**Sample Letter of Medical Necessity—Gamifant® (emapalumab-lzsg)** **for primary hemophagocytic lymphohistiocytosis (HLH)**

*[The following is a sample Letter of Medical Necessity. Highlighted information within brackets is templated and should be replaced with pertinent information for the individual patient on whose behalf you are submitting the letter. This paragraph and italicized information within brackets are intended to provide additional guidance and should be omitted from the final letter. Healthcare providers should also consider using their organization's official letterhead.]*

[Date]

[Payer medical director/contact name]

[Payer organization name]

[Street address]

[City, state, zip code]

RE: [Patient name]

Date of birth: [Patient’s DOB]

Policy ID/Group number: [Policy ID/group number]

Policy holder: [Policy holder’s name]

Dear [Payer medical director/contact name]:

I am [Physician name**,** credentials, specialty, hospital/practice], writing on behalf of my patient, [Patient name], to document the medical necessity of Gamifant® (emapalumab-lzsg), that I plan on using to treat primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy. Gamifant is a monoclonal antibody that binds to and neutralizes interferon gamma (IFNƴ) and was approved by the FDA in November 2018.

**1. Patient-Specific Rationale for Treatment**

In brief, it is my medical opinion that initiating treatment with Gamifant for [Patient name]is medically appropriate and necessary, and that both the drug and the procedures

required for its administration should be covered and reimbursable. Outlined below are [Patient name]’s medical history and prognosis and the rationale for treatment with Gamifant. The patient meets diagnostic criteria [list criteria here].

**2. Summary of Patient’s Medical History**

[*Note: This section is to be completed by the physician based on the patient’s medical history and prognosis. Italicized information within brackets is intended to provide additional guidance and should be omitted from the final letter. Payers may want you to include the following:*]

* [Patient’s diagnosis and current condition]
* [Relevant medical history or family history]
* [Patient's response to previous therapies (conventional or otherwise) for symptoms associated with HLH]
* [Date of scheduled stem cell transplant]

**3. Gamifant Dosing Information**

[*Note: This section is to be completed by the physician based on the intended treatment plan. See attached full Prescribing Information for details. Italicized information within brackets is intended to provide additional guidance and should be omitted from the final letter. Payers may want you to mention the following, based on Gamifant dosing and administration guidelines:*]

* [Starting dose]
* [Potential duration of therapy]

Please call my office at [telephone number]if you require additional information. I look forward to receiving your timely response and approval of this authorization.

Sincerely,

[Physician Name]

[Title, Institution]

[Email/phone]

[*Attach or continue with full prescribing label*.]





Gamifant is a registered trademark, owned by Sobi AG and is marketed by Sobi, Inc.

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