Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Benlysta® (belimumab)

Effective: January 1, 2026

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

Applies to:

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

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

Approval of Benlysta for SLE was based on four clinical trials in adults and one clinical trial in pediatric patients. Patients with SLE according to the American College of Rheumatology criteria were on stable standard therapy.

Approval of Benlysta for lupus nephritis was based on the BLISS-LN trial. Adults with active lupus nephritis receiving standard therapy were randomized to either Benlysta or placebo. Results demonstrated that significantly more patients who received Benlysta had a renal response at Week 104 (43% vs 32%). Furthermore, the renal response was achieved sooner with Benlysta compared to placebo (Week 52, 47% vs 35%). Risk of a renal-related event or death was a key secondary endpoint and results demonstrated the risk was lower with Benlysta compared to placebo (hazard ratio, 0.5).

Benlysta and Saphnelo have different mechanisms of actions. Benlysta inhibits B-cell stimulating factor and Saphnelo binds to subunit 1 of the type I IFN receptor, blocking the activity of type I IFNs involved in regulating the inflammatory pathways implicated in SLE.

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 adult 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 (belimumab) for Members when **ALL** of the following criteria are met:

Lupus Nephritis

1. Documented diagnosis of active lupus nephritis that has been confirmed by urine/blood tests or kidney biopsy

AND

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

AND

3. Prescribed by or in consultation with a rheumatologist or nephrologist

Systemic Lupus Erythematosus

1. Documented diagnosis of active, autobody positive systemic lupus erythematosus

AND

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

AND

3. Prescribed by or in consultation with a rheumatologist

Limitations

None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0490	Injection, belimumab, 10 mg

References

1. Benlysta [package insert]. Rockville, MD: Human Genome Sciences, Inc.; Feb 2023.
2. Furie R et al. Two-Year, Randomized, Controlled Trial of Belimumab in Lupus Nephritis. NEJM. 2020; 383(12):1117–1128
3. Dooley MA et al. Effect of belimumab treatment on renal outcomes: results from the phase 3 belimumab clinical trials in patients with SLE. Lupus. 2013;22(1):63–72
4. Hoover PJ, et al. Insights into the epidemiology and management of lupus nephritis from the US rheumatologist's perspective. Kidney Int. 2016;90(3):487-492.
5. Hahn BH, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. Arthritis Care Res (Hoboken). 2012;64(6):797-808.
6. Fanouriakis A, et al. EULAR recommendations for the management of systemic lupus erythematosus. Ann Rheum Dis. 2023; 0:1:15.

Approval And Revision History

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

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- September 12, 2023: Removed the Limitation “For the treatment of systemic lupus erythematosus, Benlysta (belimumab) will not be approved in the following instances: For Members with severe active central nervous system lupus, For Members who are autoantibody negative, for use in combination with other biologic therapies used to treat Lupus.” Minor wording changes to make coverage criteria more concise and clearer (effective10/1/2023).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)
- September 10, 2024: No changes
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.