Harvard Pilgrim Health Care

Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	Benlysta (belimumab)

1. Criteria

Product Name: Benlysta subcutaneous prefilled syringe, Benlysta subcutaneous auto-injector	
Approval Length	6 Month(s)*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 - Documentation of ALL of the following:

1.1.1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

1.1.2 - Prior to initiating therapy, the member is auto-antibody positive (e.g., ANA, anti-dsDNA, anti-Sm)

AND

1.1.3 - The member is currently receiving or has tried and failed standard therapy for SLE (alone or in combination), such as antimalarials (e.g., hydroxychloroquine), glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone), immunosuppressives (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide)

OR

1.2 - Documentation of BOTH of the following:

1.2.1 - Diagnosis of active lupus nephritis (LN)

AND

1.2.2 - The member is currently receiving or has tried and failed standard therapy for LN (alone or in combination), such as immunosuppressives (e.g., azathioprine, mycophenolate, cyclosporine, cyclophosphamide), glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone)

AND

2 - The member does NOT have severe active central nervous system lupus

Notes	*QL Override (For new starts with a diagnosis of lupus nephritis [LN] only): Please enter two PAs as follows: • First PA: Approve 4 doses (8 syringes/injectors) for the first month (MDD=0.29); • Second PA: Approve for 5 months. (NOTE: Please enter a start date 3 weeks after the initial PA.) (Benlysta is hard-coded for 4 syringes/injectors per 28 days).

Product Name: Benlysta subcutaneous prefilled syringe, Benlysta subcutaneous auto-injector	
Approval Length	12 Month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Harvard Pilgrim's initial criteria for approval has been met

AND

2 - The member has benefitted from Benlysta therapy (e.g., reduction in steroid use, decrease in pain medications)

2. Background

Benefit/Coverage/Program Information

RATIONALE
Ensure appropriate utilization of Benlysta (belimumab) consistent with its FDA approved indication and dosing.

FDA APPROVED INDICATIONS
Benlysta (belimumab) is indicated for the treatment of:

- Patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy
- Adult patients with active lupus nephritis (LN) who are receiving standard therapy.

Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics. Use of Benlysta is not recommended in these situations.

DOSAGE AND ADMINISTRATION
The subcutaneous formulation is supplied as 200 mg/mL single-dose prefilled syringes and single-dose prefilled auto-injectors.

Recommended subcutaneous dosage regimen:

- Systemic lupus erythematosus: 200 mg once weekly.
- Lupus nephritis: 400 mg dose (two 200 mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter.

REFERENCES

- Benlysta (belimumab) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2020.
- Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. Ann Rheum Dis 2019; 78:736.

- Fanouriakis A, Kostopoulou M, Cheema K, et al. 2019 update of the joint European League Against Rheumatism and European Renal Association–European Dialysis and Transplant Association (EULAR/ERA–EDTA) recommendations for the management of lupus nephritis [published online March 27, 2020]. *Ann Rheum Dis*. doi:10.1136/annrheumdis-2020-216924.

Created: 11/17
Revised: • Annual review (effective: 1/1/20) • 8/30/20 - Annual review: background changes; no criteria changes (effective: 1/1/21) • 1/20/21 - Update criteria for label expansion to include treatment of adults with active lupus nephritis (LN) who are receiving or tried and failed standard therapy
P&T Approval: 3/8/21
Effective: 3/15/21