Lupus Agents
Benlysta® (belimumab)
Lupkynis® (voclosporin)
Saphnelo® (anifrolumab-fnia)
Effective 11/01/2022

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Benlysta and Saphnelo are medical benefit only.		

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)	Benlysta® (belimumab)
Cellcept® # (mycophenolate mofetil)	Lupkynis® (voclosporin)
cyclophosphamide	Saphnelo® (anifrolumab-fnia)
Gengraf® (cyclosporine modified)*	
Imuran® # (azathioprine 50 mg tablet)	
methotrexate tablet	
Neoral® # (cyclosporine modified)	
Plaquenil® # (hydroxychloroquine)	
Sandimmune® # (cyclosporine)	

#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)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis of 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

Benlysta (belimumab)
Saphnelo (anifrolumab-FNIA)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis of systemic lupus erythematosus (SLE)
2. The member is ≥ 5 years of age (Benlysta) or ≥ 18 years of age (Saphnelo)
3. Physician documentation of 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. If the request is for Saphnelo® (anifrolumab-FNIA), physician documentation of an inadequate response, adverse reaction or contraindication to Benlysta® (belimumab)
5. Appropriate dosing

Lupkynis (voclosporin)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate 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

Continuation of Therapy

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	4 pen/syringe per 28 days
Lupkynis 7.9 mg	180 capsules per 30 days

References

1. Benlysta®[package insert]. Rockville (MD): Human Genome Sciences, Inc; 2020Dec.
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7. Falk R. Treatment of diffuse or focal proliferative lupus nephritis. In: Glassock R (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021Oct 26[cited 2021 Nov20]. Available from: http://www.utdol.com/utd/index.do
8. Lupkynis® [package insert]. Rockville (MD):Aurinia Pharmaceuticals, Inc.; 2021 Jan.
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10. 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).
11. 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.
12. 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.
13. 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.
14. 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 11/01/2022.

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