Saphnelo is a first in class type 1 interferon (IFN-1) inhibitor, 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. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderate to severe SLE; AND
4. Chart notes document at least one of the following:
   a) Positive anti-nuclear antibody (ANA) titer \(\geq 1:80\)
   b) Elevated (above normal) anti-double-stranded DNA (anti-dsDNA)
   c) Elevated (above normal) anti-Smith (anti-Sm) antibody; AND
5. Member has tried and failed all the following (unless contraindicated):
   a) Hydroxychloroquine (or chloroquine), and
   b) Corticosteroid, and
   c) A non-steroid immunosuppressant (i.e., methotrexate, azathioprine, mycophenolate mofetil) for at least 12 weeks; AND
6. At least one of the above standard therapies will be continued with Saphnelo; AND
7. Saphnelo will not be used with other biologic therapies; AND
8. Member does not have severe active lupus nephritis or severe active central nervous system lupus.
9. **Dosage allowed/Quantity limit:** 300 mg IV infusion every 4 weeks (1 vial per 28 days)

*If all the above requirements are met, the medication will be approved for 6 months.*

*For reauthorization:*
1. Chart notes must document improved disease activity such as reduced number of flares, reduced severity of skin disease, or ability to taper glucocorticoid use.

*If all the above requirements are met, the medication will be approved for an additional 12 months.*
CareSource considers Saphnelo (anifrolumab-fnia) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/15/2021</td>
<td>New policy for Saphnelo created.</td>
</tr>
<tr>
<td>08/23/2022</td>
<td>Updated billing code. Removed SELENA-SLEDAI score.</td>
</tr>
</tbody>
</table>

References:


Effective date: 01/01/2023
Revised date: 08/23/2022