HIGHMARK WHOLECARE

Updated: 07/2023
PARP Approved: 08/2023

Prior Authorization Criteria

Systemic Lupus Erythematosus (SLE) Agents

All requests for Systemic Lupus Erythematosus (SLE) Agents* require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

*Systemic Lupus Erythematosus Agents include Benlysta (belimumab) and Saphnelo (anifrolumab-fnia). New products with this classification will require the same documentation.

For all requests for SLE Agents, 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, hematologist or nephrologist
- Must not have severe active central nervous system (CNS) lupus
    - Additionally for Saphnelo, must not have severe active lupus nephritis
- 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 or immunosuppressives) or for 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.
- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

- The member will not be using the request medication in combination with another biologic agent
- Saphnelo may not be used in combination with Benlysta or IV cyclophosphamide

Benlysta (belimumab) only:
Coverage may be provided with a diagnosis of active SLE and the following criteria is met:

- 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.

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 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.
- **Reauthorization Duration of Approval:** 12 months

Saphnelo (anifrolumab-fnia) only:
Coverage may be provided with a diagnosis of moderate to severe systemic lupus erythematosus and the following criteria is met:

- The member's disease is active as evidenced by a SELENA-SLEDAI score of 6 or greater prior to initiation of therapy
- Documented laboratory testing showing the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]
- **Initial Duration of Approval:** 12 months.
- **Reauthorization Criteria:** Chart documentation demonstrating clinical benefit and tolerance.
- **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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SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AGENTS
PRIOR AUTHORIZATION FORM

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

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

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, 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

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

For SLE:

- 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
- Is there documentation of laboratory testing showing the presence of autoantibodies? ☐ Yes ☐ No

For lupus nephritis, does the member have a biopsy-proved lupus nephritis Class III, IV and/or V? ☐ 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 with treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

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DRUG NAME

PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

Add questions or options for providing information as needed.

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Add questions as needed

Has the member experienced an improvement with treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date