

<b>Policy Name:</b>	<b>Benlysta (belimumab)</b>	<b>Policy#:</b>	<b>1798P</b>
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### 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  $\geq 45\text{mL}/\text{min}/1.73\text{m}^2$
  - 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

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### HCPCS Codes

J0490	Injection, belimumab, 10 mg (Benlysta)
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## References

1. Benlysta (belimumab) [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; February 2023.
2. Fanouriakis A, Kostopoulous 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. *Ann Rheum Dis.* 2020 Jun;79(6):713-723.
3. 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.
4. Fanouriakis A, Kostopoulous M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis.* 2019 Jun;78(6):736-745.
5. Rovin BH, Adler SG, Barratt J, et al (Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group). KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int.* 2021 Oct;100(4S):S1-S276.
6. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. *Arthritis Care Res (Hoboken).* 2012 Jun;64(6):797-808.
7. Kalunian K, Merrill JT. New directions in the treatment of systemic lupus erythematosus. *Current Medical Research and Opinions.* 2009;25(6):1501-1514.

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