



## **RX.PA.072.CCH SAPHNELO (ANIFROLUMAB-FNIA)**

The purpose of this policy is to define the prior authorization process for Saphenlo (anifrolumab-fnia) for systemic lupus erythematosus (SLE).

### **DEFINITIONS**

**Systemic Lupus Erythematosus (SLE)** – a chronic inflammatory autoimmune condition that can cause disease of the skin, heart, lungs, kidneys, joints, and/or nervous system

### **POLICY**

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Saphenlo (anifrolumab-fnia), is subject to the prior authorization process.

### **PROCEDURE**

#### **Initial Authorization Criteria:**

*Must meet all the criteria listed under the respective diagnosis:*

- Must be prescribed by, or in consultation with, a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severe systemic lupus erythematosus
- Must have an adequate trial (of at least 3 months) of the following with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies:
  - Hydroxychloroquine **AND**
  - Azathioprine **OR** Methotrexate **OR** Mycophenolate
- Must be on concomitant therapy with an SLE regimen comprised of any of the following (alone or in combination): corticosteroids, antimalarials, and immunosuppressives
- Must NOT have severe active lupus nephritis or severe active central nervous system lupus
- Must not have evidence of active infection
- Must be up to date on all immunizations prior to initiating Saphnelo

- Must not be on concomitant therapy with biologic therapies, including B-cell targeted therapies
- Must be prescribed at a dose within the manufacturer’s dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

**Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member’s condition has improved based upon the prescriber’s assessment while on therapy.

**Limitations:**

<b>Length of Authorization (if above criteria met)</b>	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

**Codes:**

<b>CPT Codes / HCPCS Codes / ICD-10 Codes</b>		
Code	Brand	Description
J0491	Saphnelo	Injection, anifrolumab-fnia, 1 mg

**REFERENCES**

1. Saphnelo (anifrolumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2021
2. Belmont HM. Treatment of systemic lupus erythematosus - 2013 update. Bull Hosp Jt Dis (2013) 2013; 71:208.

**Revision History**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	05/2023

**Record Retention**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

**Disclaimer**

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.