Medical Guideline Disclaimer

Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, (“EmblemHealth”) has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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>
</tr>
</thead>
<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>
</tr>
<tr>
<td></td>
<td>• Maintenance Dose: 10 mg/kg intravenously (by a healthcare provider) every 4 weeks</td>
</tr>
</tbody>
</table>

**Authorization**
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>
</tr>
</tbody>
</table>

Applicable NDC’s

<table>
<thead>
<tr>
<th>NDC's</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>49401-0101-xx</td>
<td>Benlysta 120 mg/5 mL SDV for injection</td>
</tr>
<tr>
<td>49401-0102-xx</td>
<td>Benlysta 400 mg/20 mL SDV for injection</td>
</tr>
</tbody>
</table>

ICD-10

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>Description</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>M32.12</td>
<td>Pericarditis in systemic lupus erythematosus</td>
</tr>
<tr>
<td>M32.13</td>
<td>Lung involvement in systemic lupus erythematosus</td>
</tr>
<tr>
<td>M32.14</td>
<td>Glomerular disease in systemic lupus erythematosus</td>
</tr>
<tr>
<td>M32.15</td>
<td>Tubulo-interstitial nephropathy in systemic lupus erythematosus</td>
</tr>
<tr>
<td>M32.19</td>
<td>Other organ or system involvement in systemic lupus erythematosus</td>
</tr>
<tr>
<td>M32.8</td>
<td>Other forms of systemic lupus erythematosus</td>
</tr>
<tr>
<td>M32.9</td>
<td>Systemic lupus erythematosus, unspecified</td>
</tr>
</tbody>
</table>

Revision History

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

References