Emapalumab-Izsg (Gamifant®)

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

HCPCS: J9210 per 1 mg

Condition listed in policy (see criteria for details)

• Primary hemophagocytic lymphohistiocytosis

AHFS therapeutic class: Immunosuppressive agent

Mechanism of action: interferon gamma blocking antibody

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for emapalumab-lzsg (Gamifant®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Primary hemophagocytic lymphohistiocytosis

- 1. Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) by hematologist, AND
- 2. Prescribed by or in consultation with hematologist, AND
- 3. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy (dexamethasone, etoposide, cyclosporine, and/or anti-thymocyte globulin), AND
- 4. Being initiated concomitantly with dexamethasone

Covered Dose

Up to 10 mg/kg IV twice per week (every three to four days)

Coverage Period

Indefinite

ICD-10:

D76.1

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for emapalumab-lzsg (Gamifant®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

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<u>Please refer to the Provider Manual and User Guide for more information.</u>

(5) Additional Information

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)

(6) References

- AHFS[®]. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Gamifant® (emapalumab-Izsg) [Prescribing information]. Waltham, MA: Sobi Inc.; 6/2020.

(7) Policy Update

Date of last review: 3Q2021 Date of next review: 3Q2022

Changes from previous policy version:

• No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee

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