Mass General Brigham
Health Plan

Lupus Agents
Benlysta (belimumab)
Saphnelo (anifrolumab-fnia)
Effective 07/01/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Notes	The formulations of Benlysta (belimumab), **auto-injection and prefilled syringe**, are available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. 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 lupus nephritis and Systemic lupus erythematosus (SLE). 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
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Benlysta (belimumab) vial
1. Diagnosis of lupus nephritis
2. Member is ≥ 5 years of age
3. Member is receiving low-dose oral corticosteroids in combination with ONE of the following immunosuppressant agents:
    a. azathioprine

    b. mycophenolic acid analog
4. Member will NOT be receiving cyclophosphamide or biologics as maintenance immunosuppressive therapy
5. Appropriate dosing (weight required)

Benlysta (belimumab) vial
Saphnelo (anifrolumab-FNIA)

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. Inadequate response, adverse reaction, or contraindication to hydroxychloroquine
4. Inadequate response or adverse reaction to **ONE** OR contraindication to **ALL** of the following:
    a. azathioprine
    b. methotrexate
    c. mycophenolate
    d. cyclosporine
    e. cyclophosphamide
    f. leflunomide
5. 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

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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; 2024 Aug.
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).
10. Navarra SV, Guzman RM, Gallacher AE, Hall S, Levy RA, Jimenez RE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomized, placebo-controlled, phase 3 trial. Lancet. 2011 Feb; 377:721-31.
11. Fanouriakis A, Kostopoulou M, Alunno A, Aringer M, Bajema I, Boletis JN et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. Ann Rheum Dis 2019;78:736–745.
12. 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.
13. 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