Medical Necessity Guidelines: Benlysta® (belimumab) for Intravenous (IV) Infusion

Effective: January 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

Applies to:

Commercial Products
☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
  CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products
☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
☐ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
  *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products
☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) Approved Indications:
Benlysta (belimumab) is a B-lymphocyte stimulator (BLys)-specific inhibitor indicated for the treatment of:
• Patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.
• Patients aged 5 years and older with active lupus nephritis who are receiving standard therapy.

Clinical Guideline Coverage Criteria
The Plan may cover Benlysta (belimumab) for intravenous (IV) administration for Members when all of the following clinical criteria are met:

Active Lupus Nephritis
1. The Member has a documented diagnosis of active lupus nephritis
2. Documentation of the presence of lupus nephritis confirmed by urine/blood tests or kidney biopsy
3. The prescribing physician is a rheumatologist or nephrologist
4. Member is at least 5 years of age
5. Documentation of one of the following:
a. Member has clinically active lupus renal disease and is receiving a stable standard treatment for lupus nephritis (e.g., cyclophosphamide, mycophenolate mofetil, tacrolimus, cyclosporine, azathioprine, prednisone)  
   OR  
   b. Clinical inappropriateness to the use of ALL of the following standard treatments for lupus nephritis: cyclophosphamide, mycophenolate mofetil, tacrolimus, cyclosporine, azathioprine, prednisone  

6. The Member does not have severe active central nervous system lupus  

7. Benlysta (belimumab) will not be used in combination with other biologic therapies  

**Systemic Lupysta (belimumab)**  
1. Documented diagnosis of active, autoantibody positive systemic lupus erythematosus  
   AND  
2. Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm)  
   AND  
3. The prescribing physician is a rheumatologist  
   AND  
4. The Member is at least 5 years of age  
   AND  
5. Documentation of **one** of the following:  
   a. The Member is receiving a stable standard treatment for SLE (used alone or in combination) with any of the following: glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone), antimalarials (e.g., hydroxychloroquine), immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, or cyclophosphamide)  
   OR  
   b. Clinical inappropriateness to the use of ALL of the following standard treatments for SLE (used alone or in combination): glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone), antimalarials (e.g., hydroxychloroquine), immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, or cyclophosphamide)  
   AND  
6. The Member does not have severe active central nervous system lupus  
   AND  
7. Benlysta (belimumab) will not be used in combination with other biologic therapies  

**Limitations**  
- For the treatment of systemic lupus erythematosus (SLE), Benlysta (belimumab) will not be approved for Members who are autoantibody negative  

**Codes**  
The following code(s) require prior authorization:  

**Table 1: HCPCS Codes**  

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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J0490</td>
<td>Injection, belimumab, 10 mg</td>
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**Note:** Medical billing codes may not be used for Benlysta injection for subcutaneous use. This formulation must be obtained via the Member’s pharmacy benefit.  

**References:**  


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


Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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