

**Louisiana Medicaid
Anifrolumab-fnia (Saphnelo™)**

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for anifrolumab-fnia (Saphnelo™).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

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**
- 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

References

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.

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
Policy created / August 2021	