blue california
Promise Health Plan

emapalumab-lzsg (Gamifant)

Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: interferon gamma blocking antibody
HCPCS:
J9210:Injection, emapalumab-lzsg, 1 mg
How Supplied:

- 10 mg/2mL (5mg/mL concentration in single-dose vial)
- 50 mg/10mL (5 mg/mL concentration in single-dose vial)
- 100 mg/20 mL (5 mg/mL concentration in single-dose vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Hemophagocytic Lymphohistiocytosis (HLH) / Macrophage Activation Syndrome (MAS) in Known or Suspected Still's Disease [including Systemic Juvenile Idiopathic Arthritis (sJIA)]
- Primary Hemophagocytic Lymphohistiocytosis (HLH)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Hemophagocytic Lymphohistiocytosis (HLH) / Macrophage Activation Syndrome (MAS) in Known or Suspected Still's Disease [including Systemic Juvenile Idiopathic Arthritis (sJIA)]
Meets medical necessity if all the following are met:

1. Prescribed by or in consultation with a hematologist or rheumatologist
2. Meets ONE of the following:

a. Inadequate response or intolerance to glucocorticoids
b. Recurrent MAS

Covered Doses:
Up to 6 mg/kg, followed by 3 mg/kg every 3 days for 5 doses, then 3 mg/kg twice per week thereafter
The dose may be titrated up to a maximum of 10 mg/kg.

Coverage Period:
Initial: 1 year
Reauthorization: Yearly based on continued response to therapy

ICD-10:
D76.1, M08.20, M08.211, M08.212, M08.219, M08.221, M08.222, M08.229, M08.231, M08.232, M08.239, M08.241, M08.242, M08.249, M08.251, M08.252, M08.259, M08.261, M08.262, M08.269, M08.271, M08.272

Primary Hemophagocytic Lymphohistiocytosis (HLH)
Meets medical necessity if all the following are met:
1. Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)
2. Prescribed by or in consultation with hematologist
3. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy (dexamethasone, etoposide, cyclosporine, and/or anti-thymocyte globulin)
4. Being initiated concomitantly with dexamethasone

Covered Doses:
Up to 1 mg/kg given intravenously twice per week (every three to four days)
The dose may be titrated up to a maximum of 10 mg/kg.

Coverage Period:
Initial: 1 year
Reauthorization: Yearly based on continued response to therapy

ICD-10:
D76.1

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Gamifant (emapalumab-lzsg) Prescribing Information. Sobi Inc., Waltham, MA: 6/2025.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- HLH/MAS in known or suspected Still's Disease (including sJIA): Added new coverage for this indication *(Rationale: In June 2025, the FDA expanded the approval of Gamifant to include treatment of adult and pediatric (newborn and older) patients with HLH/MAS in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS)*

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee