

SPECIALTY GUIDELINE MANAGEMENT

BENLYSTA (belimumab)

POLICY

I. 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:

- A. Patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.
- B. Adult patients 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 lupus. Benlysta has not been studied in combination with other biologics. Use of Benlysta is not recommended in these situations.

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

II. DOCUMENTATION

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

- A. Initial requests: Medical records (e.g., chart notes, lab reports) documenting the presence of autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm).
- B. Continuation requests: Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

III. EXCLUSIONS

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

- A. Severe active central nervous system (CNS) lupus (including seizures that are attributed to CNS lupus, psychosis, organic brain syndrome, cerebrovascular accident, cerebritis, or CNS vasculitis requiring therapeutic intervention within 60 days before initiation of belimumab) in a member initiating therapy with Benlysta.
- B. Member is using Benlysta in combination with other biologics.

IV. CRITERIA FOR INITIAL APPROVAL

A. Systemic lupus erythematosus (SLE)

Reference number
1764-A

Authorization of 12 months may be granted for treatment of active SLE when all of the following criteria are met:

1. Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm)
2. The member is receiving a stable standard treatment for SLE with any of the following (alone or in combination):
 - i. Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone)
 - ii. Antimalarials (e.g., hydroxychloroquine)
 - iii. Immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide)

B. Active lupus nephritis

Authorization of 12 months may be granted for the treatment of active lupus nephritis when all of the following criteria are met:

1. Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm)
2. Member has clinically active lupus renal disease and is receiving a stable standard induction and maintenance treatment for lupus nephritis (e.g., cyclophosphamide, mycophenolate mofetil, azathioprine, glucocorticoids).

V. CONTINUATION OF THERAPY

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

VI. REFERENCES

1. Benlysta [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; March 2021.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 Update of the EULAR Recommendations for the Management of Systemic Lupus Erythematosus. *Ann Rheum Dis*. 2019;78:736-745.
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.