| Reference number(s) |
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| 2502-A |

# STANDARD MEDICARE PART B 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, and
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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
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), where applicable.
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)

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 meets either of the following criteria:
    i. The member is receiving a stable standard treatment for SLE with any of the following (alone or in combination):
        a. Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone)
        b. Antimalarials (e.g., hydroxychloroquine)
        c. Immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide)
    ii. The member has a clinical reason to avoid treatment with a standard treatment regimen.

### B. Lupus nephritis

Authorization of 12 months may be granted for treatment of active lupus nephritis when the member is receiving a stable standard therapy regimen (e.g., cyclophosphamide, mycophenolate mofetil, azathioprine, corticosteroids) or has a clinical reason to avoid treatment with a stable standard therapy regimen.

## V. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

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

A. The member is currently receiving therapy with Benlysta.
B. Benlysta is being used to treat an indication enumerated in Section IV.
C. The member is receiving benefit from therapy. Benefit is defined as disease stability or improvement.

## 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. 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.