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 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

2 - Member does NOT have severe active lupus nephritis or severe active central nervous system lupus

AND

3 - Prior to initiating therapy, the member is auto-antibody positive

AND

4 - The member is currently receiving standard therapy for SLE (e.g., antimalarials (e.g., hydroxychloroquine), azathioprine, corticosteroids, leflunomide, methotrexate, mycophenolate, NSAIDs) or has tried and had an inadequate response or intolerance to standard therapy for SLE

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 consistent with its FDA approved indication and dosing. **FDA APPROVED INDICATIONS** Benlysta is indicated for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations. **DOSAGE AND ADMINISTRATION** The subcutaneous formulation of Benlysta is supplied as 200 mg/mL syringes and auto-injectors. The recommended dose of Benlysta is 200 mg SQ once weekly. **REFERENCES** • Benlysta [Prescribing Information]. Rockville, Maryland: Human Genome Sciences, Inc. September 2019. • 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.

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