CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Benlysta (belimumab)
BILLING CODE	For medical - J0490 For Rx - must use valid NDC
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Benlysta (belimumab) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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 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 documented moderately active disease or SELENA-SLEDAI score of 6 or greater; AND
5. 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.
6. **Dosage allowed:**
   IV (Adult or Pediatric): 10mg/kg every 2 weeks for 3 doses and every 4 weeks thereafter
   subQ (Adult only): 200 mg once weekly [limit of 4 syringes/28 days]

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document at least a 4-point improvement of the SELENA-SLEDAI score (or low disease activity as measured by another validated activity score) since starting Benlysta, OR
2. Documented reduction in corticosteroid use.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

LUPUS NEPHRITIS

For **initial** authorization:

1. Member is at least 18 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:**
   IV: 10mg/kg every 2 weeks for 3 doses and every 4 weeks thereafter
   subQ: 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 member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Benlysta (belimumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Severe active central nervous system lupus

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.

References:

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