

Tezspire® (tezepelumab-ekko)

When requesting Tezspire® (tezepelumab-ekko), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Asthma

Tezspire is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Chronic Rhinosinusitis with Nasal Polyps

Tezspire is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps.

Coverage Guidelines

Severe Asthma

The individual must meet all of the following criteria for initial authorization:

- Has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and one additional asthma controller/maintenance medication (e.g., monoclonal antibody therapies, inhaled long-acting beta₂-agonists, inhaled long-acting muscarinic antagonists, a combination inhaler containing both an inhaled corticosteroid and a long acting beta₂-agonist);
- Asthma is/was uncontrolled prior to starting Tezspire or another monoclonal antibody therapy (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair) defined by ONE of the following:
 - o Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - o Has experienced one or more asthma exacerbation(s) requiring hospitalizations, emergency room visits, or urgent care visits in the previous year; OR
 - o Has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - o Has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - o Asthma worsens upon tapering of oral corticosteroid therapy;
- Is 12 years of age or older;
- Tezspire is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

The individual must meet all of the following criteria for re-authorization:

- Has already received at least 6 months of Tezspire therapy (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Tezspire should be considered under initial criteria*);
- Continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler (i.e., Flovent Diskus/HFA, ArmonAir RespiClick, Arnuity);
- Has responded to Tezspire therapy (i.e., decreased asthma symptoms or exacerbations; decreased hospitalizations, emergency room visits, urgent care visits or medical clinic visits due to asthma; decreased requirement for oral corticosteroids; improved lung function parameters).

Chronic Rhinosinusitis with Nasal Polyps

The individual must meet all of the following criteria for initial authorization:

- Is 12 years of age or older;
- Has chronic rhinosinusitis with nasal polyps as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan;
- Has had the diagnosis of chronic rhinosinusitis with nasal polyps for at least 6 months;
- Has experienced two or more of the following symptoms for at least 8 weeks: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell;
- Has received at least 4 weeks of therapy with an intranasal corticosteroid and will continue to receive an intranasal corticosteroid concomitantly with Tezspire;
- Meets ONE of the following:
 - o Has received at least one course of treatment with a systemic corticosteroid within the previous year (*Note: one course of a systemic corticosteroid is at least 3 consecutive days of treatment or one long-acting injectable dose*); OR
 - o Has a contraindication to systemic corticosteroid therapy; OR
 - o Has had prior surgery for nasal polyps;
- Tezspire is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist).

The individual must meet all of the following criteria for re-authorization:

- Has already received at least 6 months of Tezspire therapy (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Tezspire should be considered under initial criteria*);
- Continues to receive an intranasal corticosteroid therapy;
- Has responded to Tezspire therapy (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendation

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

References

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