



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Immunologicals – Nucala Drug Quantity Management Policy – Per Days

- Nucala® (mepolizumab subcutaneous injection – GlaxoSmithKline)

REVIEW DATE: 10/07/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 obstructive pulmonary disease**, as add-on maintenance treatment in patients ≥ 18 years of age with inadequately controlled disease and an eosinophilic phenotype. Limitation of Use: Nucala is not indicated for the relief of acute bronchospasm.
- **Chronic rhinosinusitis with nasal polyps**, 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.	<u>Patients ≥ 12 years of age:</u> 100 mg SC injection Q4W <u>Patients 6 to 11 years of age:</u> 40 mg SC injection Q4W
Chronic obstructive pulmonary disease , as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) or eosinophilic phenotype.	100 mg every 4 weeks
Chronic rhinosinusitis with nasal polyps , 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, autoinjector, or syringe. Nucala vials should be reconstituted and administered by a healthcare professional only. Nucala 100 mg prefilled autoinjectors and 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.

Policy Statement

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 mL (1 prefilled autoinjector)	3 mL (3 prefilled autoinjectors)
	100 mg/1 mL prefilled syringe	1 mL (1 prefilled syringe)	3 mL (3 prefilled syringes)
	100 mg/1 mL vial	1 mL (1 vial)	3 mL (3 vials)
	40 mg/0.4 mL prefilled syringe	0.4 mL (1 prefilled syringe)	1.2 mL (3 prefilled syringes)

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

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 patient is requesting Nucala for the treatment of eosinophilic granulomatosis with polyangiitis or hypereosinophilic syndrome, approve 3 mL (three autoinjectors, syringes, or vials) per 28 days at retail or 9 mL (nine autoinjectors, syringes, or vials) per 84 days at home delivery.

REFERENCES

1. Nucala® injection [prescribing information]. Philadelphia, PA: GlaxoSmithKline; May 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/06/2023
Annual Revision	No criteria changes.	10/09/2024
Annual Revision	No criteria changes.	10/07/2025

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