Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 249.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Saphnelo (anifrolumab-fnia)

I. Policy:
Saphnelo (anifrolumab-fnia)

II. Purpose/Objective:
To provide a policy of coverage regarding Saphnelo (anifrolumab-fnia).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Anifrolumab is an IgG1-kappa monoclonal antibody that blocks the biologic activity of type 1 interferon receptors (IFNAR); elevated IFNAR plays a role in the pathogenesis of systemic lupus erythematosus. This reduces inflammatory and immunological processes.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Saphnelo (anifrolumab-fnia) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of moderate to severe systemic lupus erythematosus (SLE) **AND**
- Medical record documentation that member does not have active lupus nephritis or severe active central nervous system lupus **AND**
- Medical record documentation that Saphnelo is being prescribed by or in consultation with a rheumatologist **AND**
- Medical record documentation that member is concurrently receiving a stable treatment regimen with corticosteroids, antimalarials, or immunosuppressants **AND**
- Medical record documentation that member is not being used concurrently with other biologic agents, including B-cell-targeted therapies.

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent authorizations will be for 12 months and will require:

- Medical record documentation record documentation showing clinical benefit as demonstrated by at least <u>one</u> of the following:
    - Improvement in functional impairment **OR**
    - Decrease in number of exacerbations since starting Saphnelo **OR**
    - Decrease in the daily required dose of oral corticosteroids

QUANTITY LIMIT: 2mL every 4 weeks

<u>Note</u>: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Saphnelo [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2022.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 1/18/22

Revised: 2/4/22 (prescriber “or in consultation with”), 1/27/23 (LOB carve out, Medicaid PARP statement, Medicaid business segment), 12/28/23 (references added)

Reviewed: 1/15/24

MA UM Committee approval: 12/31/23