Gamifant

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

*Patient Height:*_____*cm*

Please indicate the place of service for the requested drug:

❑ *Ambulatory Surgical* ❑ *Home* ❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital* ❑ *Office* ❑ *Pharmacy*

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

Criteria Questions:

1. What is the diagnosis?
   - ❑ Primary hemophagocytic lymphohistiocytosis (HLH)
   - ❑ Secondary (acquired) hemophagocytic lymphohistiocytosis (HLH)
   - ❑ Other _____
2. What is the ICD-10 code? _____
3. Is the patient currently receiving Gamifant? ❑ Yes ❑ No *If No, skip to Diagnosis section*
4. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to Diagnosis section.* ❑ Yes ❑ No ❑ Unknown
5. Has the patient achieved or maintained positive clinical response since starting treatment with Gamifant?
   ❑ Yes ❑ No *No further questions*

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Primary hemophagocytic lymphohistiocytosis (HLH)

6. Has the diagnosis of primary hemophagocytic lymphohistiocytosis been confirmed by presence of a mutation in any of the following genes? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s) or laboratory report.***
   - ❑ PRF1, *skip to #8*
   - ❑ STX11, *skip to #8*
   - ❑ STXBP2, *skip to #8*
   - ❑ UNC13D, *skip to #8*
   - ❑ None of the above
   - ❑ Unknown
7. Has the diagnosis been confirmed by the presence of at least 5 of the following? ***Indicate ALL that apply.*** ***ACTION REQUIRED: If Yes, please attach supporting chart note(s) or laboratory report.***
   - ❑ Fever
   - ❑ Splenomegaly
   - ❑ Cytopenias affecting at least 2 of 3 lineages in the peripheral blood: hemoglobin less than 9 g/dL (less than 10 g/dL in infants younger than 4 weeks), platelets less than 100,000/microliter, and/or neutrophils less than 1,000/microliter
   - ❑ Hypertriglyceridemia (fasting triglyceride greater than or equal to 265 mg/dL) or hypofibrinogenemia (less than or equal to 150 mg/dL)
   - ❑ Hemophagocytosis in bone marrow or spleen or lymph nodes or liver with no evidence of malignancy
   - ❑ Low or absent natural killer (NK) cell activity
   - ❑ Ferritin level greater than or equal to 500 ng/mL
   - ❑ Soluble CD25 (soluble IL-2 receptor alpha) level greater than or equal to 2400 U/mL, or above age-adjusted, laboratory-specific normal levels (defined as 2 standard deviation from the mean)
   - ❑ None of the above
8. Have possible causes of secondary or acquired forms of HLH (e.g., autoimmune disease, persistent infection, malignancy, or loss of inhibitory immune mechanisms) been ruled out? ❑ Yes ❑ No
9. Does the patient have refractory, recurrent or progressive disease or is the patient intolerant to conventional HLH therapy? ❑ Yes ❑ No
10. Has the patient been evaluated for tuberculosis (TB) risk factors and undergone pretreatment screening for latent TB with the purified protein derivative (PPD) skin test or interferon gamma release assay? ❑ Yes ❑ No
11. Does any of the following apply to the patient?
    - ❑ Patient has a positive TB test result (PPD skin test or interferon gamma release essay)
    - ❑ Patient is at risk for tuberculosis
    - ❑ None of the above, *no further questions*
12. Will the patient start prophylactic TB treatment before starting Gamifant? ❑ Yes ❑ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720