Clinical Policy Title:	anifrolumab-fnia
Policy Number:	RxA.701
Drug(s) Applied:	Saphnelo™
Original Policy Date:	8/19/2021
Last Review Date:	9/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Anifrolumab-fnia (Saphnelo™) 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.

Limitations of Use: The efficacy of Saphnelo™ has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of Saphnelo™ is not recommended in these situations.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
anifrolumab-fnia (Saphnelo™)	Systemic lupus erythematosus	300 mg as an intravenous infusion over a 30-minute period every 4 weeks.	300 mg intravenously every 4 weeks

Dosage Forms

- Injection: 300 mg/2 mL (150 mg/mL) in a single-dose vial.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Systemic lupus erythematosus (must meet all):

1. Diagnosis of active systemic lupus erythematosus;
2. Prescribed by or in consultation with Rheumatologists;
3. Age ≥ 18 years;
4. Member is receiving standard-of-care therapy with at least one of the following: prednisone (or equivalent), hydroxychloroquine, azathioprine, mycophenolate mofetil, methotrexate;
5. Member does not have severe active central nervous system (CNS) lupus;
6. Member does not have active lupus nephritis;
7. Dose does not exceed 300 mg intravenous every 4 weeks.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Systemic lupus erythematosus (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy based on reduction in signs and symptoms of SLE, which may include number of flares, disease activity in specific organs;
3. If request is for a dose increase, dose does not exceed 300 mg intravenous every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
IFN: interferon
SLE: systemic lupus erythematosus
CNS: central nervous system

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Saphnelo™ is contraindicated in patients with a history of anaphylaxis with anifrolumab-fnia.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Serious Infections: Serious and sometimes fatal infections have occurred in patients receiving Saphnelo™. Saphnelo™ increases the risk of respiratory infections and herpes zoster. Avoid initiating treatment during an active infection. Consider the individual benefit risk if using in patients with severe or chronic infections. Consider interrupting therapy with Saphnelo™ if patients develop a new infection during treatment.
- Immunization: Avoid use of live or live-attenuated vaccines in patients receiving Saphnelo™.
- Not Recommended for Use with Other Biologic Therapies.

References

1. Saphnelo™ Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761123s000lbl.pdf . Accessed August 19, 2021.
2. IPD Analytics Rx Insights_New Drug Review_ Saphnelo 08 2021. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Saphnelo . Accessed August 19, 2021.
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Accessed with subscription at: http://www.clinicalkey.com. Accessed August 19, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	8/19/2021	9/14/2021