

BENLYSTA (belimumab)

### Pre - PA Allowance

None

## **Prior-Approval Requirements**

Age 5 years of age or older

#### Diagnoses

Patient must have **ONE** of the following:

- 1. Systemic lupus erythematosus (SLE)
  - **AND ALL** of the following:
    - a. Must have active SLE
    - b. Must be autoantibody-positive
    - c. Must be receiving standard therapy [e.g., corticosteroids, NSAID, azathioprine, leflunomide, methotrexate, mycophenolate, tacrolimus, and antimalarials (e.g., hydroxychloroquine, chloroquine, quinine, quinidine, mefloquine)]
    - d. Prescriber agrees to review and discuss with Black/African American patients the limited evidence of benefit of Benlysta in this population compared to standard treatment <sup>(2)</sup>
- 2. Lupus nephritis
  - **AND ALL** of the following:
    - a. Must have active lupus nephritis
    - Must be receiving standard therapy (e.g., corticosteroids, cyclosporine, tacrolimus, cyclophosphamide, azathioprine, mycophenolate and rituximab)
    - c. Patients age **5-17 only**: Patient will be receiving Benlysta as an intravenous infusion
    - d. Prescriber agrees to review and discuss with Black/African American patients the limited evidence of benefit of Benlysta in this population compared to standard treatment <sup>(2)</sup>

AND NONE of the following for ALL indications:

- 1. Chronic infection, including, but not limited to Hepatitis B, Hepatitis C, HIV, TB
- 2. Severe active central nervous system lupus
- 3. Concurrent therapy with a biologic medication



4. Given concurrently with live vaccines

### **Prior - Approval Limits**

Duration 6 months

## Prior – Approval Renewal Requirements

Age 5 years of age or older

#### Diagnoses

Patient must have **ONE** of the following:

1. Systemic lupus erythematosus (SLE)

**AND ALL** of the following:

- a. Must be receiving standard therapy
- b. Documented clinical benefit from therapy (e.g., improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to the start of Benlysta)
- c. Prescriber agrees to review and discuss with Black/African American patients the limited evidence of benefit of Benlysta in this population compared to standard treatment <sup>(2)</sup>
- 2. Lupus nephritis

AND ALL of the following:

- a. Must be receiving standard therapy (i.e., corticosteroids, cyclosporine, tacrolimus, cyclophosphamide, azathioprine, mycophenolate and rituximab)
- b. Documented clinical benefit from therapy (i.e., decrease or stabilization of symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to the start of Benlysta)
- c. Patients age **5-17 only**: Patient will be receiving Benlysta as an intravenous infusion
- d. Prescriber agrees to review and discuss with Black/African American patients the limited evidence of benefit of Benlysta in this population compared to standard treatment <sup>(2)</sup>



**BENLYSTA** (belimumab)

**AND NONE** of the following for **ALL** indications:

- 1. Chronic infection, including, but not limited to Hepatitis B, Hepatitis C, HIV, TB
- 2. Severe active central nervous system lupus
- 3. Concurrent therapy with a biologic medication
- 4. Given concurrently with live vaccines

# Prior - Approval Renewal Limits

**Duration** 12 months