Mass General Brigham
Health Plan

Lupus Agents:
Benlysta® (belimumab)
Lupkynis® (voclosporin)
Saphnelo® (anifrolumab-fnia)
Effective 06/30/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
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
Exceptions	Benlysta IV and Saphnelo are only available through the medical benefit.		

Overview

Benlysta® (belimumab) is a monoclonal antibody indicated for lupus nephritis and Systemic lupus erythematosus (SLE). Benlysta is available for subcutaneous or intravenous administration

Lupkynis® (voclosporin) is a calcineurin inhibitor FDA-approved for the treatment of adult patients with active lupus nephritis in combination with a background immunosuppressive therapy.

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.

No PA	Drugs that require PA
Arava® # (leflunomide) Cellcept® # (mycophenolate mofetil) cyclophosphamide Gengraf® (cyclosporine modified)* Imuran® # (azathioprine 50 mg tablet) methotrexate tablet Neoral® # (cyclosporine modified) Plaquenil® # (hydroxychloroquine) Sandimmune® # (cyclosporine)	Benlysta® (belimumab) Lupkynis® (voclosporin) Saphnelo® (anifrolumab-fnia)

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

*This is a branded-generic drug for which there may be a generic available.

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)
ALL of the following:
1. Diagnosis of lupus nephritis
2. The member is ≥ 5 years of age
3. The member is receiving concurrent immunosuppressive therapy, excluding cyclophosphamide and biologics *(Examples of acceptable agents: mycophenolate mofetil and azathioprine)*
4. Appropriate dosing

Benlysta (belimumab)
Saphnelo (anifrolumab-FNIA)
ALL of the following:
1. Diagnosis of systemic lupus erythematosus (SLE)
2. The member is ≥ 5 years of age for Benlysta or ≥ 18 years of age for Saphnelo
3. 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
4. Appropriate dosing

Lupkynis (voclosporin)
ALL of the following:
1. Diagnosis of active lupus nephritis
2. The member is ≥ 18 years of age
3. The member is receiving concurrent immunosuppressive therapy, excluding cyclophosphamide and biologics *(Examples of acceptable agents: mycophenolate mofetil and azathioprine)*
4. Appropriate dosing

<u>Continuation of Therapy</u>
Reauthorization by prescriber will infer a positive response to therapy.

Limitations
1. Initial approvals may be granted for 6 months.
2. Reauthorizations may be granted for 6 months.
3. The following quantity limits apply:

Benlysta® (belimumab)	4 pen/syringe per 28 days

Lupkynis 7.9 mg	180 capsules per 30 days

4. Dosing information:

Benlysta® (belimumab) Intravenous injection: 120 mg single-use vial 400 mg single-use vial Subcutaneous injection: 200 mg autoinjector or syringe	SLE: Intravenous injection: Initial, 10 mg/kg at 2-week intervals for first 3 doses; maintenance, 10 mg/kg at 4-week intervals SLE: Subcutaneous injection: 200 mg weekly LN: Intravenous injection: Initial, 10 mg/kg at 2-week intervals for first 3 doses; maintenance, 10 mg/kg at 4-week intervals LN: Subcutaneous injection: Initial, 400 mg (two 200 mg injections) once weekly for 4 doses; maintenance, 200 mg once weekly thereafter
Lupkynis® (voclosporin) Capsule: 7.9 mg	23.7 mg twice daily
Saphnelo® (anifrolumab-fnia) Intravenous injection: 300 mg/2 mL	300 mg every four weeks

References

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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.