Gateway Health℠ It's Wholecare.

Updated: 02/2021
PARP Approved: 03/2021

Prior Authorization Criteria

Benlysta (belimumab)

All requests for Benlysta (belimumab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Benlysta (belimumab) all of the following criteria must be met:

- The member has a clinical diagnosis of SLE according to American College of Rheumatology classification criteria
- Must be prescribed by or in consultation with a rheumatologist or hematologist
- Must not have severe active central nervous system (CNS) lupus or be used in combination with other biologics or IV cyclophosphamide
- Must be currently taking or has tried and failed or had an intolerance or contraindication to at least one standard therapy for systemic lupus erythematosus (e.g. corticosteroids, antimalarials, NSAIDS, or immunosuppressives) or lupus nephritis (e.g. corticosteroids, mycophenolate, cyclophosphamide, azathioprine)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.

Coverage may be provided with a diagnosis of active systemic lupus erythematosus and the following criteria is met:

- The member is 5 years of age or older
- The member's disease is active as evidenced by a SELENA-SLEDAI score of 6 or greater prior to initiation of therapy
- Must be autoantibody-positive confirmed by documentation of one of the following:
    - anti-nuclear antibody (ANA) titer ≥ 1:80
    - anti-double stranded DNA (anti-dsDNA) ≥ 30 IU/mL
- **Initial Duration of Approval:** 12 months.
- **Reauthorization Criteria:** Chart documentation demonstrating clinical benefit and tolerance to Benlysta.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of active lupus nephritis and the following criteria is met:

- The member is 18 years of age or older
- The member has a biopsy-proved lupus nephritis Class III, IV and/or V
- **Initial Duration of Approval:** 12 months
- **Reauthorization Criteria:** chart documentation demonstrating clinical benefit and tolerance to Benlysta.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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BENLYSTA (BELIMUMAB)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Systemic lupus erythematosus ☐ Lupus nephritis ☐ Other: _____ ICD-10: _____

- Does the member have a clinical diagnosis of SLE according to the American College of Rheumatology classification criteria? ☐ Yes ☐ No
- Does the member have active disease? ☐ Yes ☐ No
- Please provide member's baseline SELENA-SLEDAI score: _____
- Is the anti-nuclear antibody (ANA) titer ≥ 1:80? ☐ Yes ☐ No
- Is the anti-double stranded DNA (anti-dsDNA) ≥ 30 IU/mL? ☐ Yes ☐ No

For lupus nephritis:

- Does the member have a clinical diagnosis of SLE according to the American College of Rheumatology classification criteria? ☐ Yes ☐ No
- Does the member have active disease? ☐ Yes ☐ No
- Does the member have a biopsy-proved lupus nephritis Class III, IV and/or V? ☐ Yes ☐ No

Has the member tried standard of care medications for SLE or lupus nephritis? ☐ Yes, please list below ☐ No

Does the member have severe active central nervous system (CNS) lupus? ☐ Yes ☐ No

Will the member be using other biologics or IV cyclophosphamide in combination with this medication? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member tolerated and experienced a clinical benefit from treatment? ☐ Yes ☐ No

Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE	
Prescribing Provider Signature	Date