AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Benlysta (belimumab)	Page:	1 of 4
Effective Date:	8/28/2026	Last Review Date:	7/2026

Applies to:	☒Illinois	☒Florida Kids	☐Michigan
	☒New Jersey	☒Maryland	☐Texas
	☒Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Benlysta under the patient's prescription drug benefit.

Description:

FDA-Approved Indications[1]

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.

Applicable Drug List:

Benlysta

Policy/Guideline:

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

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)[1-4,6,8,10]

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[1,4,5,7,8,11]

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.

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval Duration: 12 months

Quantity Level Limit:

- Benlysta 200mg/mL: 4 autoinjectors/syringes per 30 days
  - Exception limit: 8 autoinjectors/syringes per 30 days
- Benlysta 120 mg/5mL: 9 vials per 30 days
  - Exception limit:
    - Induction dose:
      - Up to 100 kg: 27 vials per 30 days
      - Above 100 kg: 51 vials per 30 days
    - Maintenance dose (above 100 kg): 17 vials per 30 days
- Benlysta 400 mg/20mL: 3 vials per 30 days
  - Exception limit:
    - Induction dose:
      - Up to 100 kg: 9 vials per 30 days
      - Above 100 kg: 15 vials per 30 days
    - Maintenance dose (above 100 kg): 5 vials per 30 days

References:

1. Benlysta [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; June 2025.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. EULAR recommendations for the management of systemic lupus erythematosus with kidney involvement: 2025 update. Ann Rheum Dis. January

2026;85(1):75-90. URL: https://ard/eular/org/article/S0003-4967%2825%2904412-7/fulltext. Accessed March 14, 2026.
3. Rovin BH, Parikh SV, Hebert LA, et al. Lupus nephritis: induction therapy in severe lupus nephritis – should MMF be considered the drug of choice? Clin J Am Soc Nephrol. 2013;8(1):147-153.
4. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. Arthritis Care & Research. 2012;64(6):797-808.
5. Furie R, Rovin BH, Houssiau F, et al. Two-Year, Randomized, Controlled Trial of Belimumab in Lupus Nephritis. N Engl J Med. 2020;383(12):1117-1128.
6. Aringer M, Costenbader K, Daikh D, et al. 2019 European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus. Ann Rheum Dis. 2019;78:1151-1159.
7. Rovin BH, Adler SG, Barratt J, et al. Kidney Disease: Improving Global Outcomes (KDIGO) Golmerular Disease Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021 Oct; 100(4S):S1-S276.
8. Gordon C, Amissah-Arthru MB, Gayed M, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults. Rheumatology (Oxford). 2018; 57(1):e1-e45.
9. Petri M, Orbai A-M, Alarcon GS, et al. Derivation and Validation of Systemic Lupus International Collaborating Clinics (SLICC) Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheum. 2012; 64:2677-2686. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3409311/. Accessed January 21, 2025.
10. Sammaritano LR, Askanase A, Bermas BL, et al. 2025 American College of Rheumatology (ACR) Guideline for the treatment of systemic lupus erythematosus. Arthritis Care Res. November 2025. URL: https://rheumatology.org/lupus-guideline. Accessed March 14, 2026.
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.