DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 08/05/2025

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

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 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. 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
- Adults: 200 mg SC once weekly (QW).
- Patients 5 to < 18 years of age who weigh 15 kg to < 40 kg: 200 mg SC once every 2 weeks (Q2W).
- Patients 5 to < 18 years of age who weigh ≥ 40 kg: 200 mg SC QW.
- If transitioning from IV Benlysta therapy, administer the first SC dose 1 to 4 weeks after the last IV dose.

Lupus Nephritis
- Adults: 400 mg (two 200 mg injections) QW for 4 doses, then 200 mg QW thereafter.
- Patients 5 to < 18 years of age who weigh 15 kg to < 40 kg: 200 mg QW for 4 doses, then 200 mg Q2W thereafter.
- Patients 5 to < 18 years of age who weigh ≥ 40 kg: 400 mg (two 200 mg injections) QW for 4 doses, then 200 mg QW thereafter.
- A patient receiving IV Benlysta therapy may transition to SC therapy any time after the patient completes the first two IV doses.

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 the duration noted below. "One-time" approvals are provided for 30 days 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		

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

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) at retail or home delivery.

REFERENCES

1. Benlysta® subcutaneous injection [prescribing information]. Rockville, MD: GlaxoSmithKline; June 2025.

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
Annual Revision	Policy Statement was clarified to note that "one-time" approvals are provided for 30 days in duration.	08/05/2025