POLICY AND PROCEDURE

POLICY NAME: Mepolizumab (Nucala)	**POLICY ID:** TX.PHAR.96
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 10/18/2021	**PRODUCT(S):** CHIP, STAR, STAR PLUS, STAR HEALTH, STAR KIDS
REVIEWED/REVISED DATE:11/30/2021, 07/01/2022, 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 Mepolizumab (Nucala).

PURPOSE:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review Mepolizumab (Nucala).

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.

Mepolizumab (Nucala®) is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa).

FDA Approved Indication(s)
Nucala is indicated for:

- Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
- Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult clients who are 18 years of age or older with inadequate response to nasal corticosteroids

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

DEFINITIONS:
EGPA: eosinophilic granulomatosis with polyangiitis
HES: hypereosinophilic syndrome
ICS: inhaled corticosteroid
LABA: Long-acting beta-agonist
LTRA: leukotriene modifier

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review Mepolizumab (Nucala).

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. Severe Asthma (must meet all):

1. Diagnosis of severe asthma with eosinophilic phenotype (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4550, J4551, J4552)

2. Age ≥ 6 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. 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 agent

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 mepolizumab, 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.

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

5. One of the following blood eosinophil counts in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection:

a. Greater than or equal to 150 cells/microliter at initiation of therapy; or

b. Greater than or equal to 300 cells/microliter within 12 months prior to initiation of therapy

Note: 1 microliter (ul) is equal to 1 cubic millimeter (mm3).

6. Documentation member is not currently smoking.

7. Nucala is not prescribed concurrently with Cinqair, Xolair, Fasenra, or any other interleukin-5 antagonist.

Approval duration: 6 months

B. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Churg-Strauss) (must meet all):

1. Confirmed diagnosis of EGPA (diagnosis code M301)

2. Age ≥ 18 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. Medical history of asthma.

4. Refractory disease or has had a history of EGPA relapse within the past 2 years from the requested date of service.

5. Presence of at least 2 of the following EGPA characteristics below:
   a. Histopathological findings of eosinophilic vasculitis, perivascularitis eosinophilic infiltration or eosinophil-rich granulomatous inflammation
   b. Neuropathy
   c. Pulmonary infiltrates, non-fixed; Sino-nasal abnormality.
   d. Cardiomyopathy
   e. Glomerulonephritis
   f. Alveolar hemorrhage
   g. Palpable purpura
   h. Anti-neutrophils cytoplasmic antibody

6. Nucala is not prescribed concurrently with Cinqair, Xolair, Fasenra, or any other interleukin-5 antagonist.

Approval duration: 6 months

D. Hypereosinophilic Syndrome (HES) (must meet all):

1. Diagnosis of HES for 6 months or longer without any non-hematologic secondary cause (diagnosis codes D72110, D72111, D72118, and D72119)

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. History of 2 or more HES flares (flare defined as worsening clinical symptoms or blood eosinophil counts requiring an increase in prior therapy) within the past 12 months prior to the initiation of mepolizumab therapy

4. Prescriber's attestation that client has been on a stable dose of HES therapy which includes, but not limited to corticosteroids, immunosuppressive and cytotoxic therapy

5. Nucala is not prescribed concurrently with Cinqair, Xolair, Fasenra, or any other interleukin-5 antagonist.

Approval duration: 6 months

D. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (must meet all):

1. Age ≥ 18
Note: Exceptions may be considered for patients younger than the FDA approved age on a case-by-case basis by the SHP medical director

2. Confirmed diagnosis of CRSwNP (diagnosis codes J330, J331, J338, J339)

3. Evidence of inadequate response to nasal corticosteroid

4. Nucala is not prescribed concurrently with Cinqair, Xolair, Fasenra, or any other interleukin-5 antagonist.

Approval duration: 6 months

D. 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. Severe Asthma (must meet all):

1. Member 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; or
    b. Increase in predicted FEV1 (forced expiratory volume) from pretreatment baseline; or
    c. Reduction in reported asthma-related symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
        i. Asthma attacks
        ii. Chest tightness or heaviness
        iii. Coughing or clearing throat
        iv. Difficulty taking deep breath or difficulty breathing out
        v. Shortness of breath
        vi. Sleep disturbance, night wakening, or symptoms upon awakening
        vii. Tiredness
        viii. Wheezing/heavy breathing/fighting for air

2. Documentation stating member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of mepolizumab.

3. Nucala is not prescribed concurrently with Cinqair, Xolair, Fasenra, or any other interleukin-5 antagonist.

4. Member must be compliant with their Nucala regimen in order to qualify for additional prior authorizations. The provider must submit a statement documenting compliance with the requests for each renewal.

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

Approval duration: 12 months

B. HES or EPGA or CRSwNP (must meet all):

1. Currently receiving medication via Centene benefit or has met all initial approval criteria.

2. Documentation supports positive response to therapy.

3. Documentation of compliance with the medication for 6 continuous months.

4. Documentation stating member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of mepolizumab.

5. Nucala is not prescribed concurrently with Cinqair, Xolair, Fasenra, or any other interleukin-5 antagonist.

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

Approval duration: 12 months

C. Other diagnoses/indications

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

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook. June 2022.

ATTACHMENTS:

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc	Added criteria for new FDA-approved indication CRSwNP Added diagnosis codes 11.30.2021	11/30/2021
Ad Hoc	Formatting Updated references Corrected diagnosis codes for asthma	07/01/2022
Ad Hoc	Added compliance statement requirement for continued approval for asthma Added that treatment must not be used with any other IL-5 antagonist	8/10/2022
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.