



A *Guide* to Requesting a Medical Exception*

*This guide is offered for informational purposes only and is not intended to provide reimbursement or legal advice. The hospital, pharmacy, or healthcare provider is responsible for determining the appropriate codes, coverage, and payment for individual patients. Sobi, Inc. does not guarantee third-party coverage, or payment, or reimbursement for denied claims.



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:	Insurance (ID#)		Date of Birth:	
Home Phone:				
Provider Information				
Prescriber Name:	Mailing Address:			
Office Phone:				
Office Secure Fax:				
Medication and Diagnosis Information				
Medication (Drug Name and Strength):	Quantity/Month:	Diagnosis:	ICD-10:	Length of Therapy start date end date
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)				
<small>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.</small>				
<input type="checkbox"/> 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

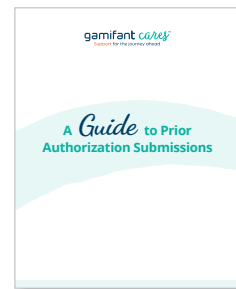
There are occasions when a benefits investigation identifies that Gamifant is not covered by a health plan. In other instances, the coverage may be denied for a particular patient. Under these circumstances, it is likely that your facility will need to request a medical exception (ME) in order for your 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 to the left), submit a Letter of Medical Necessity (see page 3), or both.

The Differences Between a Prior Authorization (PA) and an ME

A PA enables health plans to ensure that drugs are being used only to treat appropriate patients. Each health plan has its own requirements so it is important to contact the patient's insurance to obtain their specific PA submission process. You may need to complete an ME in addition to a PA in order for your patient to receive Gamifant.

For more information about the PA process and its requirements, refer to [A Guide to Prior Authorization Submissions](#).





Sample Letter of Medical Necessity—Gamifant® (emapalumab-izsg) 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-izsg), 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 (IFNγ) 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]

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 you to provide an overview of the patient's medical history and circumstances. This informs the health plan why, in your medical opinion, you are requesting the treatment for this patient. The information covered in the letter typically includes, but is not limited to, the following:

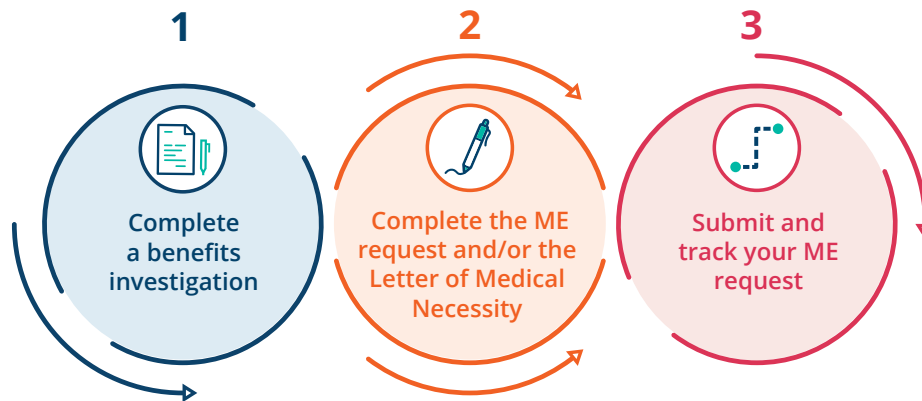
- Background information on the disease state
- Patient information (name, contact information, health plan, policy number, and claim number, if available)
- Prescriber information, such as credentials, specialty, practice, and the number of patients he or she manages with a similar condition
- Requested 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 the 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

Refer to the electronic [Sample Letter of Medical Necessity](#) that your facility can customize for your patients who may be appropriate candidates for Gamifant® (emapalumab-izsg).



Step-by-Step Guide to *Completing* an ME

THERE ARE 3 STEPS WHEN PROCESSING AN ME



STEP 1: Complete a benefits investigation



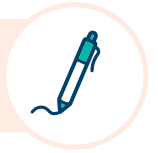
- Health plans have different requirements for submitting an ME. You will identify the ME requirements specific to Gamifant® (emapalumab-lzsg) through a benefits investigation. For more information about what to ask health plans during a benefits investigation, see [Tips for Completing a Benefits Investigation](#).
- Information that you can learn during the benefits investigation includes
 - Whether a PA, ME, and/or Letter of Medical Necessity are required
 - If there are restrictions around where the treatment can be administered
 - The patient's copay, coinsurance, deductible, secondary insurance, and any other out-of-pocket costs
 - Where and how to submit the claim

For more information on benefits investigations and PA submissions, please consult these other resources.





STEP 2:
Complete the ME request and/or the Letter of Medical Necessity



Once you have identified 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**
- 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 identify the specific criteria your patient meets. For any unmet criteria, explain why the patient should be exempted from meeting those criteria.
- 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 healthcare professionals (such as geneticists) supporting your choice of Gamifant for your patient.
 - Relevant clinical information regarding your treatment choice, such as the product's Prescribing Information. Additional information can be found in the **Gamifant Clinical Overview**.
 - Other relevant patient information may also be included, as appropriate.

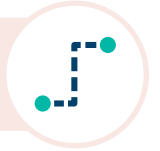


Missing or incorrect information is a common reason why an ME may be denied.

Remember to complete the ME request carefully and accurately to avoid any delay in treatment for your patient.



STEP 3:
Submit and track your ME request



- Determine how to submit an ME (or an urgent ME) request by contacting the payer 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® (emapalumab-lzsg) may be helpful. This may assist the health plan to better understand your treatment decision.

Some states have legislation requiring health plans to respond to ME requests within a predetermined time period.



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, contact the health plan for details.
- If necessary, resubmit the request with all the required information.
- Remember, Gamifant Cares 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 Gamifant Cares can help in a timely manner.

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.



Gamifant Cares offers access and reimbursement support to help patients access Gamifant® (emapalumab-lzsg). Gamifant Cares provides information regarding patient healthcare coverage options and financial assistance information that may be available to help patients with financial needs. Gamifant Cares can:

- Evaluate a patient's insurance coverage, including benefits investigation, PA, and appeal support
- Provide a Benefit Investigation Summary and, if applicable, any PA requirements
- Identify potential financial assistance options that may be available to help patients with financial needs
- Answer logistical questions and provide information and confirmation around the specialty pharmacy fulfillment process

For more information, call **Gamifant Cares** at **1-833-597-6530** Monday through Friday, 8 AM to 8 PM ET.

IMPORTANT INFORMATION: Any coding, coverage, payment, or other information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims conforming to the requirements of the relevant payer for those products and services rendered. Hospitals and pharmacies (or any other provider submitting a claim) should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials provided by Gamifant Cares are to assist providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider and information provided by Gamifant Cares or Sobi, Inc. should in no way be considered a guarantee of coverage or reimbursement for any product or service.