

Medical Policy

Tezspire™ (tezepelumab-ekko)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-107
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Tezspire™ (tezepelumab-ekko) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Tezspire will be provided for 6 months and may be renewed.

- Max Units (per dose and over time): 210 mg every 4 weeks

Initial

- A. Patient is at least 12 years of age; **AND**
- B. Tezspire will not be used in combination with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents (e.g., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab, etc.); **AND**

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- C. Tezspire will not be administered concurrently with live vaccines; **AND**
- D. Patient does not have an active or untreated helminth infection; **AND**
- E. Tezspire will not be used for the relief of acute bronchospasm or status asthmaticus;
AND

Severe Asthma

- A. Patient must have severe* disease; **AND**
- B. Tezspire will be used for add-on maintenance treatment in patients regularly receiving BOTH of the following:
 - a. Medium to high-dose inhaled corticosteroids; **AND**
 - b. An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers, etc.); **AND**
- C. Patient has had, in the previous year, two or more exacerbations requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) OR one exacerbation resulting in a hospitalization; **AND**
- D. Baseline measurement of at least one of the following for assessment of clinical status:
 - a. Use of systemic corticosteroids
 - b. Use of inhaled corticosteroids
 - c. Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
 - d. Forced expiratory volume in 1 second (FEV1)

*Severe disease may be defined by any of the following (not all inclusive):

- Symptoms throughout the day
- Nighttime awakenings, often 7x/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Renewal

- A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
- B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: parasitic (helminth) infection, severe hypersensitivity reactions, etc; **AND**
- C. Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
 - a. Use of systemic corticosteroids
 - b. Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
 - c. Hospitalizations
 - d. ER visits
 - e. Unscheduled visits to healthcare provider; **OR**
- D. Improvement from baseline in forced expiratory volume in 1 second (FEV1)

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LIMITATIONS/EXCLUSIONS

- Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

- TEZSPIRE™ (tezepelumab-ekko) injection, for subcutaneous use. Initial U.S. Approval: 2021

CODING

Applicable NDC Codes	
55513-0112-xx	Tezspire 210 mg/1.91 mL single-dose prefilled syringe
55513-0100-xx	Tezspire 210 mg/1.91 mL single-dose vial

Applicable Procedure Code	
J3590	Unclassified biologics

Applicable ICD-10 Codes	
J45.50	Severe persistent asthma, uncomplicated

EVIDENCE BASED REFERENCES

- Tezspire [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; December 2021. Accessed March 2022.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	March 1, 2023: Adopted by MA UM Committee – no changes made. January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan
P&T Committee Endorsement	5/24/2022