Date Effective: 9/2017
Reviewed: 9/2017, 12/2018, 11/2019, 9/2020, 01/2021, 4/2021, 01/2022, 9/2022, 01/2023, 12/2023, 02/2024, 3/2025 Pharmacy Scope (SQ): Medicaid Medical Scope (IV): Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

BENLYSTA (belimumab)

POLICY

Initial Criteria:

Systemic Lupus Erythematosus (SLE)

- Patient is 5 years of age or older*; **AND**
- Patient has documented diagnosis of active SLE **AND**
- Patient has one of the following:
    - Safety of Estrogen in Lupus National Assessment -Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12; **OR**
    - British Isles Lupus Assessment Group (BILAG) B organ domain score ≥2; **AND**
- Patient has failed to respond adequately to at least two (2) standard therapies such as anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, or immunosuppressives (excluding intravenous cyclophosphamide); **AND**
- Used in combination with standard therapy (e.g. anti-malarials, corticosteroids, nonsteroidal anti-inflammatory drugs, immunosuppressives); **AND**
- Patient must not have an active infection; **AND**
- Patient has not received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**
- Will not be used in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab); **AND**
- Patient does not have any of the following exclusion criteria:
    - Severe active central nervous system lupus
    - Individuals who are on other biologics

Lupus Nephritis

- Patient is 5 years of age or older**; **AND**
- Patient has active lupus nephritis Class III, IV, or V as confirmed by renal biopsy; **AND**
- Patient has failed to respond adequately to standard therapies including corticosteroids; **AND** either cyclophosphamide or mycophenolate mofetil; **AND**
- Baseline measurement of one or more of the following is provided: urine protein:creatinine ratio (uPCR), estimated glomerular filtration rate (eGFR), or urine protein; **AND**
- Used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); **AND**
- Patient must not have an active infection; **AND**

- Patient has not received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**
- Will not be used in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab); **AND**
- Patient does not have any of the following exclusion criteria:
    - Severe active central nervous system lupus
    - Individuals who are on other biologics;

*Benlysta 200mg/ml auto-injector for subcutaneous injection (not prefilled syringe) is indicated for the treatment of SLE in patients that are 5 years of age and older that weigh at least 15kg.
**Benlysta 200mg/mL subcutaneous injection (auto-injector and prefilled syringe) is indicated for the treatment of SLE and lupus nephritis in patients 18 years of age and older.

Continuation of Therapy Criteria:

- Meets all initial criteria and is tolerating treatment; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: depression, suicidal thoughts, serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reactions/anaphylaxis, serious infusion reactions, etc.; **AND**

SLE:

- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
    - Improvement in the SELENA-SLEDAI score of ≥4 points; **OR**
    - No new BILAG-A organ domain score or 2 new BILAG-B organ domain scores; **OR**
    - No worsening (<30-point point increase) in Physician's Global Assessment (PGA) score; **OR**
    - Seroconverted (negative) or had a 20% reduction in autoantibody level; **OR**

Lupus Nephritis:

- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
- Urine protein:creatinine ratio (uPCR); **OR**
- Estimated glomerular filtration rate (eGFR); **OR**
- Urine protein

Coverage Durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

Pharmacy Quantity Limit and Dosing:

Benlysta 200mg/ml subcutaneous injection has a quantity limit of 4 injections per 28 days (daily dose of 0.143), with a post-limit loading dose for of 8 injections per 28 days (daily dose of 0.286) for a diagnosis of Lupus Nephritis only.
Benlysta 200mg/ml auto-injector for subcutaneous injection (not prefilled syringe) is indicated for the treatment of SLE in patients that are 5 years of age and older and weigh at least 15kg. Benlysta 200mg/mL subcutaneous injection (auto-injector and prefilled syringe) is indicated for the treatment of SLE and lupus nephritis in patients 18 years of age and older.

Indication	**Dose (subcutaneous)**
SLE	**Patients 5 years of age and older (Auto-injector only):** 15 kg to <40 kg: 200 mg once every 2 weeks. ≥ 40 kg: 200 mg once weekly **Adults (Auto-injector or prefilled syringe):** 200 mg once weekly
Lupus Nephritis	**Adults (Auto-injector or prefilled syringe)**: Loading dose: 400mg once weekly for 4 doses Maintenance dose: 200mg once weekly

Medical Quantity Limit and Dosing:

Indication	Dose	Maximum dose (1 billable unit = 10 mg)
SLE or Lupus Nephritis	Loading Dose: 10 mg/kg intravenously (by a healthcare provider) every 2 weeks x 3 doses (days 1, 15 and 29) Maintenance Dose: 10 mg/kg intravenously (by a healthcare provider) every 4 weeks	Loading Dose (on days 1, 15 and 29): 360 billable units per 29 days Maintenance Dose: 120 billable units per 28 days

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0490	Injection, belimumab, 10mg

References:

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systemic lupus erythematosus. Arthritis Res Ther. 2008;10(5):R109. doi: 10.1186/ar2506. Epub 2008 Sep 11.

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