RX.PA.050.MPC Benlysta IV (belimumab)

The purpose of this policy is to define the prior authorization process for Benlysta IV (belimumab)

Benlysta (belimumab) intravenous, a B-lymptocute stimulator (BlyS)-specific inhibitor is indicated for the following uses:[1]

- **Lupus nephritis**, in patients ≥ 5 years of age with active disease who are receiving standard therapy.
- **Systemic lupus erythematosus** (SLE), in patients ≥ 5 years of age with active, autoantibody-positive, systemic disease in those who are receiving standard therapy.

PROCEDURE

A. Initial Authorization Criteria:

1. Lupus Nephritis. Approved for the duration noted if the patient meets all of the following:
Initial Therapy. Approve for 4 months if the patient meets ALL of the following conditions:

- Patient is ≥ 5 years of age; AND
- Patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody; AND
- Patient must have had an inadequate response to at least two of following: azathioprine, corticosteroids, cyclophosphamide or mycophenolate; AND
- Patient meets ONE of the following (a or b):
  - **a)** The prescriber and member agree to use Benlysta concurrently with at least one other standard therapy; OR
    Note: Examples of standard therapies include azathioprine, mycophenolate mofetil, cyclophosphamide.
  - **b)** Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; AND
- The medication is prescribed by or in consultation with a nephrologist or rheumatologist.
- Patient must not be concurrently using Benlysta with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Reauthorization Criteria:
Patient is Currently Receiving Benlysta Intravenous. Approve for 1 year if the patient meets one of the following (A or B):

A. MPC Renewal

- Patient has received an MPC prior authorization and has been established on therapy for least 4 months and has had a documented clinically signficant response, as determined by the provider

  Note: Examples of a response include improvement in organ dysfunction, reduction in flares, reduction in corticosteroid dose, decrease of anti-dsDNA titer, and improvement in complement levels (i.e., C3, C4).
- Patient meets ONE of the following (a or b):
  a. The medication is being used concurrently with at least one other standard therapy; OR

     Note: Examples of standard therapies include azathioprine, mycophenolate mofetil, cyclophosphamide).
  b. Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber
- Patient must not be concurrently using Benlysta with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

OR

B. Non-MPC PA Renewal
- Patients who have previously been taking Benlysta and are requesting a non-MPC renewal should be considered under criterion 1 (Initial Authorization Criteria); AND
- Patient has not been receiving medication samples for Benlysta; **AND**
- Patient has been established on therapy for at least 4 months and has had a documented clinically signficant response, as determined by the provider

2. Systemic Lupus Erythematosus (SLE). Approve for the duration noted if the patient meets all of the following:

Initial Therapy. Approve for 4 months if the patient meets ALL of the following conditions:
- Patient is ≥ 5 years of age; AND
- Patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody; AND

  Note: Not all patients with SLE are positive for anti-dsDNA, but most will be positive for ANA.
- Patient must have had an inadequate response to at least two of the following: corticosteroids, antimalarials (hydroxychloroquine/chloroquine), NSAIDs, aspirin and/or immunosuppressives such as azathioprine, methotrexate, mycophenolate; AND
- Patient meets ONE of the following (a or b):

  a) The prescriber and member agree to use Benlysta concurrently with at least one other standard therapy; OR

  Note: Examples of standard therapies include an antimalarial (e.g., hydroxychloroquine), systemic corticosteroid (e.g., prednisone), and other immunosuppressants (e.g., azathioprine, mycophenolate mofetil, methotrexate).

  b) Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; AND

- The medication is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.
- Patient must not be concurrently using Benlysta with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Reauthorization Criteria:
Patient is Currently Receiving Benlysta Intravenous. Approve for 1 year if the patient meets one of the following criteria (A or B):

A. MPC Renewal
- Patient has received an MPC prior authorization and has been established on therapy for least 4 months and has had a documented clinically signficant response, as determined by the provider

  Note: Examples of a response include reduction in flares, reduction in corticosteroid dose, decrease of anti-dsDNA titer, improvement in complement levels (i.e., C3, C4), or improvement in specific organ dysfunction (e.g., musculoskeletal, blood, hematologic, vascular, others).
- Patient meets ONE of the following (a or b):
  - **a)** The medication is being used concurrently with at least one other standard therapy; OR

    Note: Examples of standard therapies include an antimalarial (e.g., hydroxychloroquine), systemic corticosteroid (e.g., prednisone), and other immunosuppressants (e.g., azathioprine, mycophenolate mofetil, methotrexate).
  - **b)** Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber
- Patient must not be concurrently using Benlysta with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

OR

B. Non-MPC PA Renewal
- Patients who have previously been taking Benlysta and are requesting a non-MPC renewal should be considered under criterion 2 (Initial Authorization Criteria); AND
- Patient has not been receiving medication samples for Benlysta; **AND**
- Patient has been established on therapy for at least 4 months and has had a documented clinically signficant response, as determined by the provider

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 4 months
Reauthorization	Up to 1 year

Codes:

Code	Description
J0490	Injection, belimumab , 10 mg

REFERENCES

1. Benlysta® injection [prescribing information]. Rockville, MD: Human Genmome Science Inc./GlaxoSmithKline; December 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.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*05/27/2020*
Annual Revision **Lupus Nephritis:** This newly approved condition was added to the policy. For initial therapy the patient must be ≥ 18 years of age. Criteria approve for 6 months for initial therapy (1 year for continuation), if the medication is being used concurrently with at least one other standard therapy unless intolerant. For continuation, the patient must also have demonstrated a response to initial therapy. For all approvals, Benlysta must be prescribed by or in consultation with a specialist. **Conditions Not Recommended for Approval:** Concurrent use with cyclophosphamide was removed from the Conditions Not Recommended for Coverage (no longer supported in the labeling).	*01/20/2021*
Selected Revision **Lupus Nephritis:** Indication change to include patients 5 years of age and older Addition of MPC vs Non-MPC Renewal Criteria	*08/2022*
Selected Revision **Addition of criteria: No concurrent use with other biologics**	*02/2023*
Annual Review	*02/2023*