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emapalumab-lzsg

# A Guide to Requesting a Medical Exception for Gamifant® (emapalumab-lzsg)

**Indication and Usage**

Gamifant® (emapalumab-lzsg) is an interferon gamma (IFNγ)-blocking antibody indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy.

**Please see Important Safety Information on page 8 and accompanying full Prescribing Information.**

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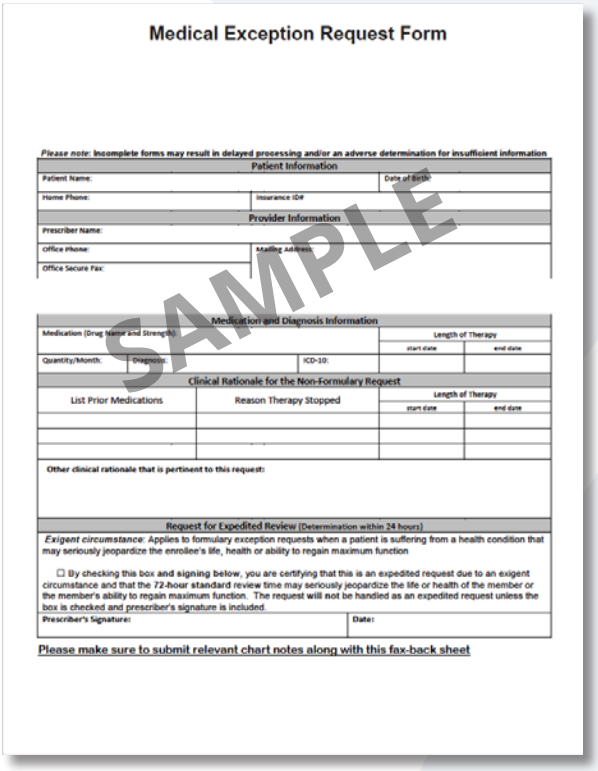
# How to Request a Medical Exception for Gamifant (emapalumab-lzsg)



Medical Exception Request Form

*Please note:* Incomplete forms may result in delayed processing and/or an adverse determination for insufficient information

Patient Information

Patient Name: | Date of Birth:

Home Phone: | Insurance ID#

Provider Information

Prescriber Name:

Office Phone: | Mailing Address:

Office Secure Fax:

SAMPLE

Medication and Diagnosis Information

Medication (Drug Name and Strength): | Length of Therapy: start date / end date

Quantity/Month: | Diagnosis: | ICD-10:

Clinical Rationale for the Non-Formulary Request

| List Prior Medications | Reason Therapy Stopped | Length of Therapy: start date | end date |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

Other clinical rationale that is pertinent to this request:

Request for Expedited Review (Determination within 24 hours)

*Exigent circumstance:* Applies to formulary exception requests when a patient is suffering from a health condition that may seriously jeopardize the enrollee's life, health or ability to regain maximum function

☐ By checking this box and signing below, you are certifying that this is an expedited request due to an exigent circumstance and that the 72-hour standard review time may seriously jeopardize the life or health of the member or the member's ability to regain maximum function. The request will not be handled as an expedited request unless the box is checked and prescriber's signature is included.

Prescriber's Signature: | Date:

Please make sure to submit relevant chart notes along with this fax-back sheet

## Understanding medical exceptions

There are occasions when a benefits investigation determines that Gamifant is not covered by a health plan. In other instances, the coverage may be denied for a certain patient. Under these circumstances, it is likely that your facility will need to request a medical exception (ME) in order for your patient to receive Gamifant. An ME communicates a physician's request, based on a patient's individual circumstances, to use a certain medication that is nonpreferred or not covered by the patient's health plan. MEs can also be referred to as formulary exceptions.

Health plans may require that you complete a form to request an ME (see sample), submit a letter of medical necessity (see page 3), or both.

## Important Safety Information

Before initiating Gamifant, patients should be evaluated for infection, including latent tuberculosis (TB). Prophylaxis for TB should be administered to patients who are at risk for TB or known to have positive purified protein derivative (PPD) test result or positive IFNγ release assay.

During Gamifant treatment, patients should be monitored for TB, adenovirus, Epstein-Barr virus (EBV), and cytomegalovirus (CMV) every 2 weeks and as clinically indicated.

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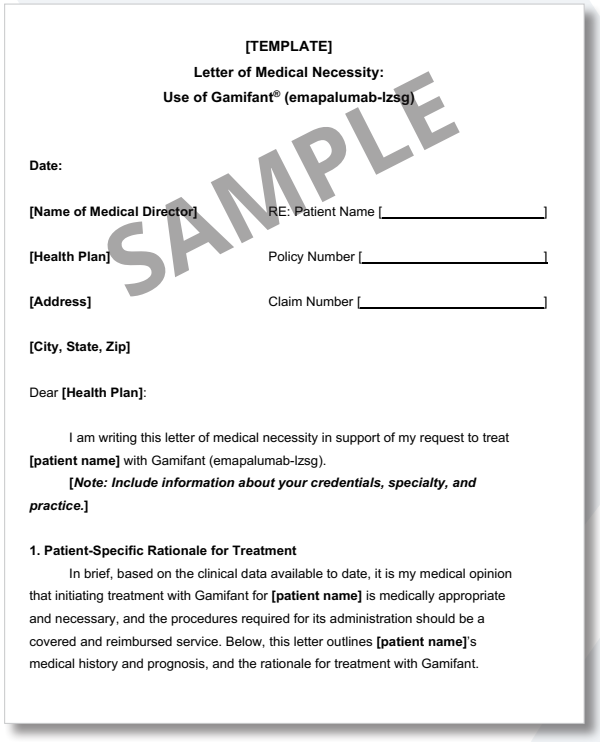


**[TEMPLATE]**

**Letter of Medical Necessity:**

**Use of Gamifant® (emapalumab-lzsg)**

SAMPLE

**Date:**

**[Name of Medical Director]** RE: Patient Name [_____]

**[Health Plan]** Policy Number [_____]

**[Address]** Claim Number [_____]

**[City, State, Zip]**

Dear **[Health Plan]**:

I am writing this letter of medical necessity in support of my request to treat **[patient name]** with Gamifant (emapalumab-lzsg).

***[Note: Include information about your credentials, specialty, and practice.]***

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

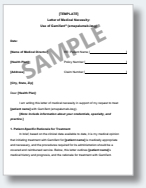
In brief, based on the clinical data available to date, it is my medical opinion that initiating treatment with Gamifant for **[patient name]** is medically appropriate and necessary, and the procedures required for its administration should be a covered and reimbursed service. Below, this letter outlines **[patient name]**'s medical history and prognosis, and the rationale for treatment with Gamifant.

## The importance of a letter of medical necessity

Along with, or instead of, an ME request form, health plans may require a letter of medical necessity to support treatments for rare diseases. A letter of medical necessity enables your facility to provide an overview of the patient's medical history and circumstances to inform a health plan about the request for treatment. The information covered in the letter typically includes, but is not limited to, the following:

- Background information on the disease state
- Patient information (name, contact information, health plan, policy number, and claim number, if available)
- Prescriber information, such as credentials, specialty, practice, and number of patients he or she manages with a similar condition
- Requested treatment and details about the treatment, eg, why it needs to be prescribed/administered
- Rationale for the patient to receive the treatment, such as
  - Summary of patient's medical history, including prior treatments and clinical outcomes
  - Patient's prognosis
- Information about the treatment being requested, including indication, dosing, administration, and clinical trial efficacy and safety from the prescribing information
- Concluding remarks that summarize the rationale for recommending that the patient receive treatment
- Sign-off
- List of references

This kit includes an electronic **Sample Letter of Medical Necessity** that your facility can customize for your patients who may be appropriate candidates for Gamifant (emapalumab-lzsg).



## Important Safety Information *(continued)*

Patients should be administered prophylaxis for herpes zoster, *Pneumocystis jirovecii*, and fungal infections prior to Gamifant administration.

Do not administer live or live attenuated vaccines to patients receiving Gamifant and for at least 4 weeks after the last dose of Gamifant. The safety of immunization with live vaccines during or following Gamifant therapy has not been studied.

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# Step-by-Step Guide to Completing an ME

**There are 3 key steps when processing an ME. In the next sections, you will find details on each of these steps**


Step 1

## Complete a benefits investigation

- Each health plan has different requirements for submitting an ME. You can determine the ME requirements specific to Gamifant (emapalumab-lzsg) during the benefits investigation. For more information about what to ask health plans during a benefits investigation, see **Tips for Completing a Benefits Investigation** in this kit
- Information that you can learn during the benefits investigation includes
  - Whether a prior authorization, ME, and/or letter of medical necessity are required
  - If there are restrictions around where the treatment can be administered
  - The patient's co-pay, coinsurance, deductible, secondary insurance, and any other out-of-pocket costs
  - Where and how to submit the claim information

For more information on benefits investigations and prior authorization submissions, please consult the other resources in this kit.


## Important Safety Information *(continued)*

### Infusion-Related Reactions

Infusion-related reactions, including drug eruption, pyrexia, rash, erythema, and hyperhidrosis, were reported with Gamifant treatment in 27% of patients. In one-third of these patients, the infusion-related reaction occurred during the first infusion.

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Step 2

## Complete the ME request and/or the letter of medical necessity

Once you determine the process for an ME from your patient's health plan, complete the necessary ME form and/or letter of medical necessity.

### What information should be included in the ME and letter of medical necessity?

**Background on your patient's condition**

- Summarize your patient's clinical status, citing the diagnostic evidence of primary HLH, and include baseline exam results and genetic testing results (if available)

**5 of 8 diagnostic criteria met**

- A molecular diagnosis through genetic testing confirms primary HLH,[1] although it takes time. Therefore, it is important to submit an ME/letter of medical necessity as soon as primary HLH is diagnosed by a clinician by observing 5 of the 8 following criteria[1]:
  - Fever
  - Splenomegaly
  - Cytopenias
  - Hypertriglyceridemia and/or hypofibrinogenemia
  - Hemophagocytosis in bone marrow, spleen, or lymph nodes
  - Low or absent natural killer cell activity
  - High ferritin
  - High soluble CD25 (soluble IL-2 receptor)

**Other tests related to HLH[2]**

Submit the ME and/or letter of medical necessity as soon as primary HLH is diagnosed by a clinician.

**Explain why, in your opinion, Gamifant (emapalumab-lzsg) is the appropriate choice for your patient**

- Provide any clinical validation supporting Gamifant treatment for your patient and cite any relevant literature
- State any patient-specific reasons for selecting Gamifant, such as the expected effect of treatment
- Review the criteria listed in the health plan's medical policy and designate the specific criteria your patient meets. For any unmet criteria, explain why the patient should be exempted from meeting those criteria

## Important Safety Information *(continued)*

### Adverse Reactions

In the pivotal trial, the most commonly reported adverse reactions (≥10%) for Gamifant included infection (56%), hypertension (41%), infusion-related reactions (27%), pyrexia (24%), hypokalemia (15%), constipation (15%), rash (12%), abdominal pain (12%), CMV infection (12%), diarrhea (12%), lymphocytosis (12%), cough (12%), irritability (12%), tachycardia (12%), and tachypnea (12%).

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Step 2

## Complete the ME request and/or the letter of medical necessity *(continued)*

### Additional documentation supporting your decision to strengthen your request

- Provide general medical history, listing comorbidities, medication history, and any other relevant patient information
- Letters from other health care professionals (such as geneticists) supporting your choice of Gamifant (emapalumab-lzsg)
- Relevant clinical information regarding your treatment choice, such as the product prescribing information. Additional information can be found in the **Gamifant® (emapalumab-lzsg) Clinical Overview** found in this kit
- Other relevant patient information may also be included, as appropriate


A form containing missing or incorrect information is a common reason why an ME may be denied. Remember to carefully and accurately complete the ME request to avoid any delay in treatment for your patient.

Step 3

## Submit and track your ME request

- Determine how the ME needs to be submitted: via phone, fax, email, or the health plan's website
- Determine the appropriate individual to contact regarding the ME request
- Track the status of the request and follow up as needed

Proactively contacting the health plan to have a peer-to-peer discussion regarding the patient, clinical issues, and the reasons for prescribing Gamifant may be helpful. This may assist the health plan in better understanding your treatment decision.

Some states have legislation requiring health plans to respond to ME requests within a predetermined time period. Contact Gamifant Patient Services to learn if this applies in your state.

## Important Safety Information *(continued)*

**Adverse Reactions** *(continued)*

Additional selected adverse reactions (all grades) that were reported in less than 10% of patients treated with Gamifant included vomiting, acute kidney injury, asthenia, bradycardia, dyspnea, gastro-intestinal hemorrhage, epistaxis, and peripheral edema.

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# What if the ME Is Denied?

If the ME is denied, determine the reason for the denial. Review the following considerations to determine your course of action.

## If the ME is denied due to inaccurate or incomplete information, revise and resubmit

- Carefully review the request to verify that the information is correct and complete and that no information has been omitted. If the reasons for the denial are not provided, consider calling the health plan for details
- If necessary, resubmit the request with all the required information
- Remember, Gamifant Patient Services (1-833-597-6530) can help you understand the process for handling an ME denial. Be sure to keep a copy of all pages of the denial letter so he or she can help more quickly

## If the ME is denied due to clinical reasons, request a peer-to-peer discussion

Contact the health plan directly and arrange for the prescribing physician to speak with a clinical representative or medical director for a peer-to-peer discussion. The physician can request to speak to an individual with a similar specialty (eg, pediatrician, neonatologist, perinatal specialist, pediatric hematologist/oncologist). A peer-to-peer discussion should include detailed information about the patient's medical history, diagnostic tests, clinical considerations, and the reason for the requested treatment. This discussion may help the health plan understand the concerns for your patient and why there is an ME request for your treatment of choice.

Sobi is available to help you navigate the ME process. Contact Gamifant Patient Services at 1-833-597-6530.

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**References: 1.** Henter J-I, Horne A, Aricò M, et al. HLH-2004: diagnostic and therapeutic guidelines for hemophagocytic lymphohistiocytosis. *Pediatr Blood Cancer*. 2007;48(2):124-131. **2.** What is HLH? Cincinnati Children's Hospital website. http://www.cincinnatichildrens.org/service/h/hlh/about. Accessed November 7, 2018.

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