Cigna®

Fax completed form to: (855) 840-1678
If this is an URGENT request, please call (800) 882-4462 (800.88.CIGNA)

# Gamifant
## (emapalumab-lzsg)

| PHYSICIAN INFORMATION | | | PATIENT INFORMATION | | |
|---|---|---|---|---|---|
| * Physician Name: | | | *Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items on this form are completed.* | | |
| Specialty: | * DEA, NPI or TIN: | | | | |
| Office Contact Person: | | | * Patient Name: | | |
| Office Phone: | | | * Cigna ID: | * Date of Birth: | |
| Office Fax: | | | * Patient Street Address: | | |
| Office Street Address: | | | City: | State: | Zip: |
| City: | State: | Zip: | Patient Phone: | | |

**Urgency:**
☐ Standard ☐ Urgent (In checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)

**Medication Requested:** ☐ Gamifant ICD10:

Dose: Frequency of administration: Duration of therapy:

What is your patient's weight?_____ lbs or kg (circle one)

**Where will this medication be obtained?**
☐ Biologics Specialty Pharmacy**
☐ Other (please specify):

** *Procurement is limited to Biologics when administered in outpatient setting*

Is the requested medication for a chronic or long-term condition for which the prescription medication may be necessary for the life of the patient? ☐ Yes ☐ No

**Diagnosis related to use:**
☐ Primary Hemophagocytic Lymphohistiocytosis (HLH)
☐ Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS) (HLH/MAS is a form of secondary HLH)
☐ other:

**Clinical Information**

****This drug requires supportive documentation (genetic testing, chart notes, lab and test results, etc). Supportive documentation for all answers must be attached with this request****

Is this a new start or continuation of therapy with the requested medication? *If patient has been taking samples of Gamifant, please pick "new start".* ☐ new start ☐ continuation of therapy

(if continuation of therapy) Has your patient had a documented clinical response (improvement in any of the clinical or laboratory parameters used to demonstrate evidence of active disease on initial authorization)? Yes ☐ No ☐

(if continuation of therapy) Is there evidence that your patient is having residual active disease? Yes ☐ No ☐

(if continuation of therapy) Has your patient been titrated to the minimum dose and frequency needed to achieve sustained clinical effect as recommended by Gamifant's FDA labeling? Yes ☐ No ☐

(if primary HLH) Does your patient have evidence of active disease? Examples include: fever, splenomegaly, central nervous system symptoms, cytopenia, elevated fibrinogen and/or D-dimer, elevated ferritin, and elevated soluble CD25 (soluble interleukin-2 receptor) levels. Yes ☐ No ☐

(if primary HLH) Did your patient have refractory, recurrent or progressive disease during conventional HLH therapy? Yes ☐ No ☐

(if no) Did your patient have an intolerance to conventional hemophagocytic lymphohistiocytosis (HLH) therapy (for example, etoposide, corticosteroids, cyclosporine, anti-thymocyte globulin, methotrexate)? Yes ☐ No ☐

(if primary HLH) Is the requested medication prescribed by, or in consultation with, a hematologist, oncologist, immunologist, transplant specialist, or physician who specializes in hemophagocytic lymphohistiocytosis or related disorders? Yes ☐ No ☐

(if primary HLH) Is documentation being provided that a diagnosis of primary hemophagocytic lymphohistiocytosis is confirmed with molecular genetic testing (for example, confirmed bi-allelic pathogenic or likely pathogenic variants in AP3B1, LYST, PRF1, UNC13D/Munc13-4, STX11, STXBP2, RAB27a, XIAP/BIRC4 or SH2D1A)? - Please note: Documentation may include, but is not limited to, chart notes, laboratory results, claims records, and/or other information. Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Yes ☐ No ☐

(if no) Is documentation being provided that a diagnosis of primary hemophagocytic lymphohistiocytosis is confirmed with at least FIVE of the following diagnostic criteria from the American Histiocyte Society (at baseline prior to treatment): a. Persistent fever; b. Splenomegaly; c. Cytopenia involving at least 2 cell lines (hemoglobin less than 9 g/dL or less than 10 g/dL in infants less than 4 weeks of age, absolute neutrophil count less than 1000/microliter, platelets less than 100,000/microliter); d. Hypertriglyceridemia (fasting triglycerides 265mg/dL or greater) or hypofibrinogenemia (fibrinogen less than 1.5 g/L or greater than 3 standard deviations less than normal value for age); e. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy; f. Low or absent natural killer (NK)-cell activity; g. Serum ferritin greater than 500 mcg/L; or h. Elevated soluble interleukin-2 (CD25) levels (greater than 2400 U/mL or very high for age)? - Please note: Documentation may include, but is not limited to, chart notes, laboratory results, claims records, and/or other information. Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Yes ☐ No ☐

(if HLH/MAS) Does the patient have a confirmed or suspected diagnosis of systemic juvenile idiopathic arthritis or Still's disease with adult onset? Yes ☐ No ☐

(if HLH/MAS) Is documentation being provided that prior to treatment, the patient has/had a ferritin level greater than 684 ng/mL and at least TWO of the following diagnostic criteria at baseline (i, ii, iii, or iv): i. Platelets less than or equal to 181 x 10^9/L; or AST greater than 48 U/L; or iii. Fasting triglyceride greater than 156 mg/dL; or iv. Fibrinogen less than or equal to 360 mg/dL? - Please note: Documentation may include, but is not limited to, chart notes, laboratory results, claims records, and/or other information. Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Yes ☐ No ☐

(if HLH/MAS) According to the prescriber, has the patient had an inadequate response or intolerance to high-dose intravenous corticosteroids? Yes ☐ No ☐

(if no) Has the patient previously received therapy with the requested medication? Yes ☐ No ☐

(if HLH/MAS) Is the requested medication prescribed by or in consultation with, a hematologist, oncologist, immunologist, rheumatologist, or physician who specializes in hemophagocytic lymphohistiocytosis or related disorders? Yes ☐ No ☐

**Additional Pertinent Information:**

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

**Prescriber Signature:**_____ **Date:**_____

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