TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Tezepelumab-ekko (Tezspire®)	**CRITERIA ID:** TX.CC.PHAR.20
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 07/01/2022	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 8/10/2022, 11/14/2022, 8/1/2023, 03/15/2024, 02/26/2025	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for Tezepelumab-ekko (Tezspire®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of Tezepelumab-ekko (Tezspire); Procedure code: J2356.

Description/Mechanism of Action:
Tezepelumab-ekko (Tezspire®) is a human monoclonal antibody.

FDA Approved Indication(s):
Tezepelumab-ekko (Tezspire®) is indicated as an add-on maintenance treatment of adult and pediatric clients who are 12 years of age and older with severe asthma.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Add-on Maintenance for Severe Asthma (must meet all):

1. The client has a confirmed diagnosis of severe asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4550, J4551)
2. The client is 12 years age or older.

Note: Exceptions may be considered for clients younger than the FDA approved age on a case-by-case basis by the CPS medical director

3. Tezspire is used as an add-on maintenance therapy. Tezspire is not to be used as a single or primary therapy.
4. The client is currently on the following as a regular treatment for severe asthma and is compliant with the therapy (a. and b):
   a. Medium or high-dose inhaled corticosteroid therapy, and
   b. An additional asthma controller
5. Documentation showing symptoms are inadequately controlled with use of a minimum of 3 months of controller medication (which includes but is not limited to a long-acting beta2-agonist [LABA], an inhaled or oral corticosteroid, leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents.
   Note: Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for Tezspire, the client's asthma severity level, and the duration of current and past therapies and lack of asthma control. Consideration for these exceptions will be reviewed by the Medical Director.
6. Tezspire should not be used to relieve acute bronchospasm or status asthmaticus.
7. Tezspire may not be used in combination with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents (i.e., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab, etc.).
8. Any client with pre-existing helminth infections should be treated before receiving Tezspire therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Tezspire should discontinue until the parasitic infection resolves.
9. Tezspire should not be administered concurrently with live attenuated vaccination.

Approval duration: 6 months

II. Continued Therapy

A. Add-on Maintenance for Severe Asthma (must meet all):

1. The client has a satisfactory clinical response to therapy (Documentation of clinical improvement must include one or more of the following (a, b, or c):
   a. Decreased utilization of rescue medications
   b. Increase in predicted FEV1 (forced expiratory volume) from pretreatment baseline
   c. Reduction in reported asthma-related symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
      - Asthma attacks
      - Chest tightness or heaviness
      - Coughing or clearing throat
      - Difficulty taking deep breath or difficulty breathing out
      - Shortness of breath
      - Sleep disturbance, night wakening, or symptoms upon awakening
      - Tiredness
      - Wheezing/heavy breathing/fighting for air
2. Documentation stating client has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of Tezspire.
3. Tezspire may not be used in combination with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents (i.e., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab, etc.).
4. The client must be compliant with their Tezspire regimen in order to qualify for additional prior authorizations.The provider must submit a statement documenting compliance with the requests for each renewal.
5. Any client with a preexisting helminth infection should be treated prior to receiving Tezspire therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Tezspire should be discontinued until parasitic infection resolves.

Note: Requests for clients who do not meet the above criteria will be reviewed for medical necessity by the Medical Director. After lapses in treatment of 3 months or greater, prior authorization requests submitted with documentation will be reviewed by a Medical Director.

Approval duration: 12 months

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	07/01/2022
Ad Hoc	Added steps 4, 5 and 6 for initial approval criteria and steps 4 and 5 for continued approval criteria to align with TMPPM	08/10/2022
Ad Hoc	Extended Approval Duration for continuation of therapy to 12 months	11/14/20/2022
Ad Hoc	Updated continued therapy criteria to align with continuation requirements for all monoclonal antibodies Update criteria verbiage to “the client” for consistency throughout document Updated age requirements throughout by removing ≥ symbol. Added additional PA requirement for all indications for initial and continuation criteria: • a client with a preexisting helminth infection should be treated prior to receiving mepolizumab therapy • If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment should be discontinued until parasitic infection resolves Updated criteria step 5 for initial therapy for indication of moderate to severe asthma to: • Documentation showing symptoms are inadequately controlled with use of a minimum of 3 months of controller medication (which includes but is not limited to a long-acting beta2-agonist [LABA], an inhaled or oral corticosteroid, leukotriene receptor antagonist [LTRA], or theophylline, unless the individual is intolerant of, or has a medical	08/01/2023

	contraindication to these agents. Removed criteria points under asthma indication referencing: smoking and pulmonary function tests Changed Superior HealthPlan/CPS to Centene Pharmacy Services/CPS throughout policy Added names/titles under Policy and Procedure Approval Section Added CHIP Perinate to Products	
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement Made a correction Under. I.A.8 and II.A.5 to change omalizumab to tezepelumab	03/15/2024
Annual Review	No Changes	02/26/2025