Tezspire (tezepelumab)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Asthma is a chronic respiratory disease that affects the airways, leading to recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. The condition is caused by a combination of genetic and environmental factors, such as allergens, pollutants, and respiratory infections. Asthma is characterized by inflammation of the airways, which makes them hypersensitive and prone to constricting in response to various triggers. The inflammation is driven by immune cells, including eosinophils, mast

cells, and T lymphocytes, which release pro-inflammatory mediators, such as histamine, leukotrienes, and cytokines.

Severe asthma is a type of asthma that is difficult to control and is characterized by persistent and frequent symptoms, exacerbations, and airflow limitation, despite adherence to maximal optimized therapy. According to the Global Initiative for Asthma (GINA), severe asthma is a subset of a "difficult-to-treat" asthma, which is defined as asthma that is uncontrolled despite medium-or high-dose inhaled corticosteroid (ICS) with a second controlled (including long-acting beta-agonists (LABA) or with maintenance oral corticosteroid, or that requires high-dose treatment to maintain good symptom control and reduce risk of exacerbation. Severe asthma is specifically defined as asthma that is uncontrolled despite maximally optimized high-dose ICS/LABA treatment and management of contributory factors (e.g., inhaler technique, adherence, comorbidities), or that worsens when high-dose treatment is decreased. In addition, severe asthma may be associated with comorbidities such as obesity, sinusitis, and gastroesophageal reflux disease (GERD), and may require additional diagnostic tests, such as lung function tests, bronchial challenge tests, and imaging studies, to confirm the diagnosis and guide treatment.

The treatment of severe asthma requires a multi-faceted approach, including medication management, environmental control, and lifestyle modifications. The goal of treatment is to improve asthma control and reduce the risk of exacerbations. The following are some of the treatment options available for severe asthma:

- High-dose inhaled corticosteroids: These medications are the mainstay of treatment for asthma and are often used in combination with long-acting beta-agonists. However, in severe asthma, higher doses may be required. As asthma progresses, patients may require the addition of a long-acting muscarinic antagonist (LAMA) to the ICS-LABA therapy.
- Biologic medications: These medications are specifically designed to target specific immune pathways that contribute to asthma. Biologics are effective in reducing exacerbations and improving asthma control in severe asthma. Examples include tezepelumab, omalizumab, mepolizumab, benralizumab, and dupilumab.
- Oral corticosteroids: In severe asthma, oral corticosteroids may be necessary for short-term management of exacerbations. However, long-term use of oral corticosteroids can lead to serious side effects and should be avoided.
- Lifestyle modifications: Lifestyle modifications such as weight loss, exercise, and smoking cessation can help improve asthma control in people with severe asthma.

Tezspire (tezepelumab), a thymic stromal lymphopoietin (TSLP) blocker which may reduce the effect of the asthma inflammatory cascade, is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. It is not indicated for the relief of acute bronchospasm or status asthmaticus. The recommended dosage of Tezspire (tezepelumab) is 210 mg administered subcutaneously once every 4 weeks. The pivotal trials, NAVIGATOR (12-80 years) and PATHWAY (18-75 years) were randomized placebo-controlled trials assessing the role of Tezpire (tezepelumab) in those with severe asthma receiving a medium-to-high dose ICS and at least one additional controlled medication, with or without oral glucocorticoids. Tezspire (tezepelumab) is unique in the lack of requirement of oral corticosteroid dependence, thus allowing those with severe asthma to receive additional therapy and avoid the potential risks of long-term corticosteroid use. In a pooled

analysis of the NAVIGATOR and PATHWAY study, they found a significant reduction in the number of annual asthma exacerbations, and exacerbation-related hospitalization and emergency department visits.

Tezspire (tezepelumab) was approved in 2025 for the indication of chronic rhinosinusitis with nasal polyps, a chronic condition affecting nasal sinuses and the lining of the nasal passage. Symptoms can include loss of smell, chronic congestion with nasal obstruction, nasal drainage and facial pressure. Management includes intranasal corticosteroids (e.g., fluticasone, mometasone), saline irrigation, systemic corticosteroids (e.g., prednisone), biologics (e.g., Dupixent [dupilumab], Xolair [omalizumab]) and nasal surgery.

Definitions

"Adjunctive therapy" refers to additional therapy, in addition to a primary treatment modality with a goal of enhancing the effectiveness of the primary treatment.

"Biomarker" is a substance found in the body that works as an indicator of exposure, effect, susceptibility, or clinical disease.

"Chronic rhinosinusitis with nasal polyposis (CRSwNP)" is chronic inflammation of the nose and paranasal sinuses with the presence of bilateral nasal polyps, often inadequately controlled with intranasal corticosteroids.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"IgG2 lambda monoclonal antibody" is a laboratory-produced molecule that acts as a substitute antibody that can restore, enhance or mimic the immune system's attack on cells.

"Inhaled corticosteroids (ICS)" refer to inhaled steroid medications, aimed at reducing inflammation associated with respiratory diseases like asthma and chronic obstructive pulmonary disease (COPD).

"Leukotriene receptor antagonists (LTRA)" are oral medications which reduce inflammation associated with leukotrienes. Leukotrienes are released by the body and can cause coughing, excessive mucus production, inflammation of airways, tightness in the chest and wheezing or difficulty breathing.

"Long-Acting Beta-Agonist (LABA)" are long-acting inhalers which relax the smooth muscle of the airways, improving airflow in patients with asthma and/or COPD.

"Long-Acting Muscarinic Antagonists (LAMA)" are inhaled medications which block the muscarinic receptor, responsible for constriction of the airways, thus reducing inflammation in the airways associated with asthma and/or COPD.

"Nasal polyps" are growths that form in the nose or the sinuses. They can be large or small, are usually found in both sides of the nose, and can make it hard to breathe through the nose.

"Phenotype" is a set of clinical characteristics, lung function and inflammation that is specific to a type of asthma as there are many different types of asthma.

"[s]" indicates state mandates may apply.

"Thymic stromal lymphopoietin (epithelial cytokine)" is a regulator of a type of immunity, which drives a broad range of allergic responses.

Medical Necessity Criteria for Initial Clinical Review

General Medical Necessity Criteria

The Plan considers Tezspire (tezepelumab) medically necessary when ALL of the following criteria are met:

1. Prescribed by or in consultation with a specialist experienced in the diagnosis and treatment of the relevant condition:
    a. Severe asthma - allergist/immunologist or pulmonologist*; or*
    b. Chronic rhinosinusitis with nasal polyps (CRSwNP) - allergist/immunologist or ENT specialist*; AND*
2. Prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature*; AND*
3. For all indications, the member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication*; AND*
4. Documentation is provided showing the member meets ALL of the following indication-specific criteria below (see Initial Indication-Specific Criteria or Subsequent Indication-Specific Criteria):

Initial Indication-Specific Criteria

Asthma, Severe

The Plan considers Tezspire (tezepelumab) medically necessary when ALL the following criteria are met:

5. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist*; AND*
6. The member is 12 years of age or older*; AND*
7. The member has a documented diagnosis of severe asthma*; AND*
8. The member has a history of one or more of the following within the last 12 months:
    a. Two or more (≥2) exacerbations requiring oral/systemic corticosteroids treatment*; or*
    b. One or more (≥1) exacerbation resulting in hospitalization or intensive care unit (ICU) admission*; and*
9. The member has tried and failed, or is unable to use, ALL of the following at optimized[#] doses [s]:
    a. High-dose inhaled corticosteroids (ICS)*; and*
    b. Adjunctive therapy (in combination with inhaled corticosteroid), such as ONE of the following:
        i. Long-Acting Beta-2 Agonists (LABA), such as formoterol or salmeterol*; or*

ii. Leukotriene Receptor Antagonist (LTRA), such as montelukast (Singulair) or zafirlukast (Accolate)*; or*
iii. Long-Acting Muscarinic Antagonists (LAMA), such as tiotropium; *or*
iv. Extended-release theophylline*. AND*

[#]*member should be receiving treatment with inhaled corticosteroid and additional controller (adjunctive therapy) for at least the previous 3 months.*

10. Tezspire (tezepelumab) will NOT be used as monotherapy.

<u>If the above prior authorization criteria are met, Tezspire (tezepelumab) will be approved for up to 6 months.</u>[s]

<u>Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)</u>

The Plan considers <u>Tezspire (tezepelumab)</u> medically necessary when ALL the following criteria are met:

5. The member is 12 years of age or older*; AND*
6. The member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)*; AND*
7. Documentation of bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril*; AND*
8. The member has nasal obstruction AND ONE (1) of the following additional symptoms:
    a. Rhinorrhea (anterior/posterior); *or*
    b. Reduction or loss of smell*; AND*
9. The member has CRSwNP despite ONE (1) of the following[s]:
    a. Prior sino-nasal surgery; *or*
    b. Tried and failed treatment with systemic corticosteroids within the last two years, unless the member is unable to use systemic corticosteroids*; AND*
10. The member has bilateral nasal polyposis and chronic symptoms of sinusitis AND the member is unable to use or has tried and failed intranasal corticosteroid treatment for at least two (2) months[s]*; AND*
11. Tezspire (tezepelumab) will be used together with a daily intranasal corticosteroid as part of the member's treatment plan, unless the member is unable to use intranasal corticosteroid.

<u>If the above prior authorization criteria are met, Tezspire (tezepelumab) will be approved for up to 6 months.</u>[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

All prior authorization renewals are subject to review. Reauthorization may be provided based on the diagnosis, response to therapy, and documented medical records and/or pharmacy claims.

Subsequent General Medical Necessity Criteria

The Plan considers Tezspire (tezepelumab) medically necessary when ALL of the following criteria are met:

1. Prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature*; AND*
2. For all indications, the member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication*; AND*
3. Documentation is provided showing the member meets ALL of the following indication-specific criteria below (see Initial Indication-Specific Criteria or Subsequent Indication-Specific Criteria):

Subsequent Indication-Specific Criteria

Asthma

The Plan considers Tezspire (tezepelumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member is 12 years of age or older; *AND*
5. The member's asthma has improved on Tezspire (tezepelumab) treatment based upon the prescriber's assessment as demonstrated by at least ONE (1) of the following:
    a. A reduction in the frequency and/or severity of symptoms and exacerbations*; or*
    b. A reduction in the daily maintenance oral corticosteroid dose*; AND*
2. Tezspire (tezepelumab) will NOT be used as monotherapy.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.[s]

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

The Plan considers Tezspire (tezepelumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member is 12 years of age or older; *AND*
5. The member's condition has improved on Tezspire (tezepelumab) treatment based upon the prescriber's assessment as demonstrated by symptomatic improvement of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use)*; AND*
6. The member will continue consistent use of intranasal corticosteroids while on Tezspire (tezepelumab) therapy, unless the member is unable to use intranasal corticosteroid.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.[s]

Experimental or Investigational / Not Medically Necessary[s]

Tezspire (tezepelumab) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Atopic dermatitis (AD)
- Chronic obstructive pulmonary disease (COPD)
- Chronic spontaneous urticaria
- Eosinophilic esophagitis (EoE)

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