

Benlysta® (belimumab) Intravenous Injection

When requesting Benlysta® (belimumab) intravenous injection, 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 systemic lupus erythematosus (SLE) who are receiving standard therapy, and
- patients aged 5 years and older with active lupus nephritis who are receiving standard therapy.

Coverage Guidelines

Systemic Lupus Erythematosus (SLE)

The individual must meet all of the following criteria for an initial authorization:

- Is 5 years of age or older;
- Has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA [anti-dsDNA] antibody);
- Benlysta is being used concurrently with at least one other standard therapy (i.e., an antimalarial [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;
- Benlysta is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.

The individual must meet all of the following criteria for re-authorization:

- Benlysta is being used concurrently with at least one other standard therapy (i.e., an antimalarial [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 and renewal): 12 months

Lupus Nephritis

The individual must meet all of the following criteria for initial authorization:

- Is 5 years of age or older;
- Diagnosis of lupus nephritis has been confirmed on biopsy;
- Benlysta is being used concurrently with an immunosuppressive regimen (e.g., azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil, and/or a systemic corticosteroid);
- Benlysta is prescribed by or in consultation with a rheumatologist or nephrologist.

The individual must meet all of the following criteria for re-authorization:

- Has responded to Benlysta therapy (e.g., improvement in organ dysfunction, reduction in flares, reduction in corticosteroid dose, decrease in anti-dsDNA titer, or, improvement in complement levels [i.e., C3, C4]);
- Benlysta is being used concurrently with an immunosuppressive regimen (e.g., azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil, and/or a systemic corticosteroid);
- Benlysta is prescribed by or in consultation with a rheumatologist or nephrologist.

Approval duration (initial and renewal): 12 months

Dosing Recommendation

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

References

1. Benlysta® injection [prescribing information]. Durham, NC: GlaxoSmithKline; February 2024.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Lupus Nephritis Work Group. KDIGO 2024 Clinical Practice Guideline for the management of LUPUS NEPHRITIS. *Kidney Int.* 2024;105(1S):S1-S69.
3. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. *Ann Rheum Dis.* 2024;83(1):15-29.
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.

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