Corporate Medical Policy: Tezepelumab-ekko (Tezspire™) **"Notification"** **POLICY EFFECTIVE JANUARY 1, 2024**

Restricted Product(s):

- tezepelumab-ekko (Tezspire™) subcutaneous injection for administration by a healthcare professional

FDA Approved Use:

- Add-on maintenance treatment of adult and pediatric patients 12 years or older with severe asthma
- Limitations of use: Not for relief of acute bronchospasm or status asthmaticus

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient is 12 years of age or older; **AND**
2. The patient has a diagnosis of **severe asthma**; **AND**
3. ALL of the following:
    a. The patient has a history of uncontrolled asthma while on and adherent to asthma control therapy as demonstrated by ONE of the following:
        i. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months; **OR**
        ii. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months; **OR**
        iii. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered; **OR**
        iv. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted; **AND**
    b. ONE of the following:
        i. The patient is NOT currently being treated with the requested agent AND is currently treated with and adherent to a maximally tolerated inhaled corticosteroid for at least 3 months; **OR**
        ii. The patient is currently being treated with the requested agent AND ONE of the following:
            1. Is currently treated with and adherent to an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms; **OR**

2. Is currently treated with and adherent to a maximally tolerated inhaled corticosteroid for at least 3 months; **OR**

iii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL inhaled corticosteroid therapy; **AND**

c. ONE of the following:

i. The patient is currently being treated and adherent for at least 3 months with ONE of the following:

1. A long-acting beta-2 agonist (LABA); **OR**
2. A leukotriene receptor antagonist (LTRA); **OR**
3. A long-acting muscarinic antagonist (LAMA); **OR**
4. Theophylline; **OR**

ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL LABA, LTRA, LAMA, and theophylline therapies; **AND**

d. The patient will continue asthma control therapy [e.g., inhaled corticosteroids (ICS), LABA, LTRA, LAMA, theophylline] in combination with the requested agent; **AND**

4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
5. The patient will NOT receive the requested agent in combination with another biologic immunomodulator agent used for the same indication [e.g., benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala), omalizumab (Xolair), reslizumab (Cinqair)]; **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
7. The patient has a physical or cognitive limitation that makes the utilization of a self-administered formulation unsafe or otherwise not feasible, as demonstrated by BOTH of the following **[medical record documentation required]**:
   a. Inability to self-administer the medication; **AND**
   b. Lack of caregiver or support system for assistance with administration of self-administered products; **AND**
8. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
9. For requests for injection or infusion administration of the requested medication in an inpatient or outpatient hospital setting, Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

Continuation Criteria for Approval:

1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time they started therapy; **AND**
3. The patient has a diagnosis of **severe asthma** AND BOTH of the following:

   a. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:
      i. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV1); **OR**
      ii. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma; **OR**
      iii. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma; **OR**
      iv. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma; **AND**
   b. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline]; **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
5. The patient will NOT receive the requested agent in combination with another biologic immunomodulator agent used for the same indication [e.g., benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala), omalizumab (Xolair), reslizumab (Cinqair)]; **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
10. The patient has a physical or cognitive limitation that makes the utilization of a self-administered formulation unsafe or otherwise not feasible, as demonstrated by BOTH of the following **[medical record documentation required]**:
    a. Inability to self-administer the medication; **AND**
    a. Lack of caregiver or support system for assistance with administration of self-administered products; **AND**
7. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
8. For requests for injection or infusion administration of the requested medication in an inpatient or outpatient hospital setting, Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
tezepelumab-ekko (Tezspire™) subcutaneous (SC) injection	Severe asthma in patients ≥ 12 years old	SC: 210 mg once every 4 weeks	J2356	2,730

***Maximum units allowed for duration of approval**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an inpatient setting, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; OR
2. For requests for injection or infusion administration in an outpatient hospital setting, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); OR
    b. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; OR
    c. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; OR
    d. Re-initiation of therapy, defined as ONE of the following:
        i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; OR
        ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; OR
    e. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q2 annually.

January 2024: Criteria change: Added requirement for use of the self-administered product unless certain criteria are met. Removed step requirements through Dupixent, Fasenra, Nucala, and Xolair for associated indications. Minor adjustments made to formatting with no change to policy intent. **Policy notification given 11/1/2023 for effective date 1/1/2024**.
January 2023: Criteria update: Added requirement within initial criteria that patient must be adherent to use of conventional asthma control therapies. **Policy notification given 11/1/2022 for effective date 1/1/2023**.
July 2022: Coding update: Added HCPCS code J2356 to dosing reference table effective 7/1/2022, deleted C9399, J3490, and J3590 termed 6/30/2022.
February 2022: Original medical policy criteria issued.