

Policy Name:	Benlysta (belimumab)	Policy#:	1798P
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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 and Health Alliance Northwest 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

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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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.