Initial Approval Date: January 19, 2022

CRITERIA FOR PRIOR AUTHORIZATION

Systemic Lupus Erythematosus (SLE) Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Anifrolumab-fnia (Saphnelo™)
Belimumab (Benlysta®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Must be prescribed by or in consultation with a rheumatologist.
- Patient must have confirmed presence of autoantibodies consistent with SLE (i.e. ANA, anti-DNA, anti-Sm, etc.).
- Patient must currently be on or have a contraindication to hydroxychloroquine. If the patient has a contraindication to hydroxychloroquine, then the patient must be on one standard of care therapy or have a contraindication to all standard of care therapies listed in Table 2.[1]
- Patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table 3. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved age and dosing limits for Systemic Lupus Erythematosus (SLE) Agents.[2-3]

Medication	Indication(s)	Age	Dosing Limits
B-lymphocyte Stimulator (BLyS)-Specific Inhibitor			
Belimumab (Benlysta®)	Moderate to severe SLE	≥ 5 years	≥ 5 years: 10 mg/kg IV at 2-week intervals for the first 3 doses and at 4-week intervals thereafter ≥ 18 years: 200 mg SC once weekly
Type 1 Interferon (IFN) Receptor Antagonist			
Anifrolumab-fnia (Saphnelo™)	Moderate to severe SLE	≥ 18 years	300 mg IV every 4 weeks

IV: intravenous; SC: subcutaneous

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed dosing limits listed in Table 1.
- Prescriber must attest that the patient has received clinical benefit from continued treatment with the requested medication.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 MONTHS

Table 2. List of standard of care therapies for treatment of SLE.[2]

Standard Therapy for SLE
Azathioprine
Cyclophosphamide
Cyclosporine, systemic
Hydroxychloroquine
Methotrexate
Mycophenolate

Table 3. List of immunomodulating biologic agents/janus kinase inhibitors (agents not to be used concurrently).

Biologic Agents/Janus Kinase Inhibitors		
Actemra® (tocilizumab)	Ilumya™ (tildrakizumab-asmn)	Siliq® (brodalumab)
Adbry™ (tralokinumab)	Kevzara® (sarilumab)	Simponi® (golimumab)
Benlysta® (belimumab)	Kineret® (anakinra)	Simponi Aria (golimumab)
Cimzia® (certolizumab)	Nucala® (mepolizumab)	Skyrizi™ (risankizumab-rzaa)
Cinqair® (reslizumab)	Olumiant® (baricitinib)	Stelara® (ustekinumab)
Cosentyx® (secukinumab)	Opzelura™ (ruxolitinib)	Taltz® (ixekizumab)
Dupixent® (dupilumab)	Orencia® (abatacept)	Tezspire™ (tezepelumab-ekko)
Enbrel® (etanercept) & biosimilars (Erelzi™, Eticovo®)	Remicade® (infliximab) & biosimilars (Avsola™, Inflectra®, Ixifi™, Renflexis®)	Tremfya® (guselkumab)
Entyvio® (vedolizumab)	Rinvoq™ (upadacitinib)	Tysabri® (natalizumab)
Fasenra™ (benralizumab)	Rituxan® (rituximab) & biosimilars (Riabni™, Ruxience™, Truxima®)	Xeljanz® (tofacitinib)
Humira® (adalimumab) & biosimilars (Abrilada™, Amjevita™, Cyltezo™, Hulio™, Hyrimoz™, Yusimry™)	Rituxan Hycela™ (rituximab/hyaluronidase)	Xeljanz XR® (tofacitinib)
Ilaris® (canakinumab)	Saphnelo™ (anifrolumab)	Xolair® (omalizumab)

References

1. Fanouriakis A, Kostopoulou M, Aringer M, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. Ann Rheum Dis 2019;78:736-745. https://ard.bmj.com/content/annrheumdis/78/6/736.full.pdf.
2. Benlysta (belimumab) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2021.
3. Saphnelo (anifrolumab-fnia) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021.