

POLICY Document for Benlysta (medical)

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria Administration of Intravenous Benlysta

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of Benlysta in an outpatient hospital setting for up to 2 doses when a member is new to therapy.

This policy provides coverage for administration of Benlysta in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
- B. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
- C. The member has severe venous access issues that require the use of a special intervention.
- D. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- E. Alternative infusion sites are not available.
- F. The member is less than 21 years of age or 65 years of age or older.

For situations where administration of Benlysta does not meet the criteria for outpatient hospital infusion, coverage for Benlysta is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
- B. Medical records supporting the member is medically unstable
- C. Medical records supporting the member has severe venous access issues

- D. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- E. Records supporting alternative infusion sites are not available

Section 2: Clinical Criteria

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

- A. Prior to initiating therapy, the member is autoantibody-positive.
- B. 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

Examples of Standard Therapy for SLE

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

REFERENCES:

SECTION 1

1. Benlysta [package insert]. Rockville, MD: Human Genome Sciences, Inc.; June 2018.

SECTION 2

1. Benlysta [package insert]. Rockville, MD: Human Genome Sciences, Inc.; June 2018.