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. 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.

III. CRITERIA FOR INITIAL APPROVAL

A. Systemic lupus erythematosus (SLE)
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
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
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).

IV. **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.

V. **REFERENCES**