Subject: Benlysta (Belimumab)*  
Effective Date: February 26, 2013  
Department: Utilization Management  

Policy: Injectable belimumab (J0490) is reimbursable under plans administered by QualCare, Inc. when eligible member benefit is in place and medical necessity exists.

Objective: To assure consistent reimbursement for injectable belimumab as a medically necessary service and to delineate criteria that provides evidence of that medical necessity.

Procedure:  
**Definition:** Belimumab is an injectable, intravenously infused, monoclonal antibody that neutralizes BlyS family of ligands, thus blocking a crucial survival signals in early B-cell development.

Requests for coverage of injectable belimumab must be applied against all of the following criteria.

1. The member is age 18 years or older with a diagnosis of active systemic lupus erythematosus (SLE), (ICD code 710.0) (ICD-10 M32.1, M32.10, M32.11, M32.12, M32.13, M32.14, M32.15, M32.19) despite being on standard therapy (see medication classes below).

2. The documentation by laboratory report of a positive test for either anti-nuclear antibody (ANA) ≥ 1:80, or anti-double stranded DNA (anti-dsDNA) ≥ 30 IU/ml at some time during the illness.

3. The member is on one or more of the following class of medications:
   - Anti-malarials (ie plaquenil)
   - Corticosteroids
   - Immuno suppressives (ie immuran, cyclosporine)(excludes IV cyclophosphamide)
✓ Non-steroidal anti-inflammatory drugs

Medical necessity will be determined on a case by case basis considering current medical literature for members with any of the following:
- Severe central nervous system involvement
- Severe lupus nephritis (serum creatinine ≥2.5; Proteinuria ≥ 6 gms/24 hrs)
- Requires hemodialysis
- On prednisone dose of > 100 mg /day
- On another biologic agent or IV cyclophosphamide

Note on authorization parameters: the standard recommended dosing for belimumab is 10mg/kg at 2 week intervals for three doses followed by the same dose at 4 week intervals. When the above medical necessity criteria are met authorization can be approved for yearly intervals.

References


Benlysta FDA Label- accessed online 02/13/13 at www.accessdata.fda.gov/drugsatfda_docs/label/2012/125370s016lbl.pdf

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*Consistent with Summary Plan Description ( SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.