

Benlysta® (belimumab)

When requesting Benlysta® (belimumab), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Benlysta 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.

Coverage Guidelines

Systemic Lupus Erythematosus (SLE)

Initial authorization

The individual must meet **all** of the following criteria for approval:

- Has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA])
- Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless intolerant due to a significant toxicity
- Is 5 years of age or older
- Benlysta is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist

Reauthorization:

The individual must meet **all** of the following criteria for renewal:

- Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless intolerant due to a significant toxicity
- Has responded to Benlysta therapy (e.g., reduction in flares, reduction in corticosteroid dose, decrease in anti-dsDNA titer, improvement in complement levels [i.e., C3, C4], or improvement in specific organ dysfunction [e.g., musculoskeletal, blood, vascular, others])
- Benlysta is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist

Approval duration (initial): 4 months

Approval duration (renewal): 12 months

Dosing Guidelines

Recommended Intravenous Dosage Regimen

The recommended intravenous dosage regimen is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter.

Recommended Subcutaneous Dosage Regimen

The recommended dosage is 200 mg once weekly given as a subcutaneous injection in the abdomen or thigh.

References

1. Benlysta® injection [prescribing information]. Rockville, MD: Human Genome Science Inc./GlaxoSmithKline; January 2020.
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3. Lupus. Mayo Clinic Web site. Updated October 2017. Accessed on May 2, 2019. Available at: <http://www.mayoclinic.org/diseases-conditions/lupus/basics/complications/CON-20019676>.
4. 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 Mar 29. [Epub ahead of print].
5. 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;64(6):797-808.
6. Stohl W, Merrill JT, McKay JD, et al. Efficacy and safety of belimumab in patients with rheumatoid arthritis: a phase II, randomized, double-blind, placebo-controlled, dose-ranging Study. *J Rheumatol*. 2013;40(5):579-589.
7. Stohl W, Schwarting A, Okada M, et al. Efficacy and safety of subcutaneous belimumab in systemic lupus erythematosus: A randomized, double-blind, placebo-controlled, 52-week study. *Arthritis Rheumatol*. 2017;69(5):1016-1027.
8. ACR classification criteria. Updated in 1997. Accessed on May 2, 2019. Available at: <https://www.rheumatology.org/Portals/0/Files/1997%20Update%20of%201982%20Revised.pdf>.