Benlysta® (belimumab)

Effective: June 9, 2015

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<th>Clinical Documentation and Prior Authorization Required</th>
<th>✓</th>
<th>Type of Review – Case Management</th>
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<td>Not Covered</td>
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<td>Type of Review – Clinical Review Fax: 617-673-0956</td>
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<td>Pharmacy (RX) or Medical (MED) Benefit</td>
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OVERVIEW

FDA-APPROVED INDICATIONS

Benlysta (belimumab) is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

The efficacy of Benlysta (belimumab) has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Benlysta (belimumab) has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta (belimumab) is not recommended in these situations.

Systemic lupus erythematosus (SLE) is a complex, multisystem, autoimmune disease characterized by variable stages of flares and remissions of various organs with an accumulation of organ involvement over time. It is estimated that half a million people in the U.S. have SLE, with the majority of these patients consisting of women between 15 to 40 years of age. People of African origin are predisposed to develop SLE more frequently than other ethnic groups and typically have a worse prognosis.

BLyS, a B-cell survival factor, is overexpressed in patients with SLE and other autoimmune diseases. The presence of circulating antinuclear antibodies is observed in approximately 90% of SLE patients, although other signs and symptoms of the disease are dependent on which organs are affected and are widely variable between patients. The American College of Rheumatology lists 11 classification criteria to aid in the diagnosis of SLE. The criteria include major clinical features, such as renal, neurologic, serosal, and mucocutaneous involvement, as well as lab values, including antinuclear antibodies and hematologic or immunologic disorders. A suggestive diagnosis of SLE is made if patients present with at least four of these criteria either at once or in succession.

SLE is associated with significant morbidity and mortality in addition to a poor quality of life for many patients. Up to two-thirds of patients may experience renal involvement, which is usually associated with a poor prognosis and increased mortality, and neuropsychiatric symptoms, such as anxiety, mood disorders, and psychosis. Other common symptoms may include fatigue, malaise, fever, anorexia, and weight loss.

FDA-approved agents for SLE include hydroxychloroquine, prednisone, aspirin, and Benlysta (belimumab). Standard treatment options for mild to moderate SLE include aspirin, antimalarials such as hydroxychloroquine, corticosteroids, and non-steroidal anti-inflammatory drugs (NSAIDs). Severe episodes of SLE may be treated with high dose corticosteroids, cytotoxic agents, or immunosuppressive agents such as cyclophosphamide and azathioprine. None of the approved treatments have been shown to prolong survival or reverse the course of the disease.

The newest agent approved for SLE, Benlysta (belimumab), is a fully human immunoglobulin G-1λ monoclonal antibody that reduces the number of CD20+ B lymphocytes and antinuclear antibodies by inhibiting the activity of BLyS.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of Benlysta (belimumab) for members when all the following criteria for a particular regimen are met and limitations do not apply:

1. Documented diagnosis of active, autoantibody positive (e.g. ANA, anti-ds-DNA, anti-Sm) systemic lupus erythematosus AND
2. Prescriber is a rheumatologist AND
3. The Member is concurrently taking and is compliant with standard therapy for systemic lupus erythematosus (e.g., corticosteroids, antimalarials, or immunosuppressives – alone or in combination).
LIMITATIONS

1. Benlysta (belimumab) will not be approved in the following instances:
   - As Monotherapy
   - For Members with severe active lupus nephritis or severe active central nervous system lupus.
   - For Members who are autoantibody negative.
   - In combination with other biologics and/or intravenous cyclophosphamide.

2. Initial authorization for Benlysta (belimumab) will be limited to 6 months.

3. For subsequent coverage requests, please submit documentation that a clinical benefit has been established and maintained compared to baseline. Reauthorization will be limited to 12-month intervals.

CODES

The following HCPCS/CPT code(s) are:

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<th>Code</th>
<th>Description</th>
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<tr>
<td>J0490</td>
<td>Injection, belimumab, 10 mg</td>
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REFERENCES


8. FDA Briefing Information, Belimumab (Benlysta), for the November 16, 2010 Meeting of the Arthritis Advisory Committee.


APPROVAL HISTORY

- June 12, 2014: Reviewed by the Pharmacy and Therapeutics Committee.
- June 9, 2015: No changes
BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.