CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Benlysta (belimumab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Benlysta, approved by the FDA in 2011, is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy and for patients aged 5 years and older with active lupus nephritis who are receiving standard therapy. Benlysta is not recommended in patients with severe active central nervous system lupus.
SLE is the most common type of lupus. It is a chronic autoimmune disease with periods of flares and remissions that causes inflammation and damage throughout the body. LN is a complication of SLE and can progress to end stage renal disease (ESRD). Proteinuria is often the first sign of LN.

Benlysta (belimumab) will be considered for coverage when the following criteria are met:

Systemic Lupus Erythematosus (SLE)

For **initial** authorization:

1. Member is at least 5 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active, autoantibody-positive SLE as confirmed by documentation of at least one of the following:
   a) Anti-nuclear antibody (ANA) titer ≥1:80
   b) Elevated (above normal) anti-double-stranded DNA (anti-dsDNA)
   c) Elevated (above normal) anti-Smith (anti-Sm) antibody; AND
4. Member has tried and failed hydroxychloroquine OR is unable to reduce steroid to an acceptable dose for chronic use (5 mg prednisone per day or less); AND
5. Standard therapy (e.g., hydroxychloroquine) will be continued unless contraindicated; AND
6. Member does NOT have severe active central nervous system (CNS) lupus.
7. Benlysta will NOT be used with other biologic therapies.
8. **Dosage allowed/Quantity limit:**
   IV (Adult or Pediatric): 10mg/kg every 2 weeks for 3 doses and every 4 weeks thereafter
   SubQ (Adult): 200 mg once weekly
   SubQ (Pediatric; autoinjector only): 200 mg once weekly if 40 kg or greater; 200 mg every 2 weeks if 15 to <40 kg
   QL (subQ): 4 syringes/autoinjectors per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document improved disease activity such as reduced number of flares or ability to taper steroid use.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Lupus Nephritis

For **initial** authorization:
1. Member is at least 5 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist or rheumatologist; AND
3. Member has a documented diagnosis of active lupus nephritis class III, IV, and/or V as confirmed by kidney biopsy; AND
4. Medication must be prescribed in combination with standard therapy such as mycophenolate mofetil (MMF) or cyclophosphamide; AND
5. Chart notes must document baseline eGFR and urine protein creatinine ratio (UPCR); AND
6. eGFR is at least 30 mL/min/1.73m^2; AND
7. Member is NOT on dialysis and has not had a kidney transplant; AND
8. Member does NOT have severe active central nervous system (CNS) lupus.
9. **Dosage allowed/Quantity limit:**
   IV (adult or pediatric): 10mg/kg every 2 weeks for 3 doses and every 4 weeks thereafter
   SubQ (adult): 400 mg once weekly for 4 doses, then 200 mg once weekly thereafter
   SubQ (pediatric, autoinjector only):
   40 kg or greater: 400 mg once weekly for 4 doses followed by 200 mg once weekly
   15 kg to less than 40 kg: 200 mg once weekly for 4 doses followed by 200 mg every 2 weeks
   QL (subQ): 8 syringes/autoinjectors per 28 days for the first fill, then 4 syringes/autoinjectors per 28 days thereafter

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Member has a reduced UPCR from baseline (goal is 0.5 mg/mg or less); AND
2. eGFR is at least 60mL/min/1.73m^2 OR has stabilized (not declined).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Benlysta (belimumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/18/2017	New policy for Benlysta created. Length of approval was increased, system involvement limitations were removed and improvement of SELENA-SLEDAI score was added in reauthorization.
07/28/2019	Age coverage expanded from adult population (18 years old and older) to pediatric population of 5 years old and older.
04/13/2021	Added criteria for new indication of lupus nephritis. SLE: Updated references and added current treatment guidelines. Removed the mandate for daily corticosteroid dependence and replaced with a general trial and failure of corticosteroid. Emphasized that a non-steroid immunosuppressive must also

	be tried first. Added “moderately active disease.” Removed IV cyclophosphamide restriction. Specified 4-point improvement or reduced steroid use for renewal and removed other renewal criteria.
08/19/2022	Transferred to new template. Updated age limit for lupus nephritis. SLE: Added reference. Added criterion 5 and 6. Removed SELENA-SLEDAI score.
01/05/2024	Updated references. Added exclusion of severe active CNS lupus. SLE: Removed requirement for non-steroid immunosuppressant trial (per EULAR 2023). Changed to only require HCQ or steroid instead of both. Added anti-sm as an option for autoantibody confirmation.
06/06/2024	Added subQ dosing for peds with SLE (autoinjector only, not PFS).
11/05/2025	Added autoinjectors to QL. LN: Updated KDIGO, ACR references. Updated dosing to allow subcutaneous use for pediatrics per label update. Specified “active” lupus nephritis (label). SLE: Updated references. ODM approved on 01/28/26.

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