POLICY NUMBER: RX.PA.072.MPC
REVISION DATE: 06/2023

RX.PA.072.MPC Saphnelo (anifrolumab)

The purpose of this policy is to define the prior authorization process for Saphnelo® (anifrolumab)

Saphnelo® (anifrolumab) 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.

PROCEDURE

A. Initial Authorization Criteria:

1. Systemic Lupus Erythematosus (SLE). All requests for IV Saphnelo (anifrolumab) must meet the following criteria:

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a documented diagnosis of moderate to severe systemic lupus erythematosus
- Documentation confirms that member is positive for an SLE autoantibody (e.g., anti-nuclear antibody (ANA), anti-double-stranded DNA (anti-dsDNA), anti-Smith (anti-Sm), antiribonucleoprotein (anti-RNP), anti-Ro/SSA, anti-La/SSB, antiphospholipid antibody)
- Must have documentation of an intolerance, contraindication to, or adequate trial and failure (of at least 3 months) of hydroxychloroquine at maximum tolerated dose AND
    - Azathioprine, mycophenolate, or methotrexate
- Must be on concomitant therapy with an SLE regimen comprised of any of the following (alone or in combination): corticosteroids, antimalarials (hydroxychloroquine), and immunosuppressives
- Must NOT have severe active lupus nephritis or severe active central nervous system lupus
- Must not have evidence of active infection
- Dose does not exceed FDA approved indication
- Must be up to date on all immunizations prior to initiating Saphnelo (anifrolumab)
- Must not be on concomitant therapy with biologic therapies, including B-cell targeted therapies

- **Saphnelo will be considered investigational or experimental for any other use and will not be covered.**

B. Reauthorization Criteria:

1. Systemic Lupus

MPC Renewal:

- All prior authorization renewals are reviewed on a 1-year interval basis to determine the Medical Necessity for continuation of therapy.
- Documentation of a clinical response, as determined by the prescriber
- Must be prescribed by a rheumatologist

Non-MPC Renewal:

- Members who have previously been taking Saphnelo (anifrolumab) and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria).
- Member has not been receiving medication samples for Saphnelo (anifrolumab)
- Provider has a documented clinical response of the member's condition which has improved based upon the prescriber's assessment

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

Codes:

Code	Description
J0491	Injection, anifrolumab-fnia, 1 mg
C9086	Injection, anifrolumab-fnia, 1 mg

REFERENCES

1. Saphnelo [package insert]. Wilmington, DE: AstraZeneca, Inc.; September 2022.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*06/2023*