HIGHMARK HEALTH OPTIONS

Updated: 11/2025
DMMA Approved: 01/2026

Request for Prior Authorization for Systemic lupus erythematosus (SLE) Agents
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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 (SLE) Agents Prior Authorization Criteria:
*Systemic Lupus Erythematosus Agents include Benlysta (belimumab), Saphnelo (anifrolumab-fnia) and Gazyva (obinutuzumab). 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 or hematologist
- 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 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 requested agent 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

Gazyva (Obinutuzumab) only:
Coverage may be provided with a diagnosis of active lupus nephritis (LN) who are receiving standard therapy and the following criteria is met:

- The member has biopsy-proven active lupus nephritis (LN) Class III or IV (with or without Class V LN)
- The member is autoantibody positive with ONE of the following:
  - ANA (anti-nuclear antibody) above the laboratory reference range **OR**
  - Anti-dsDNA (double stranded DNA antibody) above the laboratory reference range, or greater than two-fold the reference range if tested by ELISA
- The member is currently being treated with hydroxychloroquine and will continue therapy in combination with the requested agent [medical record documentation required] **OR** the member will be initiated on concurrent therapy with hydroxychloroquine [medical record documentation required] **OR** the member has a clinical intolerance/contraindication to hydroxychloroquine [medical record documentation required]
- 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:**
  - The member has achieved a complete renal response as indicated by BOTH of the following [medical record documentation required]:
    1. Reduction in proteinuria (i.e., urine protein:creatinine ratio [UPCR] < 0.5 g/g); AND
    2. Stabilization or improvement in kidney function (i.e., an estimated glomerular filtration rate [eGFR] at least 80% of baseline [no decrease in eGFR more than 20% from baseline]);

- The member is currently being treated with and will continue receiving standard immunosuppressive LN therapy (e.g., azathioprine, cyclophosphamide, glucocorticoids, mycophenolic acid analogs) [medical record documentation required]
- The member will NOT be using the requested agent in combination with another biologic immunomodulator agent

- **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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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SYSTEMIC LUPUS ERYTHEMATOUS (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 Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Mon-Fri 8:00am to 7:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
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:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

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 any contraindications, such as severe active central nervous system (CNS) lupus, to the requested medication? ☐ 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

If applicable, is there laboratory testing showing the presence of autoantibodies? ☐ Yes ☐ No

Has the member tried and failed, have an intolerance or contraindication to standard of care medications for SLE or lupus nephritis? ☐ Yes, please list below ☐ No

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

For lupus nephritis:
Does the member have a biopsy-proven active lupus nephritis Class III, IV and/or V? ☐ Yes ☐ No
Is the member autoantibody positive with ONE of the following? ☐ Yes, select which is applicable ☐ No
☐ ANA (anti-nuclear antibody) above the laboratory reference range
☐ Anti-dsDNA (double stranded DNA antibody) above the laboratory reference range, or greater than two-fold the reference range if tested by ELISA
Is the member currently being treated with hydroxychloroquine and will continue therapy in combination with the requested agent **OR** the member will be initiated on concurrent therapy with hydroxychloroquine **OR** the member has a clinical intolerance/contraindication to hydroxychloroquine? ☐ Yes ☐ No
Is the member's disease active as evidenced by a SELENA-SLEDAI score of 6 or greater prior to initiation of therapy? ☐ Yes ☐ No
Is there documented laboratory testing showing the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]? ☐ 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:
Has the member achieved a complete renal response as indicated by BOTH of the following? ☐ Yes ☐ No
☐ Reduction in proteinuria (i.e., urine protein:creatinine ratio [UPCR] < 0.5 g/g) AND
☐ Stabilization or improvement in kidney function (i.e., an estimated glomerular filtration rate [eGFR] at least 80% of baseline [no decrease in eGFR more than 20% from baseline]);
Is the member currently being treated with and will continue receiving standard immunosuppressive LN therapy (e.g., azathioprine, cyclophosphamide, glucocorticoids, mycophenolic acid analogs)? ☐ Yes ☐ No
Is the member using the requested agent in combination with another biologic immunomodulator agent? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date