TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Benlysta® (belimumab)

Effective: June 9, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	SC: RX IV: MED	Department to Review	PRECERT /MM /RXUM

These pharmacy medical necessity guidelines apply to the following:	Fax Numbers:
Commercial Products ☒ Tufts Health Plan Commercial products – large group plans ☒ Tufts Health Plan Commercial products – small group and individual plans ☒ Tufts Health Freedom Plan products – large group plans ☒ Tufts Health Freedom Plan products – small group plans • CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization **Tufts Health Public Plans Products** ☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) ☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan	*Intravenous injection* All plans except Tufts Health Public Plans: PRECERT:617.972.9409 Tufts Health Public Plans: MM: 888.415.9055 *Subcutaneous injection:* RxUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-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.

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.

Benlysta (belimumab) may be administered as an intravenous infusion or as a subcutaneous injection. Vials are intended for intravenous use only and autoinjectors and prefilled syringes are intended for subcutaneous use only.

COVERAGE GUIDELINES

The plan may authorize coverage of Benlysta (belimumab) for Members, when all of the following criteria are met:

1. Documented diagnosis of active, autoantibody positive (e.g. ANA, anti-ds-DNA, anti-Sm) systemic lupus erythematosus

   AND

2. The prescribing physician 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

- 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

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0490	Injection, belimumab, 10 mg

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

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15. Navarra SV, Guzman RM, Gallacher AE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomized, placebo-controlled, phase 3 trial. *Lancet*. 2011; 377(9767):721-31.
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APPROVAL HISTORY

July 12, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 1, 2012: Administrative update: Added HCPCS code J0490

- June 12, 2012: Administrative update: Removed HCPCS code Q2044
- May 14, 2013: No changes.
- April 8, 2014: No changes.
- March 10, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template
- March 8, 2016: No changes.
- March 14, 2017: No changes.
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- October 17, 2017: Added Benlysta for subcutaneous use to the Medical Necessity Guideline.
- September 18, 2018: No changes. Administrative update to remove the following Limitation "Benlysta (belimumab) autoinjector and prefilled syringes are covered under the pharmacy benefit. Benlysta (belimumab) vials are covered under the medical benefit." The information was added in the Codes section as the following: "Medical billing codes may not be used for Benlysta injections for subcutaneous use. This formulation must be obtained via the Member's pharmacy benefit."
- June 11, 2019: Added expended indication for the treatment of patients age 5 years and older. No changes to criteria.
- April 14, 2020: Effective June 9, 2020, removed reauthorization criteria. Added the following note in the Codes section, 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.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity 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 service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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.