Louisiana Medicaid
Immunomodulators, Lupus

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for immunomodulators, lupus agents.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Anifrolumab-fnia (Saphnelo™)

Approval Criteria

- The recipient has a documented diagnosis of moderate to severe systemic lupus erythematosus (SLE); **AND**
- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient is currently receiving at least **ONE** standard of care treatment for SLE (e.g., antimalarials, corticosteroids, or immunosuppressants) and this is **stated on the request**; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a rheumatologist; **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has a *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Saphnelo™ will not be used in recipients with a diagnosis of severe active lupus nephritis or severe active central nervous system lupus; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**

- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The recipient is currently receiving at least **ONE** standard of care treatment for SLE (e.g., antimalarials, corticosteroids, or immunosuppressants) and this is **stated on the request**; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Belimumab (Benlysta®)

Approval Criteria

- The recipient has a documented diagnosis of active, autoantibody-positive systemic lupus erythematosus (SLE); **AND**
- The recipient is 5 years of age or older on the date of the request; **AND**
- The recipient is currently receiving at least **ONE** standard of care treatment for SLE (e.g., antimalarials, corticosteroids, or immunosuppressants) and this is **stated on the request**; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a rheumatologist; **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has a *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Benlysta® will not be used in recipients with a diagnosis of severe active central nervous system lupus; **AND**
    - Laboratory testing has documented the presence of autoantibodies; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**

- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

OR

- The recipient has a documented diagnosis of active lupus nephritis; **AND**
- The recipient is 5~~18~~ years of age or older on the date of the request; **AND**
- The recipient is currently receiving at least **ONE** standard of care treatment for SLE (e.g., antimalarials, corticosteroids, or immunosuppressants) and this is **stated on the request**; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a rheumatologist or nephrologist; **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has a *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The recipient is currently receiving at least **ONE** standard of care treatment for SLE (e.g., antimalarials, corticosteroids, or immunosuppressants) and this is **stated on the request**; **AND**

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Voclosporin (Lupkynis™)

Approval Criteria

- The recipient has a documented diagnosis of systemic lupus erythematosus (SLE) with active lupus nephritis (LN); **AND**
- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient is currently receiving an immunosuppressive therapy regimen consisting of mycophenolate mofetil (MMF) and corticosteroids and this is **stated on the request**; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a nephrologist or rheumatologist; **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has a *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - If the eGFR is less than or equal to 45 mL/min/1.73 m2, the prescriber attests that benefit of Lupkynis™ outweigh the potential risks to the patient; **AND**
    - Lupkynis™ therapy will not be initiated in recipients with baseline BP >165/105 mmHg or with hypertensive emergency; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The recipient continues to receive an immunosuppressive therapy regimen consisting of mycophenolate mofetil (MMF) and corticosteroids and this is **stated on the request**; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

References

Benlysta (belimumab) [package insert]. Research Triangle Park, NC; GlaxoSmithKline; JulyMarch 20221 . https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Benlysta/pdf/BENLYSTA-PI-MG-IFU.PDF

Fanouriakis A, Kostopoulou M, Alunno A, et al 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus Annals of the Rheumatic Diseases 2019;78:736-745.

Lupkynis (voclosporin) [package insert]. Inc. Rockville, MD; Aurinia Pharma U.S.; January 2021. https://d1io3yog0oux5.cloudfront.net/auriniapharma/files/pages/lupkynis-prescribing-information/FPI-0011+Approved+USPI++MG.pdf

Saphnelo (anifrolumab-fnia) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021. https://den8dhaj6zs0e.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/44b6985c-8268-46b1-ba3e-2bb43bfd4d4c/44b6985c-8268-46b1-ba3e-2bb43bfd4d4c_viewable_rendition__v.pdf

Revision / Date	Implementation Date
Benlysta® policy created / February 2021	July 2021
Lupkynis™ policy created / July 2021	October 2021
Combined policies, added nonpreferred wording, and updated references / September 2021	January 2022
Added Saphnelo™ / December 2021	January 2022
Updated age indication on Benlysta® for lupus nephritis, updated references / July 2022	January 2023