Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 8, 2012 April 11, 2017, May 16, 2019, December 8, 2021, December 29, 2021

BENLYSTA (belimumab)

LENGTH OF AUTHORIZATION: Up to 6 months

INITIAL REVIEW CRITERIA for all indications:

- Patient does not have diagnosis of severe active CNS disease.
- Patient is not being treated for a chronic infection.
- Patient has not been vaccinated with a live vaccine in the last 30 days.
- Other biologic agents will not be used in combination with Benlysta.
- Patient is receiving standard therapy with any of the following:
    - NSAIDs
    - Antimalarials (hydroxychloroquine)
    - Systemic glucocorticoids
    - Immunosuppressive agents (cyclophosphamide, MTX, azathioprine and mycophenolate)

For diagnosis of Systemic Lupus Erythematosus (SLE)

- Patient must be ≥ 5 years of age.
- Patient has documented diagnosis of active, autoantibody positive SLE.

For diagnosis of Active Lupus Nephritis

- Patient must be ≥ 18 years of age.
- Patient has documented diagnosis of active lupus nephritis.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of improved clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING & ADMINISTRATION:

- Refer to product labeling https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as: 120 mg or 400 mg single dose vials for intravenous infusion and 200 mg/mL single-dose prefilled autoinjector or prefilled syringe for subcutaneous injection.
- Benlysta should be administered by healthcare providers prepared to manage anaphylaxis for intravenous use.