Reference number
1764-A

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 Indication
Treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.

Limitations of Use
The efficacy of Benlysta has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations.

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:
A. Severe active lupus nephritis
B. Severe active central nervous system lupus

III. CRITERIA FOR INITIAL APPROVAL

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 autoantibody-positive.
2. The member is currently receiving standard therapy for SLE (see Appendix) or has tried and had an inadequate response or intolerance to standard therapy for SLE.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. APPENDIX

Standard Therapy for SLE

- Antimalarials (e.g., hydroxychloroquine)
- Azathioprine
- Corticosteroids
- Leflunomide
- Methotrexate
- Mycophenolate mofetil
- Non-steroidal anti-inflammatory drugs

VI. REFERENCES

1. Benlysta [package insert]. Rockville, MD: Human Genome Sciences, Inc.; January 2017.