UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1288-8
Program	Prior Authorization/Notification
Medications	*Nucala® (mepolizumab) *This program applies to the prefilled autoinjector and prefilled syringe formulations.
P&T Approval Date	8/2019, 4/2020, 3/2021, 9/2021, 11/2021, 11/2022, 7/2023
Effective Date	10/1/2023; Oxford only: N/A

1. Background:

Nucala (mepolizumab) is an interleukin-5 receptor antagonist indicated for add-on maintenance treatment of patients aged 6 years and older with severe asthma and with an eosinophilic phenotype, for add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP) and an inadequate response to nasal corticosteroids, the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA), and the 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[1].

Limitations of use:
Nucala is not for relief of acute bronchospasm or status asthmaticus.

2. Coverage Criteria[a]:

A. Eosinophilic granulomatosis with polyangiitis (EGPA)

1. **Initial Authorization**

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

(1) **All** of the following:

(a) Patient has been established on therapy with Nucala for EGPA under an active UnitedHealthcare prior authorization

-AND-

(b) Documentation of positive clinical response to Nucala therapy

-AND-

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

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

-OR-

(2) **Both** of the following:

(a) Diagnosis of EGPA

-AND-

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

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Nucala therapy

-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)]

Authorization will be issued for 12 months.

B. Asthma

1. **Initial Authorization**

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

(1) **All** of the following:

(a) Patient has been established on therapy with Nucala for severe asthma under an active UnitedHealthcare prior authorization

-AND-

(b) Documentation of positive clinical response to Nucala therapy

-AND-

(c) Nucala will be used in combination with maintenance controller medications [e.g., combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA), ICS, LABA]

-AND-

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

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

-OR-

(2) **All** of the following:

(a) Diagnosis of severe asthma

-AND-

(b) Nucala will be used in combination with maintenance therapy [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-AND-

(c) Asthma is an eosinophilic phenotype

-AND-

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

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

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

-AND-

(2) Nucala is being used in combination with maintenance therapy [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-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)]
(d) Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

Authorization will be issued for 12 months.

C. Hypereosinophilic Syndrome (HES)

1. **Initial Authorization**

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

(1) **All** of the following:

(a) Patient has been established on therapy with Nucala for HES under an active UnitedHealthcare prior authorization

-AND-

(b) Documentation of positive clinical response to Nucala therapy

-AND-

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

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

-OR-

(2) All of the following:

(a) Diagnosis of HES ≥ 6 months ago

-AND-

(b) There is no identifiable non-hematologic secondary cause of the patient's HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

-AND-

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

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Nucala** will be approved based on **both** of the following criterion:

(1) Documentation of positive clinical response to Nucala therapy

-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)]

Authorization will be issued for 12 months.

D. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

1. **Initial Authorization**

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

(1) **All** of the following:

(a) Patient has been established on therapy with Nucala for CRSwNP under an active UnitedHealthcare prior authorization

-AND-

(b) Documentation of positive clinical response to Nucala therapy

-AND-

(c) Patient will continue to receive Nucala as add-on maintenance therapy

-AND-

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

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

-OR-

(2) **All** of the following:

(a) Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP).

-AND-

(b) Will be used as add-on maintenance therapy

-AND-

(c) Patient has had an inadequate resonse to nasal corticosteroids [e.g., Flonase (fluticasone), Rhinocort (budesonide), Nasonex (mometasone)];

-AND-

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

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

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Nucala** will be approved based on **both** of the following criterion:

(1) Documentation of positive clinical response to Nucala therapy

-AND-

(2) Patient will continue to receive Nucala as add-on maintenance 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)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- 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 limitations may be in place.
- Medical Necessity may be in place.
- The single-dose vial is typically covered under the medical benefit. Please refer to the United Healthcare Medical Benefit Drug Policy: "Respiratory Interleukins (Cinqair®, Fasenra®, and Nucala®)".

4. References:

1. Nucala® [package insert]. Research Triangle Park, NC; GlaxoSmithKline, LLC; January 2022.

Program	Prior Authorization/Notification - Nucala (mepolizumab)
Change Control	
8/2019	New program.
4/2020	Updated program to address specific product formulations. Updated references.
3/2021	Updated program to add HES indication and update age requirement for severe asthma indication. Added limitations of use. Updated references.
9/2021	Added coverage criteria for new indication, chronic rhinosinusitis with nasal polyps. Updated background and references.
11/2021	Added coverage criteria for patients established on therapy under UnitedHealthcare medical benefit.
1/2022	Administrative change to fix typo.
11/2022	Annual review. Updated criteria for patients established on Nucala under active UHC PA for Asthma and CRSwNP. Added state mandate footnote and updated reference.
7/2023	Within the Asthma section, added/updated examples of ICS-containing maintenance medications, removed bypass of eosinophilic phenotype requirement for patients currently dependent on maintenance therapy with oral corticosteroid, and added Tezspire to list of agents that should not be used in combination with Nucala.