CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Benlysta (belimumab)
BILLING CODE	For medical - J0490 For Rx - must use valid NDC
BENEFIT TYPE	Medical (IV) or Pharmacy (subQ)
SITE OF SERVICE ALLOWED	Home/Office
STATUS	Prior Authorization Required

Benlysta 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.

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

Systemic Lupus Erythematosus (SLE)

For **initial** authorization:

1. Member is 5 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has active, autoantibody-positive SLE as confirmed by documentation of anti-nuclear antibody (ANA) titer ≥1:80 or anti-double-stranded DNA (anti-dsDNA) ≥ 30 IU/mL; AND
4. Member has tried and failed all the following (unless contraindicated):
   a) Hydroxychloroquine (or chloroquine), and
   b) Corticosteroid, and
   c) A non-steroid immunosuppressant (methotrexate, azathioprine, mycophenolate mofetil, cyclophosphamide) for at least 12 weeks; AND
5. Standard therapy will be continued with Benlysta; AND
6. Benlysta will not be used with other biologic therapies.
7. **Dosage allowed/Quantity limit:**
   IV (Adult or Pediatric): 10mg/kg every 2 weeks for 3 doses and every 4 weeks thereafter
   SubQ (Adult only): 200 mg once weekly [4 syringes 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 reduced disease activity since starting Benlysta and/or
2. Documentation of reduction in corticosteroid 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 diagnosis of 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.
8. **Dosage allowed/Quantity limit:**
   IV (adult or pediatric): 10mg/kg every 2 weeks for 3 doses and every 4 weeks thereafter
   SubQ (adults only): 400 mg (as two 200 mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter [limit of 8 syringes/28 days for the first fill, then 4 syringes/28 days going forward]

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.

References:

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