

Clinical Oversight Review Board (CORB) Criteria for Prescribing anifrolumab-fnia IV (Saphnelo IV)

Notes:

- Quantity Limits: No
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Non-Formulary **anifrolumab-fnia (Saphnelo)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:

Non-formulary **anifrolumab-fnia (Saphnelo)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber is a rheumatologist and patient has a diagnosis of active systemic lupus erythematosus (SLE) with positive anti-nuclear antibody (ANA) and/or anti-double-stranded deoxyribonucleic acid (anti-dsDNA) and/or Sjogren's antibody (SSA or SSB) [these tests are used to diagnose lupus]
- Patient is dependent on corticosteroid therapy OR has documented contraindication or intolerance to corticosteroid therapy
- Patient has documented treatment failure/intolerance (at least a 60-day course) or contraindication to all of the following:
 - At least one nonsteroidal anti-inflammatory (NSAID) medication (e.g. aspirin, ibuprofen, naproxen, etodolac, meloxicam)
 - At least one antimalarial (e.g. hydroxychloroquine, chloroquine)
 - At least one immunomodulator (e.g. cyclophosphamide, azathioprine, methotrexate, or mycophenolate)
 - Belimumab (criteria based)

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