

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 18 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; 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

Benlysta® (belimumab)

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 18 years of age or older; 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 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 (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.

References

1. Benlysta® injection [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; March 2021.
2. 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.
3. 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.
4. 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.