Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Belimumab subcutaneous (Benlysta)

Notes:

- Quantity Limits: Yes
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria and for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Nonformulary belimumab subcutaneous (Benlysta) will be covered on the prescription drug benefit when the following criteria are met:

- 1. Prescriber is a rheumatologist and patient has a diagnosis of active systemic lupus erythematous (SLE)
 - Patient is 18 years of age or older
 - Patient has positive antinuclear antibody (ANA), anti-double-stranded deoxyribonucleic acid (anti-dsDNA), and/or Sjogren's antibody (SSA or SSB)
 - Patient is dependent on corticosteroid therapy OR documented contraindication or intolerance to corticosteroid therapy
 - Patient has a documented treatment failure (at least a 60-day course) or contraindication/intolerance to all of the following:
 - At least one nonsteroidal anti-inflammatory (NSAID) medication (e.g. aspirin, ibuprofen, naproxen, etodolac, meloxicam)
 - o At least one antimalarial (e.g. hydroxychloroquine, chloroquine)
 - At least one immunomodulator (e.g. cyclophosphamide, azathioprine, methotrexate, mycophenolate)
- 2. Prescriber is a rheumatologist and patient has a diagnosis of active lupus nephritis (LN)
 - Patient is 18 years of age or older
 - Patient has positive antinuclear antibody (ANA), anti-double-stranded deoxyribonucleic acid (anti-dsDNA), and/or Sjogren's antibody (SSA or SSB)
 - Patient is dependent on corticosteroid therapy OR documented contraindication or intolerance to corticosteroid therapy
 - Patient has a documented treatment failure (at least a 60-day course) or contraindication/intolerance to all of the following:

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- o At least one antimalarial (e.g. hydroxychloroquine, chloroquine)
- At least one immunomodulator (e.g. cyclophosphamide, azathioprine, methotrexate, mycophenolate)
- Tacrolimus

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