DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 08/31/2022

OVERVIEW

Benlysta subcutaneous, a B-lymphocyte stimulator-specific inhibitor, is indicated for the following uses:[1]
- **Lupus nephritis**, in adults with active disease who are receiving standard therapy.
- **Systemic lupus erythematosus**, in patients ≥ 18 years of age with active, autoantibody-positive, systemic disease who are receiving standard therapy.

Benlysta subcutaneous 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, there is also an intravenous (IV) formulation of Benlysta with a similar indication except use is expanded to those ≥ 5 years of age.

Dosing

Benlysta subcutaneous (SC) is not approved for use in patients < 18 years of age.[1]

Systemic Lupus Erythematosus
- 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 patients 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.

Automation: None.

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 prefilled syringes	12 prefilled syringes
	200 mg/mL auto-injector	4 auto-injectors	12 auto-injectors

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 up to eight prefilled syringes or auto-injectors as a 28-day supply at retail or mail order.

REFERENCES

1. Benlysta® injection [prescribing information]. Rockville, MD: Human Genmome Sciences/GlaxoSmithKline; March 2021.