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/24hrs)
- 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.

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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.