Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 12/14/2023

Tezspire™ (tezepelumab-ekko)

HCPCS: J2356

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria:
   a. FDA approved indication
   b. FDA approved age
   c. For severe asthma, including eosinophilic, allergic, and oral corticosteroid (OCS) dependent phenotypes:
      i. Must be used as add-on maintenance treatment with severe uncontrolled asthma and patient will continue to receive standard of care regimen
      ii. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids (listed in table 1) in combination with:
         1. Long acting inhaled β2 agonist (LABA) for at least 3 months fails to maintain adequate control
            OR
         2. Leukotriene modifier for at least 3 months fails to maintain adequate control
            OR
         3. LAMA (long-acting muscarinic antagonists) for at least 3 months fails to maintain adequate control
   d. Cannot be used in combination with other biologics for asthma
   e. The member will self-administer Tezspire unless clinically unable to do so
   f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents.

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Tezspire is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
    - Limitations of use: Not for relief of acute bronchospasm or status asthmaticus.
- TSLP is a key epithelial cytokine in allergy and asthma pathophysiology and is overexpressed in asthmatic patients. Once released, TSLP drives multiple downstream innate and adaptive immune responses.
- Severe asthma is uncontrolled despite adherence with maximal optimized high dose inhaled corticosteroids/long-acting beta agonists (ICS/LABA), or that requires high dose ICS/LABA to prevent it from becoming uncontrolled.
- Asthma affects 25 million Americans with 1.6 million ER visits, 180,000 hospitalizations, and 3,500 deaths each year. Severe asthma afflicts 5 to 10 percent of the asthma population but drives the majority of the morbidity and costs of the disease.
- Add-on treatments for severe asthma include LAMAs, leukotriene receptor antagonists (LTRA), low dose azithromycin (adults), and biologic agents for severe allergic or severe type 2 asthma. Type 2 inflammation is found in a majority of people with severe asthma and is characterized by the production of cytokines such as interleukin (IL). The Global Institute for Asthma (GINA) 2022 guidelines have the following recommendations for add-on biologic therapy for severe asthma:
    - Add-on anti-immunoglobulin E (anti-IgE) (omalizumab) treatment: for patients aged ≥6 years with moderate or severe allergic asthma that is uncontrolled on Step 4–5 treatment (Evidence A).
    - Add-on anti-IL-5/5R treatment (subcutaneous mepolizumab for patients aged ≥6 years; intravenous reslizumab for ages ≥18 years; or subcutaneous benralizumab for ages ≥12 years), with severe eosinophilic asthma that is uncontrolled on Step 4–5 treatment. Efficacy data for mepolizumab in children 6–11 years are limited to one very small open label uncontrolled study.
    - Add-on anti-IL-4Rα treatment (subcutaneous dupilumab) for patients aged ≥6 years with severe eosinophilic/Type 2 asthma, or for adults or adolescents requiring treatment with maintenance OCS.
    - Add-on anti-thymic stromal lymphopoietin (anti-TSLP) (subcutaneous tezepelumab): for patients aged ≥12 years with severe asthma (Evidence A).
- Per the GINA 2022 guidelines, a trial of at least 4 months of an add-on biologic therapy is recommended before assessing response.
- Eosinophilic asthma is a sub-phenotype of severe asthma characterized by elevated sputum and blood eosinophil levels as well as increased asthma severity, atopy, late-onset disease, and steroid refractoriness.
- A peripheral blood eosinophil count is an indirect way to estimate airway inflammation. A blood eosinophil count ≥ 300 cells/microliter may help to predict asthmatics who are at increased risk for exacerbations in the next year.

Furthermore, a count-response relationship exists between blood eosinophil counts and asthma-related outcomes. The European Respiratory Society/American Thoracic Society guidelines from 2020 suggest that treatment of severe asthma be guided by clinical criteria and biomarkers such as blood eosinophil levels or fractional exhaled nitric oxide (FeNO), rather than by clinical criteria alone. In addition, it also suggests that a blood eosinophil count cut-off point of ≥ 150 cells/microliter can be used to guide anti-IL5 therapy initiation in adult patients with severe asthma and a history of prior asthma exacerbations.

- Type 2 inflammation is found in a majority of people with severe asthma and is characterized by production of cytokines such as interleukin and can also include immunoglobulin E (IgE)-mediated events involving mast cells and basophils (in particular, mast cells, eosinophils, T lymphocytes, macrophages, neutrophils, and epithelial cells). Anti-IgE monoclonal antibodies reduce the levels of circulating IgE and inhibit the binding of IgE to mast cells to prevent activation of the allergic cascade and decrease inflammation.

    - IgE levels of >30 but <700 IU/mL for patients 12 years of age and older and IgE levels >30 but <1,300 IU/mL for patients between the ages of 6 to <12 years were used in the efficacy data from Xolair clinical trials and showed where Xolair was most effective.

- Clinical reasons a patient may be unable to self-administer Tezspire include:

    - Patient or caregivers are unable to perform subcutaneous (SC) injections with proper technique.

    - Member requires monthly medical support from the physician.

References:

1. Tezspire [prescribing information]. Thousand Oaks, CA. Amgen Inc. May 2023.
2. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J 2020; 55.
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.
4. PRNewswire press release; FDA approves Tezspire™ (tezepelumab-ekko) in the U.S. for severe asthma (prnewswire.com) accessed December, 2021.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.4</td><td>Effective Date: 12/14/2023</td><td>Updated to remove specific step therapy for lowest net-cost strategy</td></tr>
<tr><td>1.3</td><td>Effective Date: 04/06/2023</td><td>Update to require 4 month trial of appropriate step therapy and to require self-administration of new prefilled pen product for those clinically able to do so</td></tr>
<tr><td>1.2</td><td>Effective Date: 02/02/2023</td><td>Update to require pharmacy benefit options when clinically appropriate</td></tr>
<tr><td>1.1</td><td>Effective Date: 02/17/2022</td><td>UM medical management system update for BCBSM and BCN
<table>
<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>Yes</td></tr>
<tr><td>BCN</td><td>Yes</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
<tr><td>BCNA</td><td>No</td></tr>
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<tr><td>1.0</td><td>Effective Date: 02/10/2022</td><td>New Policy
<table>
<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>No</td></tr>
<tr><td>BCN</td><td>No</td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

Table 1: Comparative cumulative daily dosing of inhaled corticosteroids (mcg/day)

Inhaled Corticosteroid	Ages 12 and up			Ages 6-11		
	Low Dose	Medium Dose	High Dose	Low Dose	Medium Dose	High Dose
Beclomethasone dipropionate HFA	100 – 200	>200 – 400	>400	50 – 100	>100 – 200	>200
Budesonide DPI	200 – 400	>400 – 800	>800	100 – 200	>200 – 400	>400
Budesonide nebules	NA	NA	NA	250 – 500	>500 – 1,000	>1,000
Ciclesonide HFA	80 – 160	>160 – 320	>320	80	>80 – 160	>160
Fluticasone furoate DPI	100	NA	200	NA	NA	NA
Fluticasone propionate DPI	100 – 250	>250 – 500	>500	100 – 200	>200 – 400	>400
Fluticasone propionate HFA	100 – 250	>250 – 500	>500	100 – 200	>200 – 500	>500
Mometasone furoate	110 – 220	>220 – 440	>440	110	≥220 - <440	≥440
Triamcinolone acetonide	400 – 1,000	>1,000 – 2,000	>2,000	400 – 800	>800 – 1,200	>1,200

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form
Tezspire™ (tezepelumab-ekko)
HCPCS CODE: J2356

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This form is to be used by participating physicians to obtain coverage for Tezspire™. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: ☐ Initiation ☐ Continuation ***Date patient started therapy***: _____
2. Is this request for self or office administration? ☐ Self- administration ☐ Office administration
   a. If office, please provide the NPI number for the place of administration: _____
3. **Initiation AND Continuation of therapy:**
   a. Please check the patient's diagnosis**:** ☐ Severe asthma **(go to b)** ☐ Other: _____
      ☐ Severe eosinophilic asthma (**EA, go to b, c and d**)
      ☐ Allergic asthma **(go to b and e)**
      ☐ Oral corticosteroid dependent phenotype **(OCS, go to b and d)**
   b. Which treatment(s) did not adequately control the patient's severe asthma, EA, allergic asthma, or OCS dependent symptoms after a trial of at least 3 months?
      ☐ Systemic corticosteroid: _____ Date: *Start:* _____ *End:* _____
      ☐ High dose inhaled corticosteroids: _____ Date: *Start:* _____ *End:* _____
      ☐ Long acting beta2-agonist: _____ Date: *Start:* _____ *End:* _____
      ☐ Leukotriene receptor antagonist: _____ Date: *Start:* _____ *End:* _____
      ☐ Combination asthma inhaler with a HIGH dose corticosteroid and a long acting beta agonist: _____ Date: *Start:* _____ *End:* _____
      ☐ Combination asthma inhaler with a MEDIUM dose corticosteroid and a long acting beta agonist: _____ Date: *Start:* _____ *End:* _____
      ☐ Long acting muscarinic antagonist (LAMA): _____ Date: *Start:* _____ *End:* _____
      ☐ Other: _____ Date: *Start:* _____ *End:* _____
   c. **EA:** Please select the preferred product(s) the patient has tried for at least 4 months and experienced intolerance, contraindication, or adverse event for the requested indication.
      ☐ Nucala ☐ Fasenra ☐ Dupixent ☐ Other: _____
   d. **EA and OCS dependent asthma:** Please select the preferred product(s) the patient has tried for at least 4 months and experienced intolerance, contraindication, or adverse event to for the requested indication.
      ☐ Dupixent ☐ Other: _____
   e. **Allergic asthma:** Please select the preferred product(s) the patient has tried for at least 4 months and experienced intolerance, contraindication, or adverse event to for the requested indication.
      ☐ Xolair ☐ Other: _____
   f. Will the patient be using Tezspire in combination with other biologic agents (for example: Xolair, Nucala, Cinqair, or Fasenra)?
      ☐ Yes ☐ No Comment: _____
   g. Is the patient currently receiving and will continue to receive a standard of care regimen for their diagnosis with Tezspire?
      ☐ Yes ☐ No Comment: _____
4. **Continuation request:** (please answer above questions as well): **Tezspire start date**: _____
   a. Have the patient's signs and symptoms improved with Tezspire?
      ☐ Yes ☐ No, Comment: _____ ☐ Other:_____
5. Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name **Physician Signature** **Date**

Step 2 Checklist	☐ Form Completely Filled Out ☐ Attach Chart Notes	☐ Attach Diagnostic Tests
Step 3 Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**