Neighborhood Health Plan OF RHODE ISLAND™

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.

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)

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.

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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.