7. Member has received vaccines or prophylaxis for Herpes Zoster, Pneumocystis jiroveccii, and fungal infections.
8. **Dosage allowed/Quantity limit:** Start with 1 mg/kg as an intravenous infusion twice per week; may increase based on clinical response, up to a max of 10 mg/kg. See prescribing information for dose titration criteria.

If all the above requirements are met, the medication will be approved for 8 weeks.

For **reauthorization**:
1. Member has documented chart notes indicating ONE of the following:
   a) 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 mg/L, fibrinogen > 1.50 g/L, D-dimer < 500 ug/L, normal CNS symptoms, no worsening of soluble CD25 > 2-fold baseline)
   b) Partial response, defined as normalization of ≥ 3 HLH abnormalities (see above)
   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 initial authorization.

If all the above requirements are met, the medication will be approved for an additional 6 months.

CareSource considers Gamifant (emapalumab-lzsg) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/23/2019	New policy for Gamifant created.
09/21/2023	Updated template. Revised references. Rearranged numbering. Added starting dose. Removed MTX, hydrocortisone from conventional therapy since they are not always used; added cyclosporine. Shortened renewal duration from 12 months to 6 months. Removed concomitant disease exclusion. Removed family history as diagnostic verification.

References:

1.