

| PHARMACY POLICY STATEMENT Indiana Medicaid | |
|--|------------------------------|
| DRUG NAME | Saphnelo (anifrolumab-fnia) |
| BENEFIT TYPE | Medical |
| STATUS | Prior Authorization Required |

Saphnelo, approved by the FDA in 2021, is a first in class type I interferon (IFN) receptor antagonist, and the first drug to target IFN-1 for the treatment of Systemic Lupus Erythematosus (SLE). Saphnelo is indicated for adults with moderate to severe SLE, in combination with standard therapy.

SLE is the most common type of lupus. It is a chronic autoimmune disease with periods of flares and remissions that causes inflammation and damage throughout the body. Up to 60-80% of adult SLE patients have increased type 1 IFN signaling, which is associated with higher disease activity/severity. Pooled clinical trial data for Saphnelo demonstrates improved overall disease activity.

Saphnelo (anifrolumab-fnia) will be considered for coverage when the following criteria are met:

Systemic Lupus Erythematosus (SLE)

For **initial** authorization:

- 1. Member is at least 18 years of age; AND
- 2.



DATE