Policy Title:	Tezspire (tezepelumab-ekko)		
		Department:	PHA
Effective Date:	06/01/2022		
Review Date:	05/05/2022, 07/13/2023, 12/07/2023, 01/04/2024		

Purpose: To support safe, effective, and appropriate use of Tezspire (tezepelumab-ekko).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Tezspire (tezepelumab-ekko) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Tezspire (tezepelumab-ekko) will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:

Tezspire (tezepelumab) is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. The NAVIGATOR trial is a phase 3, randomized, double-blind, placebo-controlled 52-week trial with 1,061 patients who had a history of at least 2 asthma exacerbations resulting in corticosteroid treatment or hospitalization within the past 12 months. Tezspire met its primary endpoint demonstrating a 56% reduction in annual asthma exacerbation rate (AAER) compared with placebo (AAER 0.93 vs. 2.10; rate ratio 0.44 [95% CI 0.37, 0.53]). The use of Tezspire also resulted in a statistically significant reduction in asthma exacerbations in patients when stratified by baseline eosinophil levels, including the group with a baseline of <150 cells/μL, compared with placebo (rate ratio 0.61 [95% CI 0.42, 0.88]).

Initial Criteria:

- Member is 12 years of age or older; AND
- Tezspire is prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist; AND
- Member has documentation of severe asthma (see Appendix); AND
- Member is adherent to current treatment with both of the following medications at optimized doses for at least 3 months with or without oral corticosteroids:
    - High-dose inhaled corticosteroid; AND
    - Additional controller medication (e.g., long acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier); AND

- Member has inadequate asthma control with two or more exacerbations in the previous year requiring systemic corticosteroid treatment in addition to the regular maintenance therapy defined above OR one asthma exacerbation resulting in hospitalization; AND
- Member will use Tezspire as add-on maintenance treatment (not as monotherapy); AND
- Documentation of baseline blood eosinophil level is provided; AND
- If baseline blood eosinophil level is ≥150 cells/μL, member has had an inadequate treatment response or intolerance to treatment with at least one biologic indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair); AND
- Member will not use Tezspire in combination with another biologic agent indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair); AND
- Baseline measurement of at least one of the following for assessment of clinical status:
    - Use of systemic corticosteroids
    - Use of inhaled corticosteroids
    - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to asthma condition
    - Forced expiratory volume in 1 second (FEV1); AND
- Member will not receive concurrently with live vaccines; AND
- Member does not have an active or untreated parasitic (helminth) infection; AND
- Tezspire will not be used for the relief of acute bronchospasm or status asthmaticus.

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of Therapy Criteria:

- Member is 12 years of age or older; AND
- Tezspire is prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist; AND
- Member has documentation of severe asthma (see Appendix); AND
- Member is tolerating treatment; AND
- Member has achieved and maintained a positive clinical response with Tezspire therapy for asthma with documentation of improvement as evidenced by:
    - A decrease in one or more of the following:
        - Use of systemic corticosteroids
        - Hospitalizations
        - ER visits
        - Unscheduled visits to healthcare provider; OR
    - Improvement from baseline in forced expiratory volume in 1 second (FEV1)
- Member will use Tezspire as add-on maintenance treatment (not as monotherapy); AND
- Member will not use Tezspire in combination with another biologic agent indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair).

Coverage Durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Rationale: Tezspire was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Tezspire according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	Dose	Quantity Limit/ Maximum Dose (1 billable unit = 1 mg)
Severe Asthma	210 mg administered subcutaneously once every 4 weeks. Tezspire is intended for administration by a healthcare provider.	1 single-dose syringe or vial (210 units) per 28 days

Appendix:

Components of Severity for Classifying Asthma as Severe may include any of the following (not all inclusive):

- Symptoms throughout the day
- Nighttime awakenings, often 7x/week
- Short-acting beta agonist (SABA) use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2356	Injection, tezepelumab-ekko, 1 mg

References:

1. Tezspire [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; May 2023. Accessed November 2023.
2. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS Guidelines on Definition, Evaluation, and Treatment of Severe Asthma. Eur Respir J 2014; 43: 343-373.
3. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European
4. Respiratory Society/American Thoracic Society guideline. Eur Respir J 2020; 55: 1900588 [https://doi.org/10.1183/13993003.00588-2019].
5. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007
6. National Asthma Education and Prevention Program (NAEPP). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); December 2020.
7. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2021 Update. Available from: http://www.ginasthma.org. Accessed December 2021.
8. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in Adults and Adolescents with Severe, Uncontrolled Asthma. N Engl J Med. 2021 May 13;384(19):1800-1809. doi: 10.1056/NEJMoa2034975.

9. Menzies-Gow A, Colice G, Griffiths JM, et al. NAVIGATOR: a phase 3 multicentre, randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy and safety of tezepelumab in adults and adolescents with severe, uncontrolled asthma. Respir Res. 2020 Oct 13;21(1):266. doi: 10.1186/s12931-020-01526-6.