**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<br>Small Group: ALL<br>Medicare Advantage: ALL |



## 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**

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)

## LIMITATIONS/EXCLUSIONS

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

## DEFINITIONS

A. 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

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

## POLICY HISTORY

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