

Benlysta® (belimumab)

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

FDA-approved indication

- For the treatment of an adult with active, autoantibody-positive, systemic lupus erythematosus who is receiving standard therapy

Approved Off-label Compendial use(s)

- None

Coverage Guidelines

Active systemic lupus erythematosus (SLE)

Initial authorization:

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

- The patient is an adult who is greater than or equal to 18 years of age
- The patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA])
- The drug 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 the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician
- The drug is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist

Approval duration: 4 months

Reauthorization:

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

- The patient is an adult who is greater than or equal to 18 years of age
- The drug 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 the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician
- The drug is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist

- The patient has responded to Benlysta (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), as determined by the prescriber

Approval duration: 12 months

Dosing Guidelines

- The dose is 10 mg/kg as an IV infusion at weeks 0, 2, and 4, then every 4 weeks thereafter

References

1. Benlysta® injection [prescribing information]. Rockville, MD: Human Genome Science Inc./GlaxoSmithKline; June 2018.
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3. Lupus. Mayo Clinic Web site. Updated October 2017. Accessed on July 18, 2018. Available at: <http://www.mayoclinic.org/diseases-conditions/lupus/basics/complications/CON-20019676>.
4. Andreoli L, Bertias GK, Agmon-Levin N, et al. EULAR recommendations for women's health and the management of family planning, assisted reproduction, pregnancy and menopause in patients with systemic lupus erythematosus and/or antiphospholipid syndrome. *Ann Rheum Dis*. 2017;76(3):476-485.
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 July 18, 2018. Available at: <https://www.rheumatology.org/Portals/0/Files/1997%20Update%20of%201982%20Revised.pdf>.