**Medical Guideline Disclaimer**

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**Definition**

Benlysta is a human IgG1 lambda monoclonal antibody that inhibits the binding of soluble B lymphocyte stimulator protein (BlyS) to its B cell receptors.

**Length of Authorization**

Coverage will be provided for 12 months and may be renewed.

**Dosing Limits**

**Max Units (per dose and over time) [Medical Benefit]:**

- **Loading Dose (doses administered on days 1, 15 and 29):**
  - 360 billable units per 29 days
- **Maintenance Dose:**
  - 120 billable units per 28 days

**Guideline**

I. **INITIAL APPROVAL CRITERIA**

**Systemic Lupus Erythematosus (SLE) †**

- Adult patient (5 years or older); **AND**
- Patient has a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA); **AND**
• Patient has failed to respond adequately to at least two (2) standard therapies (anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives (excluding intravenous cyclophosphamide)); **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
  – British Isles Lupus Assessment Group (BILAG) A organ domain score ≥1
  – BILAG B organ domain score ≥2; **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**

• Patient does not have any of the following exclusion criteria:
  – Severe active central nervous system lupus
  – Severe active lupus nephritis
  – Individuals who are on other biologics or IV cyclophosphamide

† FDA Approved Indication(s)

II. **RENEWAL CRITERIA**

Authorizations can be renewed based on the following criteria:

• Patient continues to meet the criteria identified in section III; **AND**

• 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 (<0.30-point increase) in Physician’s Global Assessment (PGA) score; **OR**
  – Seroconverted (negative) or had a 20% reduction in autoantibody level; **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 reaction, etc.

### Dosing/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Systemic lupus erythematosus (SLE)</td>
<td>• Loading Dose: 10 mg/kg intravenously (by a healthcare provider) every 2 weeks x 3 doses (days 1, 15 and 29)</td>
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<tr>
<td></td>
<td>• Maintenance Dose: 10 mg/kg intravenously (by a healthcare provider) every 4 weeks</td>
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Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0490</td>
<td>Injection, belimumab, 10 mg; 1 billable unit = 10 mg</td>
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</table>

Applicable NDC’s

<table>
<thead>
<tr>
<th>NDC</th>
<th>Description</th>
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<tbody>
<tr>
<td>49401-0101-xx</td>
<td>Benlysta 120 mg/5 mL SDV for injection</td>
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<tr>
<td>49401-0102-xx</td>
<td>Benlysta 400 mg/20 mL SDV for injection</td>
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<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>M32.10</td>
<td>Systemic lupus erythematosus organ or system involvement unspecified</td>
</tr>
<tr>
<td>M32.11</td>
<td>Endocarditis in systemic lupus erythematosus</td>
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<tr>
<td>M32.12</td>
<td>Pericarditis in systemic lupus erythematosus</td>
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<tr>
<td>M32.13</td>
<td>Lung involvement in systemic lupus erythematosus</td>
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<td>M32.14</td>
<td>Glomerular disease in systemic lupus erythematosus</td>
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<td>M32.15</td>
<td>Tubulo-interstitial nephropathy in systemic lupus erythematosus</td>
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<td>M32.19</td>
<td>Other organ or system involvement in systemic lupus erythematosus</td>
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<td>M32.8</td>
<td>Other forms of systemic lupus erythematosus</td>
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<tr>
<td>M32.9</td>
<td>Systemic lupus erythematosus, unspecified</td>
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</tbody>
</table>

Revision History

8/12/2019  Updated age range from 18 to 5 years of age and older for IV

References

11.