UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Nucala

Program	Prior Authorization
Medication	Nucala® (mepolizumab) auto-injector and pre-filled syringe
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	8/2019
Pharmacy and Therapeutics Approval Date	8/2020
Effective Date	10/2020

1. Background:

Nucala (mepolizumab) is an interleukin-5 receptor antagonist indicated for add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. Nucala is also indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

2. Coverage Criteria:

A. Eosinophilic granulomatosis with polyangiitis (EGPA)

1. Initial Authorization

a. **Nucala** will be approved based on **all** of the following criteria:

(1) Diagnosis of relapsing or refractory EGPA as defined by **all** of the following:

(a) Diagnosis of EGPA

-AND-

(b) Past medical history or presence of asthma

-AND-

(c) Presence of at least **two** of the following characteristics typical of EGPA:

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i. Histopathological evidence of **all** of the following:
   - Eosinophilic vasculitis
   - Perivascular eosinophilic infiltration
   - Eosinophil-rich granulomatous inflammation

ii. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
iii. Pulmonary infiltrates, non-fixed
iv. Sino-nasal abnormality
v. Cardiomyopathy (established by echocardiography or MRI)
vi. Glomerulonephritis (hematuria, red cell casts, proteinuria)
vii. Alveolar hemorrhage
viii. Palpable purpura
ix. Anti-neutrophil cytoplasmic antibody (ANCA) positive

-AND-

(d) History of relapsing or refractory disease defined as **one** of the following:

i. Relapsing disease as defined as a past history (within the past 2 years) of at least one EGPA relapse (requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization)
ii. Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens

-AND-

(2) Patient is currently taking standard therapy (corticosteroids with or without immunosuppressive therapy)

-AND-

(3) Patient is not receiving Nucala in combination with **any** of the following:

(a) Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

-AND-

(4) Prescribed by **one** of the following:

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(a) Pulmonologist
(b) Rheumatologist
(c) Allergist
(d) Immunologist

Authorization will be issued for 12 months.

2. Reauthorization

a. **Nucala** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Nucala therapy as demonstrated by at least **one** of the following:

(a) Reduction in the frequency and/or severity of relapses
(b) Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
(c) Disease remission
(d) Reduction in severity or frequency of EGPA-related symptoms

-AND-

(2) Patient is not receiving Nucala in combination with **any** of the following:

(a) Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

-AND-

(3) Prescribed by **one** of the following:

(a) Pulmonologist
(b) Rheumatologist
(c) Allergist
(d) Immunologist

Authorization will be issued for 12 months.

B. Severe Asthma

1. Initial Authorization

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a. **Nucala** will be approved based on **all** of the following criteria:

(1) Diagnosis of severe asthma

-AND-

(2) Classification of asthma as uncontrolled or inadequately controlled as defined by at least **one** of the following

(a) Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
(b) Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
(c) Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
(d) Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
(e) Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

(3) Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting **one** of the following:

(a) Asthma is an eosinophilic phenotype as defined by a baseline (pre-mepolizumab treatment) peripheral blood eosinophil level ≥ 150 cells/μL within the past 6 weeks

-OR-

(b) Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma

-AND-

(4) Nucala will be used in combination with **one** of the following:

(a) **One** high dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol),

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Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

-OR-

(b) Combination therapy including **both** of the following:

i. **One** high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

-AND-

ii. **One** additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

-AND-

(5) Patient is not receiving Nucala in combination with **any** of the following:

(a) Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

-AND-

(6) Prescribed by **one** of the following:

(a) Pulmonologist
(b) Allergist
(c) Immunologist

-AND-

(7) History of failure to a 4 month trial of Fasenra (benralizumab), or contraindication or intolerance Fasenra

Authorization will be issued for 12 months.

2. Reauthorization

a. **Nucala** will be approved based on **all** of the following criteria:

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(1) Documentation of positive clinical response to Nucala therapy as demonstrated by at least **one** of the following:

(a) Reduction in the frequency of exacerbations
(b) Decreased utilization of rescue medications
(c) Increase in percent predicted FEV1 from pretreatment baseline
(d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
(e) Reduction in oral corticosteroid requirements

-AND-

(2) Nucala is being used in combination with an ICS-containing controller medication

-AND-

(3) Patient is not receiving Nucala in combination with **any** of the following:

(a) Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

-AND-

(4) Prescribed by **one** of the following:

(a) Pulmonologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

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4. References:

1. Nucala® [prescribing information]. Research Triangle Park, NC; GlaxoSmithKline, LLC; September 2019.
2. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J.* 2014 Feb:43(2):343-73.
3. Institute for Clinical and Economic Review (ICER). Mepolizumab (Nucala®, GlaxoSmithKline plc.) for the Treatment of Severe Asthma with Eosinophilia: Effectiveness, Value, and Value-Based Price Benchmarks. March 14, 2016. Available at http://icer-review.org/material/asthma-final-report/. Accessed April 25, 2016.
4. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention,2020. Available at http://www.ginasthma.org. Accessed July 2020.
5. Bel EH, Wenzel SE, Thompson PJ, Prazma CM, et al. Oral Glucocorticoid-Sparing Effect of Mepolizumab in Eosinophilic Asthma. *New Eng J Med*. 2014 Sept:371(13):1189-97.
6. Parameswaran KN, Dasgupta A, et al. Mepolizumab in COPD with Eosinophilic Bronchitis: A Randomized Clinical Trial. Poster session presented at the Annual Meeting of the American Academy of Allergy, Asthma and Immunology, Los Angeles, CA. March 6, 2016.
7. Centers for Disease Control and Prevention. Asthma. Available at http://www.cdc.gov. Accessed June 13, 2019.
8. National Heart, Lung and Blood Institute. Explore Asthma. Available at http://www.nhlbi.nih.gov. Accessed May 16, 2016.

Program	Prior Authorization
Change Control	
Date	Change
8/2019	New program
1/2020	Added step through Fasenra for severe asthma due to PDL changes. Updated background and references.
8/2020	Annual review. No changes in clinical criteria. Updated references.

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