Pharmacy Drug Policy & Procedure

Policy Name:	Gamifant (emapalumab)	Policy#:	2705P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Gamifant (emapalumab).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Gamifant under the specialty medical benefit when the following criteria for coverage have been met.

Criteria

1. Coverage Criteria

1.1 Documented diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) confirmed by one of the following: confirmation of a gene mutation known to cause primary HLH (e.g., PRFl, UNC13D), OR confirmation that 5 of the following clinical characteristics are present:

- Fever 101.3°F
- Splenomegaly
- Two of the following cytopenias in the peripheral blood:
  - Hemoglobin < 9 g/dL
  - Platelet count < 100 x 109/L
  - Neutrophils < 1 x 109/L
- One of the following:
  - Hypertriglyceridemia defined as fasting triglycerides 3mmol/L or 265mg/dL, OR
  - Hypofibrinogenemia defined as fibrinogen 1.5 g/L
- Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy
- Low or absent natural killer cell activity (according to local laboratory reference)
- Ferritin 500 mg/L

1.2 Prescribed by or with a hematologist (blood doctor)

1.3 Documentation that patient has refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy

- etoposide + dexamethasone
- Cyclosporine A
- anti-thymocyte globulin

1.4 Documentation that Gamifant will be administered with dexamethasone,

1.5 Documentation that patient is a candidate for stem cell transplant

1.6 Documentation that Gamifant is being used as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant

1.7 Review of chart notes and labs documenting diagnosis and confirming that patient has met all

of the above requirements for treatment with Gamifant by both a pharmacist and medical director

2. Exclusion Criteria

2.1 Gamifant use is excluded from coverage for the treatment of secondary HLH as this is considered experimental use.

3. Approval Period

3.1 6 months

- Health Alliance will only approve medical claims for Gamifant from a contracted vendor and will not allow provider offices to buy and bill.

3.2 Requests for treatment beyond the initial 6 months will require documentation of clinical improvement with lab work, as well as documentation indicating when member is expected to undergo stem cell transplant

CPT Codes

HCPCS Codes

J9210	Injection, emapalumab-lzsg, 1mg

References

1. Gamifant (emapalumab-lzsg) [prescribing information]. Waltham, MA; Sobi Inc; July 2024.
2. Locatelli F, Jordan MB, Allen C, et al. Emapalumab in Children with Primary Hemophagocytic Lymphohistiocytosis. N Engl J Med 2020; 382:1811.
3. Marsh RA, Jordan MB, Talano JA, et al. Salvage therapy for refractory hemophagocytic lymphohistiocytosis: A review of the published experience. Pediatr Blood Cancer 2017; 64.

Created Date: 10/02/19
Effective Date: 10/02/19
Posted to Website: 01/01/22
Revision Date: 10/02/24