Sample Letter of Medical Necessity—Gamifant® (emapalumab-lzsg) for primary hemophagocytic lymphohistiocytosis (HLH) or HLH/macrophage activation syndrome (MAS) in Still's disease

[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). Gamifant is a monoclonal antibody that binds to and neutralizes interferon gamma.
[I plan to use Gamifant to treat primary hemophagocytic lymphohistiocytosis (HLH). Gamifant was approved by the U.S. Food and Drug Administration in November 2018 to treat primary HLH with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy.]
[I plan to use Gamifant to treat hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease. Gamifant was approved by the U.S. Food and Drug Administration in June 2025 to treat HLH/MAS in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.]

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 and Support for Using Gamifant

[*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]
- [Relevant family history (for primary HLH)]
- [Patient's response to previous therapies (conventional or otherwise) for symptoms associated with primary HLH or HLH/MAS in Still's disease]
- [Date of relevant procedures (for primary HLH)]
- [Peer-reviewed journal articles]
- [Guideline recommendations]
- [Additional evidence from the provided compendia or current published data to support requested therapy]

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-Full-Prescribing-Information.pdf