Cigna National Preferred Formulary Coverage Policy

Drug Quantity Management – Per Days
Immunologicals – Nucala® (mepolizumab subcutaneous injection)

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Product Identifier(s)

Effective 1/1/23 to 3/21/23: 108853

Effective 3/22/23: 65514

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to manage potential dose escalation of Nucala. If the Drug Quantity Management rule is not met for the requested at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 days
Nucala® (mepolizumab subcutaneous injection)	100 mg/1 mL prefilled autoinjector	1 prefilled autoinjector	3 prefilled autoinjectors
	100 mg/1 mL prefilled syringe	1 prefilled syringe	3 prefilled syringes
	100 mg vial	1 vial	3 vials
	40 mg/0.4 mL prefilled syringe	1 prefilled syringe	3 prefilled syringes

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Nucala 40 mg/0.4 mL prefilled syringes

No overrides recommended.

Nucala 100 mg/mL autoinjectors, 100 mg/mL prefilled syringes, and 100 mg vials

1. If the individual is requesting Nucala for the treatment of eosinophilic granulomatosis with polyangiitis or hypereosinophilic syndrome, approve the requested quantity not to exceed 3 autoinjectors, syringes, or vials per 28 days at retail or 9 autoinjectors, syringes, or vials per 84 days.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Nucala, an interleukin (IL)-5 antagonist monoclonal antibody, is indicated for the following uses:[1]

- **Asthma**, as add-on maintenance treatment of patients ≥ 6 years of age with severe disease and an eosinophilic phenotype. Limitations of Use: Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.
- **Chronic rhinosinusitis with nasal polyposis**, as an add-on maintenance treatment in patients ≥ 18 years of age with an inadequate response to nasal corticosteroids.
- **Eosinophilic granulomatosis with polyangiitis** (formerly known as Churg-Strauss Syndrome) in adult patients.
- **Hypereosinophilic syndrome** in patients ≥ 12 years of age who have had the condition for ≥ 6 months without an identifiable non-hematologic secondary cause.

Dosing

Table 1. Nucala Dosing and Administration.[1]

Indications	Dosing and Administration
Asthma, as add-on maintenance treatment of patients ≥ 6 years of age with severe disease and an eosinophilic phenotype.	Patients ≥ 12 years of age: 100 mg SC injection Q4W Patients 6 to 11 years of age: 40 mg SC injection Q4W
Chronic rhinosinusitis with nasal polyposis, as an add-on maintenance treatment in patients ≥ 18 years of age with an inadequate response to nasal corticosteroids.	100 mg SC Q4W
Eosinophilic granulomatosis with polyangiitis [formerly known as Churg-Strauss Syndrome] in adult patients.	300 mg SC Q4W (administered as three separate 100 mg SC injections)
Hypereosinophilic syndrome in patients ≥ 12 years of age who have had hypereosinophilic syndrome for ≥ 6 months without an identifiable non-hematologic secondary cause.	300 mg SC Q4W (administered as three separate 100 mg SC injections)

SC – Subcutaneous; Q4W – Once every 4 weeks.

Availability

Nucala is supplied as 100 mg single-dose vials, 100 mg/1 mL single-dose prefilled autoinjectors, 100 mg/1 mL single-dose prefilled syringes, and 40 mg/0.4 mL single-dose prefilled syringes.[1] Cartons of Nucala each contain one single-dose vial, one prefilled autoinjector, or one prefilled syringe. Nucala vials should be reconstituted and administered by a healthcare professional only. Nucala 100 mg prefilled autoinjectors and 100 mg prefilled syringes are only labeled for use in patients ≥ 12 years of age and may be self-administered by the patient or administered by the caregiver after a healthcare provider determines it is appropriate. The 40 mg prefilled

syringes may also be administered by the patient or caregiver after a healthcare provider determines it is appropriate.

References

1. Nucala® injection [prescribing information]. Philadelphia, PA: GlaxoSmithKline; January 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy was updated to include the existing quantity limits when the product is obtained via home delivery. No change to criteria.	10/05/2022