Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs

Benlysta® (belimumab) Intravenous

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Public Plans Products

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration-Approved Indications

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

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Benlysta Intravenous 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 biologic therapies

Systemic Lupus Erythematosus

1. Documented diagnosis of active systemic lupus erythematosus

AND

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

AND

3. Prescribed by or in consultation with a rheumatologist

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. b. Clinical inappropriateness of use of all of the following standard of care therapeutic categories: Antimalarials, corticosteroids, and immunosuppressants

AND

6. Documentation that Benlysta will not be used in combination with other biologic therapies

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0490	Injection, belimumab, 10 mg

Note: Medical billing codes may not be used for Benlysta injection for subcutaneous use. This formulation must be obtained via the Member's pharmacy benefit.

References

1. American College of Rheumatology. Systemic Lupus Erythematosus (Lupus). URL: rheumatology.org/practice/clinical/patients/diseases_and_conditions/lupus.asp. Available from Internet. Accessed 2023 July.
2. Benlysta (belimumab) [package insert]. Rockville, MD: Human Genome Sciences, Inc., June 2025.
3. Bertsias GK, Ioannidis JP, Aringer M, et al. EULAR recommendations for the management of systemic lupus erythematosus with neuropsychiatric manifestations: report of a task force of the EULAR standing committee for clinical affairs. *Ann Rheum Dis*. 2010 Dec;69(12):2074-82.
4. Bertsias GK, Ioannidis JP, Boletis J, et al. EULAR points to consider for conducting clinical trials in systemic lupus erythematosus: literature-based evidence for the selection of endpoints. *Ann Rheum Dis*. 2009; 68(4):477-83.
5. Bertsias G, Ioannidis JP, Boletis J et al. EULAR recommendations for the management of systemic lupus erythematosus. Report of a task force of the EULAR Standing Committee for international clinical studies including therapeutics. *Ann Rheum Dis*. 2008; 67(2):195-205.
6. Bezalel S, Asher I, Elbirt D, Sthoeger ZM. Novel biological treatments for systemic lupus erythematosus: current and future modalities. *Isr Med Assoc J*. 2012 Aug;14(8):508-14.
7. Dooley MA, Houssiau F, Aranow C, et al. Effect of belimumab treatment on renal outcomes: results from the phase 3 belimumab clinical trials in patients with SLE. *Lupus*. 2013 Jan;22(1):63-72.
9. Furie R, Petri M, Zamani O, et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. *Arthritis Rheum*. 2011 Dec;63(12):3918-30.
10. Ginzler EM, Wallace DJ, Merrill JT, et al. Disease control and safety of belimumab plus standard therapy over 7 years in patients with systemic lupus erythematosus. *J Rheumatol*. 2014 Feb;41(2):300-9.
11. Gurevitz SL, Snyder JA, Wessel EK, et al. Systemic lupus erythematosus: a review of the disease and treatment options. *Consult Pharm*. 2013 Feb;28(2):110-21.
12. Manzi S, Sánchez-Guerrero J, Merrill JT, et al. Effects of belimumab, a B lymphocyte stimulator- specific inhibitor, on disease activity across multiple organ domains in patients with systemic lupus erythematosus: combined results from two phase III trials. *Ann Rheum Dis*. 2012 Nov;71(11):1833- 8.
13. Falk, R, Dall'Era M, Appel G. Lupus nephritis: Initial and subsequent therapy for focal or diffuse lupus nephritis. UpToDate. January 11, 2022. Accessed March 25, 2022.
14. Wallace D. Overview of the management and prognosis of systemic lupus erythematosus in adults. UpToDate. October 15, 2021. Accessed March 25, 2022.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).
- September 12, 2023: Minor wording changes to make coverage criteria more concise and clearer. Updated title of Medical Necessity Guideline "Benlysta (belimumab) Intravenous". Removed "The Member does not have severe active central nervous system lupus." Removed the Limitation "For the treatment of systemic lupus erythematosus (SLE), Benlysta (belimumab) will not be approved for Members who are autoantibody negative" Updated wording for requirements for standard therapies (effective 12/1/23).
- September 10, 2024: No changes.
- December 2025: Evote, no changes (effective 1/1/26)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along

with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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