Medical Policy:
Spevigo (spesolimab-sbzo), Intravenous Infusion

<table>
<thead>
<tr>
<th>POLICY NUMBER</th>
<th>LAST REVIEW</th>
<th>ORIGIN DATE</th>
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<tr>
<td>MG.MM.PH.367</td>
<td>November 10, 2022</td>
<td>November 10, 2022</td>
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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

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.

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Definitions
Spevigo, an interleukin-36 receptor antagonist is indicated for the treatment of generalized pustular psoriasis flares in adults.

Length of Authorization
1 month (30 days)

Dosing Limits [Medical Benefit]
Approve the following dosing regimens (A, B, and C):
A. Approve 900 mg per dose administered by intravenous (IV) infusion; **AND**
B. If a second dose is administered, 7 days elapse between the doses; **AND**
C. If this a new flare, at least 12 weeks have elapsed since the last dose of Spevigo.

Guideline
I. Initial Criteria
1. **Generalized Pustular Psoriasis.** Approve for up to two doses if the patient meets **ALL** of the following criteria (A, B, C, and D):
   
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient is experiencing a flare of moderate-to-severe intensity and meets all of the following (i, ii, iii, and iv):
      
      i. Patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 3 points; **AND**
         
         *Note: The Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score ranges from 0 [clear skin] to 4 [severe disease].*
      
      ii. Patient has a GPPGA pustulation subscore of ≥ 2 points; **AND**
      
      iii. Patient has new or worsening pustules; **AND**
      
      iv. Patient has erythema and pustules which affects ≥ 5% of body surface area; **AND**
   
   C. The medication is prescribed by or in consultation with a dermatologist.

II. **Renewal Criteria:**
   
   A. Patient continues to meet initial criteria; **AND**
   
   B. Patient has **not** already received two doses of Spevigo for treatment of the current flare; **AND**
   
   C. If this is a new flare, at least 12 weeks have elapsed since the last dose of Spevigo

### Applicable Procedure Codes

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<td>J3590</td>
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### Applicable NDCs

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<td>00597-0035-10</td>
<td>Spevigo (spesolimab-sbzo) 60mg/mL (7.5mL vial)</td>
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### ICD-10 Diagnoses

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### Revision History

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<tr>
<td>EmblemHealth &amp; ConnectiCare</td>
<td>11/10/2022</td>
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### References