Gamifant (emapalumab-lzsg)

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

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

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<tr>
<th>Code</th>
<th>Description</th>
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<td>Injection, emapalumab-lzsg, 1 mg, effective 10/01/2019.</td>
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<td>C9050</td>
<td>Injection, emapalumab-lzsg, 1 mg</td>
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### Applicable NDCs

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<th>NDC</th>
<th>Description</th>
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<td>Gamifant 10 mg/2 mL single dose vial</td>
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<td>72171-0505-01</td>
<td>Gamifant 50 mg/10 mL single dose vial</td>
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### Applicable Diagnosis Codes

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<th>ICD-10</th>
<th>ICD-10 Description</th>
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Hemophagocytic lymphohistiocytosis

Revision History

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

References