

## 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.