



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

## **BENLYSTA® (belimumab)**

**LENGTH OF AUTHORIZATION: UP TO SIX MONTHS**

**REVIEW CRITERIA:**

- Patient must be **5 years or older**
- Prescriber is a rheumatologist
- Patient has documented diagnosis of systemic lupus erythematosus, active, autoantibody-positive
- Tried and failed a trial of standard therapy:
  - NSAIDs
  - Antimalarials (hydroxychloroquine)
  - Systemic glucocorticoids
  - Immunosuppressive agents (cyclophosphamide, MTX, azathioprine and mycophenolate)
- Patient does not have an indication of severe active lupus nephritis or 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 or IV cyclophosphamide will not be used in combination with Benlysta.

**DOSING & ADMINISTRATION:**

- **Benlysta should be administered by healthcare providers prepared to manage anaphylaxis.**
- Recommended intravenous dosage regimen for ages **5 years** and older is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter; over a period of an hour.
- **Recommended subcutaneous dosage for ages 18 and older is 200mg once weekly.**
- Dosage form: Intravenous- 120mg in a 5ml single dose vial, 400mg in a 20ml single-dose vial.  
**Subcutaneous-200mg/ml single-dose prefilled autoinjector, 200mg/ml single-dose prefilled syringe.**