Mass General Brigham
Health Plan

# Lupus Agents
# Benlysta (belimumab vial)
# Saphnelo (anifrolumab-fnia vial)
# Effective 01/04/2027

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|---|---|---|---|
| **Plan** | ☒ MassHealth UPPL<br>☐Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☐ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☐ Pharmacy Benefit<br>☒ Medical Benefit | | |
| **Specialty Limitations** | N/A | | |
| **Contact Information** | **Medical Benefit**<br>**Pharmacy Benefit** | Phone: 833-895-2611<br>Phone: 800-711-4555 | Fax: 888-656-6671<br>Fax: 844-403-1029 |
| **Notes** | The auto-injection and prefilled syringe formulations of Benlysta and Saphnelo are only available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.<br><br>Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. | | |

**Overview**
Benlysta (belimumab) is a monoclonal antibody indicated for adult patients with active lupus nephritis who are receiving standard therapy and patients five years of age and older with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy. Benlysta is available for subcutaneous or intravenous administration

Saphnelo (anifrolumab-fnia) is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.

**Coverage Guidelines**
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
**OR**
Authorization may be granted when all of the following criteria are met:

**Benlysta (belimumab) vial**
1. Diagnosis of lupus nephritis
2. Member is ≥ 5 years of age
3. Prescriber is a rheumatologist or nephrologist or consult notes from a rheumatologist or nephrologist are provided
4. Requested agent will be used in combination with low dose glucocorticoids and ONE of the following immunosuppressant agents:
    a. azathioprine

b. mycophenolic acid analog
c. Low dose intravenous cyclophosphamide as an induction treatment regimen

5. Requested agent will **NOT** be used in combination with other biologics (e.g., rituximab, other B-cell targeted therapies, etc.) or cyclophosphamide as long term maintenance immunosuppressive therapy
6. Appropriate dosing (weight required)

**Benlysta (belimumab) vial**
**Saphnelo (anifrolumab-FNIA) vial**

1. Diagnosis of systemic lupus erythematosus (SLE)
2. **ONE** of the following:
   a. For Benlysta, member is ≥ 5 years of age
   b. For Saphnelo, member is ≥ 18 years of age
3. Prescriber is a specialist (e.g., rheumatologist, dermatologist, etc.) or consult notes from a specialist are provided
4. Inadequate response, adverse reaction, or contraindication to hydroxychloroquine
5. Inadequate response or adverse reaction to **ONE** OR contraindication to **ALL** of the following:
   a. azathioprine
   b. methotrexate
   c. mycophenolic acid analog
   d. cyclosporine
   e. cyclophosphamide
   f. leflunomide
7. Appropriate dosing (weight required)

**Continuation of Therapy**

Reauthorization by prescriber will infer a positive response to therapy.

**Limitations**

1. Approvals may be granted for 6 months.

**References**


1. Benlysta [package insert]. Rockville (MD): Human Genome Sciences, Inc; 2025 Jun.
2. Gladman DD. Overview of the clinical manifestations of systemic lupus erythematosus in adults. In: PisetskyDS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Sep [cited 2021 Oct 25].Available from: http://www.utdol.com/utd/index.do.
3. Belimumab: drug information. UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2021[cited 2021Nov20]. Available from: http://www.utdol.com/utd/index.do.
4. Wallace DJ. Overview of the management and prognosis of systemic lupus erythematosus in adults. In: Pisetsky DS, Schur PH (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Sep [cited 2021 Oct 25]. Available from: http://www.utdol.com/utd/index.do.
5. Lam NC, Ghetu MV, Bieniek ML. Systemic Lupus Erythematosus: Primary Care Approach to Diagnosis and Management. Am Fam Physician. 2016 Aug 15;94(4):284-94.
6. Bomback A. Lupus nephritis: Diagnosis and classification. In: Glassock R (Ed). UpToDate[database on the internet]. Waltham (MA): UpToDate; 2021Nov 15[cited 2021 Nov20]. Available from: http://www.utdol.com/utd/index.do
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8. Saphnelo [package insert]. Wilmington (DE): AstraZeneca Pharmaceuticals L; 2026 Apr.
9. Saphnelo (anifrolumab) approved in the US for moderate to severe systemic lupus erythematosus [press release on the Internet]. Wilmington (DE): Food and Drug Administration (US): 2021 Aug 2 [cited 2021 Oct 25]. Available from: Saphnelo (anifrolumab) approved in the US for moderate to severe systemic lupus erythematosus (astrazeneca.com).
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11. Fanouriakis A, Kostopoulou M, Anders HJ, Andersen J, Aringer M, Beresford MW, et al. EULAR recommendations for the management of systemic lupus erythematosus with kidney involvement: 2025 update. Ann Rheum Dis. 2026;85(1):75-90.Andreoli L, Bertsias GK, Agmon-Levin N, Brown S, Cervera R, Costedoat-Chalumeau N, et al. EULAR recommendations for women's health and the management of family planning, assisted reproduction, pregnancy and menopause in patients with systemic lupus erythematosus and/or antiphospholipid syndrome. Ann Rheum Dis.2017 Mar;76(3):476-485.
12. Berman BL, Smith NA. Pregnancy in women with systemic lupus erythematosus. In: Pisetsky DS, Lockwood CJ(Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Oct [cited 2021Nov20]. Available from: http://www.utdol.com/utd/index.do.

**Review History**

09/21/22 – Reviewed and Created for September P&T. Separated out Comm/Exch vs. MassHealth. Matched MH criteria. Renamed criteria to Lupus Agents. Added new drug Saphnelo and Lupkynis. Effective 11/1/22.
05/10/23 – Reviewed and updated for P&T. Added Dosage Information. Effective 6/5/23
06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement from Saphnelo on MB (not required to align with MH). Effective 6/30/23.
07/10/24 – Reviewed and updated for P&T. Added Benlysta auto-injector/syringe to reference table. No clinical changes to criteria. Effective 08/12/24
06/11/25 – Reviewed and updated for P&T. Benlysta SLE criteria was updated to include a step through hydroxychloroquine. Benlysta LN criteria updated to specify trial requirement of an oral glucocortiocoid in addition to either azathioprine or mycophenolic acid analog. Updated formatting and references. Effective 7/1/25
07/15/26 – Reviewed and updated for P&T. Added cyclophosphamide for induction as an option for Benlysta in LN. Added a step-through trial with Benlysta or cutaneous manifestation for Saphnelo in SLE. Specialist involvement has been added throughout. Added mycophenolic acid analog as an option for Benlysta and Saphnelo in SLE. Effective 8/10/26
11/04/26 – Reviewed and updated for P&T. Updated criteria for Saphnelo vial to remove step through Benlysta or option to bypass with documentation of cutaneous SLE. Updated formatting and references. Effective 1/4/27