Pharmacy Medical Necessity Guidelines:
Benlysta® (belimumab) Subcutaneous

Effective: March 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RxUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Benlysta (belimumab) subcutaneous is a B-lymphocyte stimulator (BLys)-specific inhibitor indicated for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy. Benlysta (belimumab) is also indicated for the treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy.

The efficacy of Benlysta (belimumab) has not been evaluated in patients with severe active central nervous system lupus. Benlysta (belimumab) has not been studied in combination with other biologics. Use of Benlysta (belimumab) is not recommended in these situations.

COVERAGE GUIDELINES

The plan may authorize coverage of **Benlysta (belimumab)** Subcutaneous for Members, when **ALL** of the following criteria are met:

Lupus Nephritis

1. Documented diagnosis of active lupus nephritis

AND

2. Documentation the diagnosis of active lupus nephritis is confirmed by urine/blood tests or kidney biopsy

AND

3. The prescribing physician is a rheumatologist or nephrologist

AND

4. The patient is at least 5 years of age or older

AND

5. Documentation of **one (1) of the following**:
    a. Use in combination with at least one agent from the following standard of care therapeutic categories: Antimalarials (e.g., hydroxychloroquine), corticosteroids (e.g., prednisone), or immunosuppressants (e.g., methotrexate)
    b. Clinical inappropriateness of use of all of the following standard of care therapeutic categories: Antimalarials, corticosteroids, and immunosuppressants

AND

6. Documentation Benlysta will not be used in combination with other biologics

Systemic Lupus Erythematosus

1. Documented diagnosis of active systemic lupus erythematosus

AND

2. Documentation that prior to initiating therapy with the requested agent, the patient is auto-antibody positive (e.g., ANA, anti-dsDNA, anti-Sm)

AND

3. The patient is at least 5 years of age or older

AND

4. Prescribed by or in consultation with a rheumatologist

AND

5. Documentation of **one (1) of the following**:

a. Use in combination with at least one agent from the following standard of care therapeutic categories: Antimalarials (e.g., hydroxychloroquine), corticosteroids (e.g., prednisone), or immunosuppressants (e.g., methotrexate)
b. Clinical inappropriateness of use of all of the following standard of care therapeutic categories: Antimalarials, corticosteroids, and immunosuppressants

AND

6. Documentation Benlysta will not be used in combination with other biologics

LIMITATIONS

None

CODES

None

REFERENCES

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APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

- June 13, 2023: No changes
- April 9, 2024: No changes
- March 11, 2025: No changes (eff 3/11/25)
- March 10, 2026: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.