Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions: _____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

Horizon NJ Health

Gamifant (Emapalumab-lzsg) – Medical Necessity Request

Complete page 1 for Initial Requests Only*

Diagnosis Information (please indicate diagnosis and answer related questions):

□ Primary Hemophagocytic Lymphohistiocytosis (HLH)

□ Other, please specify _____

General Questions:

1. For primary Hemophagocytic Lymphohistiocytosis (HLH), has the diagnosis been confirmed by one the following and if so, please specify which one(s)?
   - □ Member has a genetic mutation known to cause HLH
   - □ Member has a family history consistent with primary HLH
   - □ Member has at least FIVE of the following 8 diagnostic criteria per HLH-2004 protocol and the American Histiocyte Society:
     - i. Fever
     - ii. Splenomegaly
     - iii. Cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9g/dL (< 10g/dL in infants < 4 weeks), platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L)
     - iv. Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL or hypofibrinogenemia ≤ 1.5g/dL)
     - v. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
     - vi. Low or absent natural killer (NK) cell activity
     - vii. Ferritin ≥ 500 mcg/L
     - viii. Elevation of soluble CD25 (> 2 standard deviation [SD] from the mean)
   - □ None of the above
2. Does the member have active disease? **Yes or No**
3. Does the member have disease that is refractory and has an inadequate response to, has a contraindication, or is intolerant to conventional HLH therapy (e.g., dexamethasone, etoposide, cyclosporine, anti-thymocyte globulin.)? **Yes or No**
4. Is the prescribing physician a Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders? **Yes or No**
5. Is the member a candidate for hematopoietic stem cell transplant (HSCT)? **Yes or No**
6. Is the member receiving prophylactic pre-medications (for example antivirals, antibiotics, antifungals) for Herpes Zoster, Pneumocystis jirovecii, and other fungal infections? **Yes or No**
7. Has the member been screened for tuberculosis, adenovirus, Epstein-Barr Virus and Cytomegalovirus as clinically indicated? **Yes or No**
8. Will Gamifant be used in combination with dexamethasone? **Yes or No**
9. Has the member been tested for tuberculosis (TB) prior to the initiation of therapy? **Yes or No**
10. What is the member's current weight? _____lbs or _____kg

Physician office's signature*_____ Print Name_____
***Form must be completed and signed by physician or licensed representative from the physician's office**

Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions: _____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

Horizon NJ Health

Gamifant (Emapalumab-lzsg) – Medical Necessity Request

*****Complete page 2 only for Subsequent/Renewal requests*****

Diagnosis Information (please indicate diagnosis and answer related questions):

□ Primary Hemophagocytic Lymphohistiocytosis (HLH)

1. Is there documentation that the member has experienced a positive clinical response demonstrated in changes in the following laboratory parameters? **Yes or No**
    i. Fever
    ii. Splenomegaly
    iii. Cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9g/dL (< 10g/dL in infants < 4 weeks), platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L)
    iv. Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL or hypofibrinogenemia ≤ 1.5g/dL)
    v. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
    vi. Low or absent natural killer (NK) cell activity
    vii. Ferritin ≥ 500 mcg/L
    viii. Elevation of soluble CD25 (> 2 standard deviation [SD] from the mean)

2. Is the member receiving prophylactic pre-medications (for example antivirals, antibiotics, antifungals) for Herpes Zoster, Pneumocystis jirovecii, and other fungal infections? **Yes or No**

3. Has the member been monitored while on therapy for tuberculosis, adenovirus, Epstein-Barr Virus and Cytomegalovirus? **Yes or No**

4. Will Gamifant be used in combination with dexamethasone? **Yes or No**

5. What is the member's current weight? _____lbs or _____kg

□ Other, please specify _____

Physician office's signature*_____ Print Name_____
***Form must be completed and signed by physician or licensed representative from the physician's office**