ALASKA MEDICAID
Prior Authorization Criteria

Benlysta®
(belimumab)

FDA INDICATIONS AND USAGE[1]

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 (SLE) who are receiving standard therapy and adult patients with active lupus nephritis who are receiving standard therapy. The efficacy of Benlysta® has not been evaluated in patients with severe active central nervous system lupus. Benlysta® has not been studied in combination with other biologics and the use of Benlysta® is not recommended in these situations.

APPROVAL CRITERIA[1,2,3]

Systemic Lupus Erythematosus

1. Patient is 5 to 17 years of age and will be receiving IV infusions **OR**;
2. Patient is 18 years of age or older receiving either IV or subcutaneous injections **AND**;
3. Patient has a diagnosis of systemic lupus erythematosus **AND**;
4. Prescribed by or in consultation with a rheumatologist, immunologist, nephrologist, neurologist, or dermatologist **AND**;
5. Patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody **AND**;
6. Patient is currently receiving standard immunosuppressive therapy (i.e., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate) or has a contraindication to standard therapy.

Lupus Nephritis

1. Patient is 18 years of age or older **AND**;
2. Patient has a diagnosis of lupus nephritis **AND**;
3. The medication is prescribed by or in consultation with a nephrologist or rheumatologist **AND**;
4. Patient has an International Society of Nephrology/Renal Pathology Society (ISN/RPS) biopsy-proven active Class III or IV lupus nephritis alone or in combination with Class V lupus nephritis **AND**;
5. Patient is currently receiving standard immunosuppressive therapy (i.e., azathioprine, mycophenolate mofetil, cyclophosphamide) or has a contraindication to standard therapy.

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient is taking concomitantly a biologic DMARD or Lupkynis **OR**;
3. Patient has severe active central nervous system lupus.

CAUTIONS[1]

- Use with caution in patients with severe or chronic infections. Serious and sometimes fatal infections have occurred in patients receiving immunosuppressive agents, including Benlysta®.
- Evaluate patients with new-onset or deteriorating neurological signs and symptoms for Progressive Multifocal Leukoencephalopathy (PML).
- Consider administering premedication for prophylaxis against infusion reactions and hypersensitivity reactions.
- Depression and suicidality have been reported in trials with Benlysta®. Assess for depression and risk of suicide before treatment with Benlysta® and monitor during treatment.

DURATION OF APPROVAL

- Initial Approval: up to 4 months
- Reauthorization Approval: up to 12 months if the prescriber documents the patient has disease improvement

QUANTITY LIMIT

- 120 mg, 400 mg vial for intravenous (IV) infusion - Initiation of therapy of Benlysta vials for IV infusion, may approve 10 mg/kg dosing at 2 week intervals for the first 3 doses, then 10 mg/kg every 4 weeks.
- 200 mg/ml prefilled autoinjector/syringe for subcutaneous use - Initiation of therapy of subcutaneous Benlysta for active lupus nephritis, may approve 8 injections for the first 28 days, then 4 injections per 28 days.
- HCPCS: J0490

REFERENCES / FOOTNOTES:

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