Pharmacy Drug Policy & Procedure

Policy Name:	Benlysta (belimumab)	Policy#:	1798P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Benlysta (belimumab).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Benlysta (belimumab) if the following criteria are met.

Criteria

1. Criteria for Coverage for Systemic Lupus Erythematosus (SLE)

1.1 Diagnosis of active SLE including hematologic disease
1.2 Age 5 years or older
1.3 Prescribed by or in consultation with a rheumatologist (musculoskeletal doctor)
1.4 Documented compliance with hydroxychloroquine or chloroquine, unless contraindicated
- Compliance defined as possession of 150 days-worth of drug in 6 months

1.5 Documented failure/intolerance/contraindication to treatment with at least one other standard therapy such as prednisone, azathioprine, leflunomide, methotrexate, mycophenolate, NSAIDs

2. Criteria for Coverage for Lupus Nephritis

2.1 Diagnosis of active lupus nephritis with an eGFR $\geq$ 45mL/min/1.73m^2
2.2 Age 5 years or older
2.3 Prescribed by or in consultation with a nephrologist (kidney doctor) or rheumatologist (musculoskeletal doctor)
2.4 Documented trial of glucocorticoids with mycophenolate mofetil (MMF) or cyclophosphamide for at least 3 months

3. Approval Time

3.1 Initial Approval: 12 months
3.2 Re-approval: 12 months with documentation of a beneficial response of therapy

4. Exclusion Criteria

4.1 Treatment of severe active central nervous system lupus are considered experimental at this time due to a lack of studies which show efficacy
4.2 When used in conjunction with biologic agents or intravenous cyclophosphamide
4.3 Benlysta will not be covered if used in combination with Saphnelo or Lupkynis

CPT Codes	
HCPCS Codes	
J0490	Injection, belimumab, 10 mg (Benlysta)

References

1. Benlysta (belimumab) [prescribing information]. Durham, NC: GlaxoSmithKline LLC; May 2024.
2. Furie R, Petri M, Zamani O et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. Arthritis Rheum. 2011;(63)12:3918-30.
3. Kidney Disease: Improving Global Outcomes (KDIGO) Lupus Nephritis Work Group. KDIGO 2024 Clinical Practice Guideline for the management of LUPUS NEPHRITIS. Kidney Int. 2024 Jan;105(1S):S1-S69.
4. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. Ann Rheum Dis. 2024 Jan 2;83(1):15-29.

Created Date: 09/15/2011
Effective Date: 09/15/2011
Posted to Website: 01/01/2022
Revision Date: 04/02/2025