TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Mepolizumab (Nucala®)	**CRITERIA ID:** TX.CC.PHAR.14
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 10/18/2021	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE:11/30/2021, 07/01/2022, 11/14/2022, 08/01/2023, 03/15/2024, 5/1/2024, 3/25/2025	**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 Mepolizumab (Nucala®).

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:
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 and Centene Pharmacy Services to follow state guidance for medical necessity review mepolizumab (Nucala®); procedure code: J2182.

Description/Mechanism of Action:
Mepolizumab (Nucala®) is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa).

FDA Approved Indications:
Mepolizumab (Nucala®) is indicated for the following treatments:

- Add-on maintenance in clients who are 6 years of age or older with severe asthma with an eosinophilic phenotype
- Adult clients who are 18 years of age or older with eosinophilic granulomatosis with polyangiitis (EGPA)
- Adult and pediatric clients who are 12 years of age or older with hypereosinophilic syndrome (HES) for 6 months or longer 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

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. The client has a 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 J45.50, J45.51, J45.52, and J82.83)
2. The client is 6 years of age or older.
   Note: Exceptions may be considered for clients younger than the FDA approved age on a case-by-case basis by the Medical Director.
3. 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 mepolizumab, 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.
4. Nucala is not prescribed concurrently with Xolair or any other interleukin-5 antagonist.
5. Any client with a preexisting helminth infection should be treated prior to receiving Nucala therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Nucala should be discontinued until parasitic infection resolves.

Approval duration: 6 months

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

1. The client has a confirmed diagnosis of EGPA (diagnosis code: M30.1).
2. The client is 18 years of age or older.
   Note: Exceptions may be considered for clients younger than the FDA approved age on a case-by-case basis by the Medical Director.
3. Documentation that the client has a medical history of asthma.
4. Documentation that the client has refractory disease or has had a history of EGPA relapse.
5. Presence of at least 2 of the following EGPA characteristics below:
   a. Histopathological findings of eosinophilic vascularitis, 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 Xolair or any other interleukin-5 antagonist.
7. Documentation that the client has been on an oral glucocorticoid and/or cyclophosphamide, azathioprine, methotrexate or leflunomide.
8. Any client with a preexisting helminth infection should be treated prior to receiving Nucala therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Nucala should be discontinued until parasitic infection resolves.

Approval duration: 6 months

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

1. The client has a diagnosis of HES for 6 months or longer without any non-hematologic secondary cause (diagnosis codes: D72.110, D72.111, D72.118, D72.119)
2. The client is 12 years of age or older.
   Note: Exceptions may be considered for clients younger than the FDA approved age on a case-by-case basis by the Medical Director.
3. Documentation that the client has a 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 attestation that the 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.

6. Any 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 with mepolizumab should be discontinued until parasitic infection resolves.

Approval duration: 6 months

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

1. The client has a confirmed diagnosis of CRSwNP (diagnosis codes: J33.0, J33.1, J33.8, J33.9).
2. The client is 18 years of age or older.
   Note: Exceptions may be considered for clients younger than the FDA approved age on a case-by-case basis by the Medical Director.
3. Documentation that the client has had an inadequate response to nasal corticosteroid.
4. Nucala is not prescribed concurrently with Cinqair, Xolair, Fasenra, or any other interleukin-5 antagonist.
5. Any client with a preexisting helminth infection should be treated prior to receiving Nucala therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Nucala should be discontinued until parasitic infection resolves.

Approval duration: 6 months

II. Continued Therapy

A. 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; 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 client 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. The client 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.
5. Any client with a preexisting helminth infection should be treated prior to receiving Nucala therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Nucala 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

B. HES or EGPA or CRSwNP (must meet all):
1. Currently receiving medication via Centene benefit or has met all initial approval criteria.
2. Documentation showing that the client has had positive response to therapy.
3. Documentation showing that the client has been compliant with the medication for 6 continuous months.
4. Documentation stating that client 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.
6. Any client with a preexisting helminth infection should be treated prior to receiving Nucala therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Nucala 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
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
Ad Hoc	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 Added additional criteria step for initial approval for indication of EGPA: • A client has been on an oral glucocorticoid and/or cyclophosphamide, azathioprine, methotrexate or leflunomide. Updated criteria step 3 for indication of 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 contraindication to these agents. Updated criteria step verbiage to "the client" for consistency throughout document. Removed criteria points under asthma indication referencing: smoking, pulmonary function tests and eosinophil counts Changed Superior HealthPlan/SHP to Centene Pharmacy Services/CPS throughout policy Replaced Karen Tadlock, Director, V.P. Regional Pharmacy with Thomas Nguyen, Sr. Pharmacy Director under Policy and Procedure Approval section Rearranged Purpose and Policy sections Added CHIP Perinate to Products	08/01/2023
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement In continuation criteria, corrected EPGA to EGPA	03/15/2024
Ad Hoc Review	Added J82.83 under I.A.1 as clarification for eosinophilic asthma Corrected first I,D under initial criteria to I.C Realigned bullets I.B, I.C, and I.D, II.A and II.B to indented spaces for formatting purposes	5/1/2024

Annual Review	Removed reference to Fasenra and Nucala in I.A.4 and II.A.3. to align with verbiage in TMHP CAD Manual (reslizumab may not be used concurrently with omalizumab or any other interleukin-5 antagonist).	3/25/2025