POLICY AND PROCEDURE

POLICY NAME: Tezepelumab-ekko (Tezspire)	**POLICY ID:** TX.PHAR.105
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 07/01/2022	**PRODUCT(S):** CHIP, STAR, STAR PLUS, STAR HEALTH, STAR KIDS
REVIEWED/REVISED DATE: 8/10/2022, 11/14/2022	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
The purpose of this Clinical Policy is to provide a guide to medical necessity reviews for Tezepelumab-ekko (Tezspire).

PURPOSE:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review Tezepelumab-ekko (Tezspire).

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 policy and prior authorization requirements.

Tezepelumab-ekko (Tezspire) is a human monoclonal antibody indicated as an add-on maintenance therapy treatment for severe asthma in pediatric and adult clients 12 and older.

SCOPE:
This policy applies to Superior HealthPlan Pharmacy Department, Medical Directors, Claims.

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review Tezepelumab-ekko (Tezspire).

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. 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. Age ≥ 12 years
Note: Exceptions may be considered for patients younger than the FDA approved age on a case-by-case basis by the SHP 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 one of the following combination therapies (a or b):

a. 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents
b. 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (a LABA, 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 omalizumab, the member'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 SHP medical director.

6. Pulmonary function tests must have been performed within a three-month period
Note: Exceptions may be considered with documentation of medical reasons explaining why pulmonary function tests cannot be performed.

7. Documentation member is not currently smoking.

8. Tezspire should not be used to relieve acute bronchospasm or status asthmaticus.

9. 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.)

10. Any client with pre-existing helminth infections should be treated before receiving Tezspire (tezepelumab-ekko) 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.

11. Tezspire (tezepelumab-ekko) should not be administered concurrently with live attenuated vaccination.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid/CHIP.

II. Continued Therapy

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

1. Member continues to meet the initial authorization approval criteria for Tezspire.

2. Member has not had any hypersensitivity reactions or unacceptable adverse events like helminth infection due to therapy.

3. Member experienced a positive clinical response to therapy, as demonstrated by no increase in asthma exacerbations or improvement in asthma symptoms.

4. Member must be compliant with Tezspire regimen to qualify for additional prior authorization. The provider must submit a statement documenting compliance with the requests for each renewal.

5. 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.)

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	07/01/22
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	8/10/22
Ad Hoc	Extended Approval Duration for continuation of therapy to 12 months	11/14/2022

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.