Oscar Clinical Guideline: Tezspire (tezepelumab) (PG118, Ver. 4)

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 defined as asthma that requires treatment with guideline-specified high-dose inhaled corticosteroids (ICS) plus a second controller medication, and/or systemic corticosteroids to prevent it from becoming uncontrolled, or that remains uncontrolled despite this therapy. 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.
- 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 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) 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.

Definitions

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

"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.

"**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.

"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 Authorization

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

1. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist***; AND***
2. The member is 12 years of age or older***; AND***
3. The member has a documented diagnosis of severe asthma***; AND***
4. 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 ICU admission***; and***
5. The member has tried and failed, or is unable to use, **ALL** of the following at optimized[#] doses:
    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. Extended-release theophylline***; and***
    c. Oral/systemic corticosteroids (at least 5 mg per day of prednisone/prednisolone or equivalent); ***AND***

    [#]*member should be receiving treatment with inhaled corticosteroid and additional controller (adjunctive therapy) for at least the previous 3 months, and oral/systemic corticosteroids for most days during the previous 6 months [e.g. 50% of days, 3 steroid bursts in the previous 6 months]*
6. Clinical chart documentation is provided showing **BOTH** of the following:
    a. Tezspire (tezepelumab) will not be used as monotherapy***; and***
    b. Tezspire (tezepelumab) will not be used concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair) in the treatment of asthma***; AND***
7. Tezspire (tezepelumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature***; AND***
8. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Tezspire (tezepelumab) will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted for members 12 years of age or older when recent chart documentation (within the past 6 months) is provided showing **ALL** of the following criteria are met:

1. The member's asthma has improved on Tezspire (tezepelumab) treatment based upon the prescriber's assessment as demonstrated by at least **ONE** 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. Clinical chart documentation is provided showing **BOTH** of the following:
   a. Tezspire (tezepelumab) will not be used as monotherapy***; and***
   b. Tezspire (tezepelumab) will not be used concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair) in the treatment of asthma***; AND***
3. Tezspire (tezepelumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

Experimental or Investigational / Not Medically Necessary

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 rhinosinusitis with nasal polyps
- Chronic obstructive pulmonary disease
- Chronic spontaneous urticaria
- Eosinophilic esophagitis (EoE)

References

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Clinical Guideline Revision / History Information

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