Policy Title:	**Saphnelo (anifrolumab-fnia)** (Intravenous)		
		Department:	PHA
Effective Date:	12/15/2021		
Review Date:	12/2/2021, 7/7/2022, 1/26/2023, 12/07/2023, 01/04/2024		

Purpose: To support safe, effective, and appropriate use of Saphnelo (anifrolumab-fnia).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:
Saphnelo (anifrolumab-fnia) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:
Coverage of will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:
Saphnelo (anifrolumab-fnia) was approved for the treatment of moderate to severe systemic lupus erythematosus (SLE) in adult patients receiving standard therapy. Saphnelo's approval was based on the results of the MUSE, TULIP-1, and TULIP-2 trials. Both the MUSE and TULIP-2 trials showed statistical significance for the Saphnelo 300mg treatment arms whereas TULIP-1 displayed no statistical significance. Side effects seen with Saphnelo were bronchitis, infusion reactions, and serious infections.

Initial Criteria:

- Patient is 18 years or older; AND
- Patient has documented diagnosis of active moderate to severe Systemic Lupus Erythematosus (SLE); AND
- Patient has moderate to severe disease as evidenced by all of the following:
  - Physician's Global Assessment [PGA] score of ≥ 1; AND
  - Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI 2K) score of ≥ 6; AND
  - British Isles Lupus Assessment Group-2004 (BILAG) B organ domain score of ≥ 2
- Patient has failed to respond adequately to at least two (2) standard therapies such as anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, or immunosuppressives (excluding intravenous cyclophosphamide); AND
- Used in combination with standard therapy (e.g., prednisone, hydroxychloroquine, azathioprine, mycophenolate mofetil, methotrexate); AND
- Patient has tried and failed Benlysta or has a documented contraindication to Benlysta; AND
- Patient must not have an active infection; AND

- Patient has not received a live vaccine within 30 days before starting or concurrently with Saphnelo; AND
- Medication is not being used concurrently with Benlysta, Lupkynis or another biologic agent; AND
- Patient does not have severe active central nervous system (CNS) lupus and/or active lupus nephritis;

Continuation of Therapy Criteria:

- Patient continues to meet all initial criteria and is tolerating therapy with Saphnelo; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections, malignancy, severe hypersensitivity reactions/anaphylaxis, etc.; AND
- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
    - No worsening in the SLEDAI-2K score where worsening is defined as >0 point increase;
    - Reduction of baseline BILAG-2004 B to C/D, and no BILAG-2004 worsening in other organ systems, as defined by ≥2 new BILAG-2004 B;
    - No worsening (<.30-point increase) in Physician's Global Assessment (PGA) score; OR
    - Seroconverted (negative)

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD)

Policy Rationale:
Saphnelo was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Saphnelo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = *1* mg)
SLE	300mg every 4 weeks	300units every 28 days

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0491	Injection, anifrolumab-fnia, 1mg

References:

1. Saphnelo [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2023.