DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Lupus – Benlysta Subcutaneous Drug Quantity Management Policy – Per Days
- Benlysta® (belimumab subcutaneous injection – GlaxoSmithKline)

REVIEW DATE: 09/06/2024

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

Benlysta subcutaneous (SC), a B-lymphocyte stimulator-specific inhibitor, is indicated for the following uses:[1]
- **Lupus nephritis**, in patients ≥ 5 years of age with active disease who are receiving standard therapy.
- **Systemic lupus erythematosus**, in patients ≥ 5 years of age with active, autoantibody-positive, systemic disease who are receiving standard therapy.

Benlysta SC has not been studied and is not recommended in those with severe, active central nervous system lupus, or in combination with other biologics. In some of the clinical trials involving Benlysta, Black patients had a lower response rate for the primary endpoint relative to Black patients receiving placebo; therefore, caution is recommended when considering Benlysta in Black patients. Of note, intravenous (IV) Benlysta is not targeted in this policy.

Dosing

Benlysta SC is not approved for use in patients < 5 years of age.[1]

Systemic Lupus Erythematosus

- Patients 15 kg to <40 kg: 200 mg SC once every 2 weeks.
- Patients ≥ 40 kg: 200 mg SC once weekly.
- If transitioning from IV Benlysta therapy, administer the first SC dose 1 to 4 weeks after the last IV dose.

Lupus Nephritis

- In adults initiating therapy with Benlysta for active lupus nephritis, the recommended dose is 400 mg (two 200 mg injections) once weekly, for 4 doses, then 200 mg once weekly thereafter.
- A patient receiving IV Benlysta therapy may transition to SC therapy any time after the patient completes the first two IV doses. The recommended SC dose in this scenario is 200 mg given 1 to 2 weeks after the last IV dose.

Availability

Benlysta SC is available as a 200 mg/mL prefilled syringe and auto-injector.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential premature dose escalation of Benlysta. If the Drug Quantity Management rule is not met 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 Quantity per 84 days
Benlysta® (belimumab subcutaneous injection)	200 mg/mL prefilled syringe	4 mL (4 prefilled syringes)	12 mL (12 prefilled syringes)
	200 mg/mL auto-injector	4 mL (4 auto-injectors)	12 mL (12 auto-injectors)

Lupus – Benlysta Subcutaneous 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

1. If the patient is initiating treatment for lupus nephritis or requires additional induction dosing, as verified by the absence of claims for Benlysta in the past 130 days, approve a one-time override for 8 mL (eight prefilled syringes or auto-injectors) as a 28-day supply at retail or home delivery.

REFERENCES

1. Benlysta® subcutaneous injection [prescribing information]. Rockville, MD: GlaxoSmithKline; June 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/05/2023
Annual Revision	No criteria changes.	09/06/2024