# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Immunologicals – Nucala Drug Quantity Management Policy – Per Days
- Nucala® (mepolizumab subcutaneous injection – GlaxoSmithKline)

**REVIEW DATE:** 10/09/2024

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***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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 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<br>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<br>(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<br>(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.

## 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<br>(1 prefilled autoinjector) | 3 mL<br>(3 prefilled autoinjectors) |
| | 100 mg/1 mL prefilled syringe | 1 mL<br>(1 prefilled syringe) | 3 mL<br>(3 prefilled syringes) |
| | 100 mg/1 mL vial | 1 mL<br>(1 vial) | 3 mL<br>(3 vials) |
| | 40 mg/0.4 mL prefilled syringe | 0.4 mL<br>(1 prefilled syringe) | 1.2 mL<br>(3 prefilled syringes) |

**Immunologicals – Nucala Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(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; March 2023.

## 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 |