Pharmacy Drug Policy Checklist

POLICY NAME	Gamifant (emapalumab)	POLICY #	2705P

Criteria

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., PRFI, 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 CPT Codes HCPCS Codes J9210 Injection, emapalumab-lzsg, 1mg References of the above requirements for treatment with Gamifant by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

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

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