RX.PA.077.CCH TEZSPIRE (TEZEPELUMAB)

The purpose of this policy is to define the prior authorization process for Tezspire™ (Tezepelumab) for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

DEFINITIONS

Severe Asthma – As defined by the European Respiratory Society (ERS)/American Thoracic Society (ATS), severe asthma is "asthma that requires treatment with high dose inhaled corticosteroids […] plus a second controller (and/or systemic corticosteroids) to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy".

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Tezspire™ (Tezepelumab) is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist
- Must be age 12 years or older
- Must have chart documentation supporting a diagnosis of severe, persistent asthma
- Must have asthma symptoms that have not been adequately controlled despite adherence to an optimized medication therapy regimen, defined by ONE of the following:
    - Hospitalization for asthma in the past year
    - Requirement for systemic (oral, parenteral) corticosteroids to control exacerbations of asthma on 2 occurrences in the past year
    - On daily corticosteroid with inability to taper off

- Must have tried a high dose inhaled corticosteroid (*see table 1 below*) in combination with ONE of the following:
    - Inhaled long-acting beta agonist
    - Inhaled long-acting muscarinic antagonist
    - Leukotriene receptor antagonist
    - Theophylline
- Must not be used concurrently with Xolair, Dupixent, or another anti-IL5 biologic (e.g., Nucala, Cinqair, Fasenra) when used for the treatment of asthma
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Table 1: High daily metered doses of inhaled corticosteroids – adapted from GINA 2022 guidelines.

Inhaled corticosteroid (ICS)	Total Daily ICS High dose (mcg) Ages 6 to 11 years	Total Daily ICS High dose (mcg) Ages ≥12 years
Beclometasone diproprionate (pMDI, standard particle, HFA)	>400	>1000
Beclometasone diproprionate (DPI or pMDI, extrafine particle, HFA)	>200	>400
Budesonide (DPI, or pMDI, standard particle, HFA)	>400	>800
Budesonide (nebules)	>1000	N/A
Ciclesonide (pMDI, extrafine particle, HFA)	>160	>320
Fluticasone furoate (DPI)	N/A	200
Fluticasone propionate (DPI, or pMDI, standard particle, HFA)	>200	>500
Mometasone furoate (pMDI, standard particle, HFA)	200	>400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber of the following:

- The member's condition has improved based upon the prescriber's assessment while on therapy.
- Reduction in exacerbations, hospitalizations, emergency department visits, or requirement for oral corticosteroid therapy
- Reduction in reported symptoms of asthma attacks (e.g., shortness of breath, chest tightness, tiredness, sleep disturbance, total asthma symptom score)
- Must not be used concurrently with Xolair, Dupixent, or another anti-IL5 biologic (e.g., Nucala, Cinqair, Fasenra) when used for the treatment of asthma

- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J2356	Tezspire	Injection, tezepelumab-ekko, 1 mg

REFERENCES

1. Tezspire [Prescribing Information]. Gaithersburg, MD: Amgen Inc. and AstraZeneca; 2021
2. 2022 GINA Report, Global Strategy for Asthma Management and Prevention. Available from: https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf
3. 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: 1900588 [https://doi.org/10.1183/13993003.00588-2019].

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	XX/XX

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

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CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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