

## Benlysta® (belimumab) Intravenous Injection

When requesting Benlysta® (belimumab) intravenous injection, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications 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
- 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; June 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.