CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Gamifant (emapalumab-lzsg)
BILLING CODE	J9210
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include dexamethasone, etoposide, methotrexate, hydrocortisone, etc. QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Gamifant (emapalumab-lzsg) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (HLH)

For **initial** authorization:

1. Member has diagnosis of primary HLH with either refractory, recurrent, or progressive disease during conventional HLH therapy (e.g., dexamethasone, etoposide, methotrexate, hydrocortisone, etc.) or who were intolerant of conventional HLH therapy (Documentation required); AND
2. HLH diagnosis confirmed by ONE of the following:
   a) Genetic testing;
   b) Chart notes indicating family history consistent with primary HLH;
   c) Five out of 8 criteria fulfilled:
      i) Fever;
      ii) Splenomegaly;
      iii) Cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9, platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L);
      iv) Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤ 1.5 g/L);
      v) Hemophagocytosis in bone marrow, spleen or lymph nodes with no evidence of malignancy;
      vi) Low or absent NK-cell activity;
      vii) Ferritin ≥ 500 mcg/L;
      viii) Soluble CD25 ≥ 2400 U/mL; AND
3. Medication must be prescribed by or in consultation with a hematologist; AND
4. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Medication must be administered concomitantly with dexamethasone at a dose of at least 5 mg/m^2; AND
6. Member does not have ANY of the following:
   a) Diagnosis of secondary HLH consequent to a proven rheumatic or neoplastic disease;
   b) Body weight < 3 kg;
   c) Active Mycobacteria, Histoplasma Capsulatum, Shigella, Salmonella, Campylobacter and Leishmania infections;

d) Presence of malignancy;
e) Concomitant disease or malformation severely affecting the cardiovascular, pulmonary, liver or renal function; AND

7. Member has received vaccines or prophylaxis for Herpes Zoster, Pneumocystis jiroveccii, and fungal infections (Documentation required).
8. **Dosage allowed:** Up to a maximum of 10 mg/kg as an intravenous infusion twice per week. See prescribing information for dose titration criteria.

If member meets all the requirements listed above, the medication will be approved for 8 weeks.

For **reauthorization**:

1. Member has documented chart notes indicating ONE of the following:
   a) Partial response, defined as normalization of ≥ 3 HLH abnormalities;
   b) Complete response, defined as normalization of all HLH abnormalities (i.e., no fever, no splenomegaly, neutrophils > $1x10^9$ /L, platelets > $100x10^9$ /L, ferritin < 2,000 μg/L, fibrinogen > 1.50 g/L, D-dimer < 500 ug/L, normal CNS symptoms, no worsening of soluble CD25 > 2-fold baseline); OR
   c) HLH improvement, defined as ≥ 3 HLH abnormalities improved by at least 50% from baseline; AND
2. Member has not received a hematopoietic stem cell transplant since receiving initial authorization.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Gamifant (emapalumab-lzsg) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
09/23/2019	New policy for Gamifant created.

References:

1. McClain K. Treatment and prognosis of hemophagocytic lymphohistiocytosis. UpToDate [serial on the Internet] 2018 Dec 14 [cited 2019 Sept 9]. Available at: https://www.uptodate.com/contents/treatment-and-prognosis-of-hemophagocytic-lymphohistiocytosis.
2. Gamifant [prescribing information]. Waltham, MA: Sobi Inc.; November 2018.
3. ClinicalTrials.gov Identifier: NCT01818492. A Study to Investigate the Safety and Efficacy of an Anti-IFNγ mAb in Children Affected by Primary Haemophagocytic Lymphohistiocytosis. Available at: https://clinicaltrials.gov/ct2/show/NCT01818492?term=NCT01818492&rank=1.
4. McClain KL, Newburger P, Rosmarin AG. Treatment and prognosis of hemophagocytic lymphohistiocytosis. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com/contents/treatment-and-prognosis-of-hemophagocytic-lymphohistiocytosis?search=hemophagocytic%20lymphohistiocytosis%20(HLH)&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2. Accessed September 23, 2019.

Effective date: 04/01/2020
Revised date: 09/23/2019