Corporate Medical Policy: Tezepelumab-ekko (Tezspire®) **"Notification"** **POLICY EFFECTIVE JULY 1, 2026**

Restricted Product(s):

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

FDA Approved Use:

- For the 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
- For the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)

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 has a diagnosis of **severe asthma**; **AND**
   a. The patient is 12 years of age or older; **AND**
   b. ALL of the following:
      i. The patient has a history of inadequately controlled asthma despite adherence to asthma control therapy (i.e., inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA] combination therapy) as demonstrated by ONE of the following **[medical record documentation required]**:
         1. Two or more severe asthma exacerbations (i.e., required treatment with a systemic corticosteroids [steroid burst]) within the past 12 months; **OR**
         2. One or more serious asthma exacerbation(s) (i.e., required hospitalization, mechanical ventilation, or visit to the emergency room or urgent care) within the past 12 months; **OR**
         3. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered; **OR**
         4. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted; **AND**
      ii. The patient is currently treated with and adherent to maximally tolerated conventional therapies to include BOTH of the following:
         1. An inhaled corticosteroid regimen for the past 3 months **[medical record documentation required]**; **OR**

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a. The patient has a clinical intolerance/contraindication to ALL inhaled corticosteroid therapy **[medical record documentation required]**; **AND**

2. A regimen containing either a long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline, or zileuton for the past 3 months **[medical record documentation required]**; **OR**
    a. The patient has a clinical intolerance/contraindication to ALL LABA, LTRA, LAMA, and zileuton therapies **[medical record documentation required]**; **AND**

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

2. The patient has a diagnosis of **chronic rhinosinusitis with nasal polyposis (CRSwNP)**; **AND**
    a. The patient is 12 years of age or older; **AND**
    b. The patient has at least TWO of the following inadequately controlled symptoms consistent with chronic rhinosinusitis for at least 12 consecutive weeks prior to therapy initiation:
        i. Nasal obstruction, blockage, or congestion; **OR**
        ii. Nasal discharge (rhinorrhea or post-nasal drainage); **OR**
        iii. Facial pain or pressure; **OR**
        iv. Reduction or loss of smell (hyposmia/anosmia); **AND**
    c. The patient's diagnosis has been confirmed by ONE of the following **[medical record documentation required]**:
        i. Anterior rhinoscopy; **OR**
        ii. Nasal endoscopy; **OR**
        iii. Computed tomography (CT) of the sinuses; **AND**
    d. ONE of the following:
        i. The patient has had prior surgery for nasal polyps (e.g., adenoidectomy in pediatric patients, functional endoscopic sinus surgery [FESS], etc.) **[medical record documentation required]**; **OR**
        ii. The patient is not a candidate for sinus surgery **[medical record documentation required]**; **AND**
    e. ONE of the following:
        i. The patient has tried and had an inadequate response to an intranasal corticosteroid therapy (e.g., budesonide, fluticasone, mometasone, Sinuva) for at least 4 consecutive weeks within 12 weeks prior to therapy initiation **[medical record documentation required]**; **OR**
        ii. The patient has an intolerance or hypersensitivity to an intranasal corticosteroid therapy (e.g., budesonide, fluticasone, mometasone, Sinuva) **[medical record documentation required]**; **OR**
        iii. The patient has a clinical contraindication to ALL intranasal corticosteroid therapies **[medical record documentation required]**; **AND**

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f. ONE of the following:
    i. The patient is currently being treated and will continue to be treated with an intranasal corticosteroid therapy; **OR**
    ii. The patient has a clinical contraindication or intolerance to ALL intranasal corticosteroid therapies **[medical record documentation required]**; **AND**

3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist, otolaryngologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
4. The patient will NOT receive the requested agent in combination with another biologic immunomodulator agent used for the same indication (e.g., benralizumab [Fasenra], depemokimab [Exdensur], dupilumab [Dupixent], mepolizumab [Nucala], omalizumab [Xolair], reslizumab [Cinqair], etc.); **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
6. 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**
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)

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 or more of the following **[medical record documentation required]**:
        i. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV1) from pretreatment baseline; **OR**
        ii. The patient has had a decrease in utilization of rescue medications; **OR**
        iii. The patient has had a decrease in frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids); **OR**

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iv. The patient has had a reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing; **AND**

b. The patient is currently treated and is compliant with asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline); **OR**

4. The patient has a diagnosis of **chronic rhinosinusitis with nasal polyposis (CRSwNP)**; **AND**
   a. The patient has demonstrated positive clinical response while using the medication (e.g., improvement in nasal congestion/obstruction, reduction in nasal polyp score [NPS], improvement in sinus CT scan score, improved sense of smell, etc.) **[medical record documentation required]**; **AND**
   b. ONE of the following:
      i. The patient is currently being treated and will continue to be treated with an intranasal corticosteroid therapy; **OR**
      ii. The patient has a clinical contraindication or intolerance to ALL intranasal corticosteroid therapies **[medical record documentation required]**; **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist, otolaryngologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
6. The patient will NOT receive the requested agent in combination with another biologic immunomodulator agent used for the same indication (e.g., benralizumab [Fasenra], depemokimab [Exdensur], dupilumab [Dupixent], mepolizumab [Nucala], omalizumab [Xolair], reslizumab [Cinqair], etc.); **AND**
7. The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
8. 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**
9. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
10. 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)

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
tezepelumab-ekko (Tezspire®) subcutaneous (SC) injection	Severe asthma in patients ≥ 12 years old CRSwNP 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 a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
    c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    f. 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**
    g. Requirement of a change in the requested restricted product formulation; **AND**

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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.

1. Orlandi RR, Kingdom TT, Smith TL, et al. International consensus statement on allergy and rhinology: rhinosinusitis 2021. International Forum of Allergy & Rhinology. 2021;11(3):213-739.
2. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol*. 2023;151(2):386-398.

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.

July 2026: Criteria change: For CRSwNP indication: Added diagnostic requirements of presence of at least 2 inadequately controlled symptoms for at least 12 consecutive weeks prior to therapy initiation, and documented diagnostic confirmation by either anterior rhinoscopy, nasal endoscopy, or sinus CT imaging. Removed required trial and failure of Xhance or oral systemic corticosteroids, and updated trial and failure requirements to only include an intranasal corticosteroid for at least 4 consecutive weeks within 12 weeks prior to therapy initiation. Removed requirement of no combination use with Xhance. For CRSwNP continuation criteria, added requirement for documented demonstration of positive clinical response. Adjusted verbiage for current treatment with an intranasal corticosteroid within initial and continuation sections to add that the patient will continue to be treated with the intranasal corticosteroid. For asthma indication: Reformatted description of exacerbation history demonstrating uncontrolled disease despite adherence to asthma control therapy for clarity with no change to intent. Adjusted list of biologic immunomodulator agents not to be used in combination for clarity. Other minor adjustments made throughout policy for clarity with no change to policy intent. References added. **Policy notification given 5/1/2026 for effective date 7/1/2026**.
November 2025 v2: Criteria change: Added new indication for chronic rhinosinusitis with nasal polyps in patients 12 years and older, with corresponding criteria and dosing table updates.
November 2025: Criteria change: Updated Site of Care medical necessity criteria to add additional bypass for patients with a history of severe adverse events or conditions that cause an increased risk for severe adverse event to align with the Place of Service for Medical Infusions policy for clarity of intent.
July 2025: Criteria change: For initial criteria: Added required medical record documentation for demonstration of inadequate asthma control despite adherence to asthma control therapy. Reformatted criteria for current, adherent treatment with maximally tolerated conventional therapies for clarity, and added zileuton as an option. Added required medical record documentation for current, adherent treatment with maximally tolerated conventional therapies. For continuation criteria: Added required medical record documentation for demonstration of

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improvement or stabilization from baseline, and adjusted formatting and improvement/stability parameters to include decreased utilization of rescue medications, decreased exacerbation frequency, or reduced reported asthma-related symptoms. Other minor updates made throughout policy for clarity with no change to policy intent. **Policy notification given 5/2/2025 for effective date 7/1/2025**.
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.

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