Tezspire (Tezepelumab-ekko)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Tezspire (Tezepelumab-ekko) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Tezspire is indicated for 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.

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review (initial requests only):

A) Asthma:

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
2. Continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

Criteria for Initial Approval

A. Asthma

Authorization of **6 months** may be granted for treatment of severe asthma when all of the following criteria are met:

1. Tezspire is being prescribed by or in consultation with an allergist/immunologist or pulmonologist.
2. Member is 12 years of age or older
3. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
    a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
    b. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit
    c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
4. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
    a. High dose inhaled corticosteroid
    b. Additional controller (long acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
5. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Tezspire
6. Member will not use Tezspire concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair).

Continuation of Therapy

A. Asthma

Authorization of 12 months may be granted for members for continuation of treatment of severe asthma when all of the following criteria are met:

1. Tezspire is being prescribed by or in consultation with an allergist/immunologist or pulmonologist.
2. Member is 12 years of age or older
3. Asthma control has improved on Tezspire treatment as demonstrated by at least one of the following:
    a. A reduction in the frequency and/or severity of symptoms and exacerbations
    b. A reduction in the daily maintenance oral corticosteroid dose
4. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Tezspire
5. Member will not use Tezspire concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Xolair)

Tezspire is considered **not medically necessary** for members who do not meet the criteria set forth above.

Other

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Quantity Limit	FDA-recommended dosing
Tezspire (Tezepelumab-ekko) 210 mg/ 1.91 mL single-dose glass vial	1 vial per 28 days	210 mg every 4 weeks
Tezspire (Tezepelumab-ekko) 210 mg/ 1.91 mL single-dose pre-filled syringe	1 syringe per 28 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3590 – unclassified biologics
- C9399 – unclassified drugs or biologics
- J2356 – Injection, tezepelumab-ekko, 1mg

REFERENCES

- Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2021.
- Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2021 update. Available at https://ginasthma.org/wp-content/uploads/2021/05/GINA-Main-Report-2021-V2-WMS.pdf. Accessed December 21, 2021.
- Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA.* 2020;324(22): 2301-2317.
- AstraZeneca plc. (2020, December 22). Update on SOURCE Phase III trial for Tezepelumab in patients with severe, oral corticosteroid-dependent asthma. Available at: https://www.astrazeneca.com/media-centre/press-releases/2020/update-on-source-phase-iii-trial-for-tezepelumab-in-patients-with-severe-oral-corticosteroid-dependent-asthma.html. Last accessed December 27, 2021.

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POLICY HISTORY

Policy #: 05.04.59
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