2356	Injection, tezepelumab-ekko, 1 mg

Applicable NDCs

Code	Description
55513-0112-01	Tezspire 210mg/1.91mL single-dose prefilled syringe
55513-0100-xx	Tezspire 210 mg/1.91 mL single-dose vial

ICD-10 Diagnoses

Code	Description
J45.50	Severe persistent asthma, uncomplicated

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	02/11/2025	Annual Review: No Criteria changes
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Added NDC 5513-0100-xx, no criteria changes
EmblemHealth & ConnectiCare	5/02/2023	Annual Review: added "Conditions not recommended for approval: 1. Concurrent use of Tezspire with another Monoclonal Antibody Therapy (i.e., Cinqair, Fasentra, Nucala, Dupixent, Xolair, or Adbry); AND 2. Concurrent use with live vaccines"
EmblemHealth & ConnectiCare	5/12/2022	New Policy

References

1. Tezspire™ [package insert]. Thousand Oaks, CA, Amgen, Inc. Updated December 2021. Accessed March 31st, 2022.