

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 Indications

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.

Benlysta is indicated for the treatment of patients aged 5 years and older with active lupus nephritis 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, defined as 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 (18 years of age or older for subcutaneous formulation);
AND
- 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]); AND
- 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

Lupus Nephritis

Initial authorization

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

- Has autoantibody-positive SLE, defined as 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., azathioprine, mycophenolate mofetil, cyclophosphamide) unless intolerant due to a significant toxicity;
- Is 5 years of age or older (18 years of age or older for subcutaneous formulation); AND
- Benlysta is prescribed by or in consultation with a rheumatologist or nephrologist.

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., azathioprine, mycophenolate mofetil, cyclophosphamide) unless intolerant due to a significant toxicity;
- Has responded to Benlysta therapy (e.g., improvement in organ dysfunction, reduction in flares, reduction in corticosteroid dose, decrease in anti-dsDNA titer, improvement in complement levels [i.e., C3, C4]); AND
- Benlysta is prescribed by or in consultation with a rheumatologist or nephrologist.

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendations

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 (Adult Patients with SLE)

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

Recommended Subcutaneous Dosage Regimen (Adult Patients with Lupus Nephritis)

The recommended dosage is 400 mg (two 200 mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter, given as a subcutaneous injection in the abdomen or thigh.

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References

1. Benlysta® injection [prescribing information]. Rockville, MD: Human Genome Sciences/GlaxoSmithKline; July 2022.
2. 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.
3. Rovin BH, Adler SG, Barratt J, et al. Executive summary of the KDIGO 2021 guideline for the management of glomerular diseases. *Kidney Int*. 2021;100(4):753-779.
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;78(6):736-745.
5. 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.
6. Lupkynis™ capsules [prescribing information]. Rockville, MD: Aurinia; January 2021.