

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 22, 2020

GAMIFANT™ (emapalumab-lzsg)

LENGTH OF AUTHORIZATION: ONE MONTH (INITIAL); 3 MONTHS (CONTINUATION)

REVIEW CRITERIA:

- Patient has been diagnosed with Primary Hemophagocytic Lymphohistiocytosis (HLH); **AND**
- The prescribing physician is a Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders; **AND**
- Patient has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g. etoposide, dexamethasone) or has recurrent disease; **AND**
- Patient is a candidate for hematopoietic stem cell transplant (HSCT); **AND**
- Patient is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, Pneumocystis jirovecii, and other fungal infections; **AND**
- Patient will receive concomitant therapy with dexamethasone; **AND**
- Patient does NOT have a diagnosis of Secondary HLH due to a proven rheumatic or neoplastic disease or an infection **OR** have undergone HSCT; **AND**
- Patient has been screened for tuberculosis, adenovirus, Epstein-Barr Virus and Cytomegalovirus as clinically indicated.

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Clinical response to therapy is submitted; **AND**
- Patient is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, Pneumocystis jirovecii, and other fungal infections; **AND**
- Patient has been monitored while on therapy for tuberculosis, adenovirus, Epstein-Barr Virus and Cytomegalovirus; **AND**
- Patient is receiving concomitant therapy with dexamethasone; **AND**
- Patient has not undergone HSCT (Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT).

DOSING AND ADMINISTRATION:

- Recommended starting dose: 1 mg/kg intravenous infusion over 1 hour twice per week; administer with dexamethasone.