Gamifant (emapalumab-lzsg)

Effective Date: January 1, 2021
Number: MG.MM.PH.312

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, EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC and Health Insurance Plan of Greater New York (HIP), ConnectiCare, Inc., ConnectiCare Insurance Company, Inc. ConnectiCare Benefits, Inc., and ConnectiCare of Massachusetts, Inc. related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Gamifant is a fully human monoclonal antibody against interferon gamma (IFN-γ). It is indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) [also referred to as familial HLH] with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy. Per product labeling, Gamifant should be administered concomitantly with systemic dexamethasone and with prophylaxis for Herpes Zoster, Pneumocystis jirovecii, and fungal infections.

Dosing

Approve up to a maximum dose of 10 mg/kg by intravenous infusion, not more frequently than twice weekly (once every 3 to 4 days).

Length of Coverage

- Approvals will be granted for 6 months

Guideline

Hemophagocytic Lymphohistiocytosis, Primary

- The patient has a diagnosis of hemophagocytic lymphohistiocytosis determined by at least one of the following:
- The patient has a molecular genetic diagnosis consistent with hemophagocytic lymphohistiocytosis; OR
- Prior to treatment, the patient meets at least **FIVE** of the following diagnostic criteria at baseline (FIVE of: a, b, c, d, e, f, g, or h):
  - Fever ≥ 38.5 °C;
  - Splenomegaly;
  - Cytopenias defined as at least **TWO** of the following (1, 2, or 3):
    - Hemoglobin < 9 g/dL (or < 10 g/dL in infants less than 4 weeks of age);
    - Platelets < 100 x 10^9/L;
    - Neutrophils < 1.0 x 10^9/L;
  - Fasting triglycerides ≥ 265 mg/dL OR fibrinogen ≤ 1.5 g/L;
  - Hemophagocytosis in bone marrow, spleen, or lymph nodes;
  - Low or absent natural killer cell activity (according to local laboratory reference);
  - Ferritin ≥ 500 mcg/L;
  - Soluble CD25 (i.e., soluble interleukin-2 receptor) ≥ 2,400 U/mL; AND
- The patient has tried at least **one** conventional therapy (e.g., etoposide, cyclosporine A, or anti-thymocyte globulin); AND
- According to the prescriber, the patient has experienced at least **ONE** of the following:
  - Refractory, recurrent, or progressive disease during conventional therapy (e.g., etoposide, cyclosporine A, or anti-thymocyte globulin); OR
  - Intolerance to conventional therapy (e.g., etoposide, cyclosporine A, or anti-thymocyte globulin); AND
- The medication is prescribed by, or in consultation with, a hematologist, oncologist, immunologist, transplant specialist, or physician who specializes in hemophagocytic lymphohistiocytosis or related disorders.

**Limitations/Exclusions**
- Coverage is not recommended for circumstances not listed in the Guideline. Criteria will be updated as new published data are available.

**Applicable Procedure Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J9210</td>
<td>Injection, emapalumab-lzsg, 1 mg, effective 10/01/2019.</td>
</tr>
<tr>
<td>C9050</td>
<td>Injection, emapalumab-lzsg, 1 mg</td>
</tr>
</tbody>
</table>

**Applicable NDCs**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>72171-0501-01</td>
<td>Gamifant 10 mg/2 mL single dose vial</td>
</tr>
<tr>
<td>72171-0505-01</td>
<td>Gamifant 50 mg/10 mL single dose vial</td>
</tr>
</tbody>
</table>

**Applicable Diagnosis Codes**

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
</table>
Revision History

1/1/2021 Criteria apply to Commercial, Medicare, and Medicaid members.

References