

Medical Policy Manual **Approved Rev: Do Not Implement until 9/30/26**

Belimumab (Benlysta®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Benlysta is indicated for the treatment of:

- Patients 5 years of age and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy.
- Patients 5 years of age and older with active lupus nephritis who are receiving standard therapy.

Limitations of Use

The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system (CNS) lupus. Use of Benlysta is not recommended in this situation.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Medical records (e.g., chart notes, laboratory reports) documenting the presence of autoantibodies relevant to SLE (e.g., antinuclear antibodies [ANA] by immunofluorescence [IFA] 1:80 or higher, anti-double-stranded DNA [anti-ds DNA], anti-Smith [anti-Sm], antiphospholipid antibodies, low complement proteins), or kidney biopsy supporting the diagnosis (where applicable).

Continuation requests

- Medical records (e.g., chart notes, laboratory reports) documenting disease stability or improvement.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with the following:

- Systemic lupus erythematosus (SLE): a rheumatologist or a specialist in the treatment of systemic lupus erythematosus
- Active lupus nephritis: a rheumatologist, nephrologist, or a specialist in the treatment of lupus nephritis.

EXCLUSIONS

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Coverage will not be provided for members with any of the following exclusions:

- Severe active central nervous system (CNS) lupus (including seizures that are attributed to CNS lupus, psychosis, organic brain syndrome, cerebritis, or CNS vasculitis requiring therapeutic intervention before initiation of belimumab) in a member initiating therapy with Benlysta.
- Member is using Benlysta in combination with other biologics.

COVERAGE CRITERIA

Systemic Lupus Erythematosus (SLE)

Authorization of 12 months may be granted for treatment of active SLE in members 5 years of age or older when both of the following criteria are met:

- Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA by IFA 1:80 or higher, anti-ds DNA, anti-Sm, antiphospholipid antibodies, low complement proteins)
- The member is receiving standard treatment for SLE with any of the following (alone or in combination):
 - Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone)
 - Antimalarials (e.g., hydroxychloroquine)
 - Immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide)

Active Lupus Nephritis

Authorization of 12 months may be granted for treatment of active lupus nephritis in members 5 years of age or older when both of the following criteria are met:

- The member meets either of the following:
 - Lupus nephritis is confirmed on kidney biopsy
 - If a kidney biopsy is not feasible or if the member is not a candidate for kidney biopsy, prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA by IFA 1:80 or higher, anti-ds DNA, anti-Sm, antiphospholipid antibodies, low complement proteins)
- Member is receiving a standard therapy regimen (e.g., cyclophosphamide, mycophenolate mofetil, azathioprine, hydroxychloroquine, glucocorticoids).

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Benlysta (Belimumab)	Systemic Lupus Erythematosus or Lupus Nephritis	Route of Administration: Intravenous ≥5 year(s) Initial: 10mg/kg every 2 weeks for 3 doses Maintenance: 10mg/kg every 4 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

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BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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11. Sammaritano LR, Askanase A, Bermas BL, et al. **2024 American College of Rheumatology (ACR) Guideline for the Screening, Treatment, and management of Lupus Nephritis**. Arthritis and Rheumatology. 2025;1115-1135.

EFFECTIVE DATE

9/30/2026

ID_CHS_2026