

Policy: MBP 259.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Tezspire (tezepelumab-ekko)

I. Policy:

Tezspire (tezepelumab-ekko)

II. Purpose/Objective:

To provide a policy of coverage regarding Tezspire (tezepelumab-ekko).

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Tezspire (tezepelumab-ekko) is a human monoclonal antibody IgG2λ that binds to human thymic stromal lymphopoietin (TSLP), an epithelial cytokine, and prevents human TSLP from interacting with the heterodimeric TSLP receptor. Blocking TSLP with tezepelumab-ekko reduces biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, IgE, FeNO, IL-5, and IL-13; however, the mechanism of tezepelumab-ekko action in asthma has not been definitively established.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Tezspire (tezepelumab-ekko) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Prescription written by or in consultation with an allergist, immunologist, or pulmonologist **AND**
 - Medical record documentation of age greater than or equal to 12 years **AND**
 - Medical record documentation of severe asthma **AND**
 - Medical record documentation that Tezspire will be used as an add-on maintenance treatment **AND**
 - Medical record documentation of one of the following:
 - Poor control or intolerance, despite a 3 month trial of: medium–high dose inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists) with or without oral corticosteroids **OR**
 - Two or more asthma exacerbations requiring systemic corticosteroid treatment or one asthma exacerbation resulting in hospitalization in the past 12 months despite current therapy to medium- high inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists)
- AND**
- Medical record documentation that Tezspire will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Xolair, Nucala, Fasenra, Dupixent, Cinqair)

AUTHORIZATION DURATION: Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

QUANTITY LIMITS: 1.91 mL (210 mg) every 28 days

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Tezspire (tezepelumab) [prescribing information]. Thousand Oaks, CA: Amgen, Inc; February 2023.
2. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma. 2023 July [cited 2023 Dec 26]. Available from: <https://ginasthma.org/2023-gina-main-report/>

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/17/22

Revised: 5/11/23 (Medicaid business segment), 12/28/23 (references added), 5/10/24 (LOB carve out)

Reviewed:

MA UM Committee approval: 12/31/23