SmartHealth Ascension

Belimumab

(Benlysta®) J0490 (10mg)

Covered with prior authorization

Belimumab (Benlysta®) may be authorized when the following criteria are met:

Systemic Lupus Erythematosus (SLE)

- **For initial therapy, all of the following:**
  - Individual has a diagnosis of active systemic lupus erythematosus, without severe active central nervous system lupus; **AND**
  - An insufficient response to two (2) standard of care drug classes:
    - Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone)
    - Antimalarials (e.g., hydroxychloroquine)
    - Immunosuppressives (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide, chlorambucil, nitrogen mustard). **AND**
  - Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]; **AND**
  - Individual is currently receiving at least one standard of care treatment (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic, **OR** is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; **AND**
  - Individual is **NOT** receiving Benlysta® in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); **AND**
  - Benlysta® is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.
  - Benlysta® is initiated and titrated according to the U.S. Food and Drug Administration's labeled dosing for SLE.

- **For continuation of therapy, all of the following:**
  - Individual has previously received Benlysta injection for intravenous infusion with documentation of positive clinical response; 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).; **AND**
  - Individual is currently receiving at least one standard of care treatment (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic, **OR** is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; **AND**
  - Individual is **NOT** receiving Benlysta® in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); **AND**

- Benlysta® is dosed according to the U.S. Food and Drug Administration's labeled dosing for SLE.

Lupus Nephritis (LN)

- **For initial therapy, all of the following:**
  - Individual has a diagnosis of active lupus nephritis, without severe active central nervous system lupus; **AND**
  - Individual is currently receiving at least one standard of care treatment (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic, **OR** is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; **AND**
  - Individual is **NOT** receiving Benlysta® in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); **AND**
  - Benlysta® is initiated and titrated according to the U.S. Food and Drug Administration's labeled dosing.

- **For continuation of therapy, all of the following:**
  - Individual has previously received Benlysta® injection for intravenous infusion with documentation of positive clinical response. 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).; **AND**
  - Individual is currently receiving at least one standard of care treatment (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic, **OR** is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; **AND**
  - Individual is **NOT** receiving Benlysta® in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); **AND**
  - Benlysta® is dosed according to the U.S. Food and Drug Administration's labeled dosing.

Exclusion criteria:

- Antineutrophil cytoplasmic antibody-associated vasculitis
- Rheumatoid arthritis
- Severe active central nervous system (CNS) lupus
- Sjögren's syndrome
- Use in combination with other biologics
- Waldenström macroglobulinemia
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Benlysta® is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy and adult patients with active lupus nephritis who are receiving standard therapy.

References:

1. Benlysta® [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; August 2022.
2. Furie R, Petri M, Zamani O, et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. Arthritis Rheum. 2011 Dec;63(12):3918-30.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022
4. Navarra SV, Guzmán RM, Gallacher AE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomized, placebo-controlled, phase 3 trial. Lancet. 2011 Feb 26;377(9767):721-31.
5. Wallace DJ, Stohl W, Furie RA, et al. A phase II, randomized, double-blind, placebo-controlled, dose-ranging study of belimumab in patients with active systemic lupus erythematosus. Arthritis Rheum. 2009 Sep 15;61(9):1168-78.
6. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus in adults. Arthritis Rheum. 1999 Sep;42(9):1785–96.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.