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A *Guide* to Prior Authorization Submissions*

*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.

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Table of Contents

PA=prior authorization.

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An *Introduction* to Submitting a PA for Gamifant® (emapalumab-lzsg)

Your facility may need to obtain prior approval from a health plan before it will cover Gamifant. This request for approval is referred to as a PA, precertification, or coverage determination.

PAs are very common for orphan drugs that treat rare diseases, such as primary hemophagocytic lymphohistiocytosis (HLH), because they enable health plans to ensure that drugs are being used only to treat appropriate patients. For drugs that are used to treat rare diseases, some health plans may require a PA renewal (reauthorization) after a certain period of time. Typically, this is a 3-month or 6-month reauthorization period. It is important to know the renewal period for Gamifant for your patients' health plans. You may need to start the PA process well before the renewal deadline to ensure that your patients can continue coverage.

Gamifant Cares offers access and reimbursement support to help patients access Gamifant. 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.

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HOW THIS GUIDE CAN HELP WITH PA SUBMISSIONS

To help you understand the submission process for a PA for Gamifant® (emapalumab-lzsg), this guide will provide information on

Key steps to a PA submission

Required fields to complete on a PA form

Additional supporting documentation

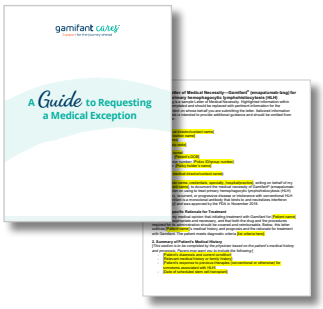
SITE-OF-CARE RESTRICTIONS FOR INFUSED TREATMENTS

For infused treatments, it is important to determine whether a patient's health plan imposes site-of-care restrictions for infused drugs. These are special restrictions used to determine where the infusion may be administered (eg, a hospital or an outpatient center). Check your patient's health plan to determine if there is a site-of-care restriction.

The Differences Between a PA and a Medical Exception

A medical exception (ME) is a process that allows a physician to prescribe a drug that is not on a health plan's formulary. Typically more complex than PAs, an ME request requires specific documentation, including a Letter of Medical Necessity and more information about the patient's medical history. 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 ME process and its requirements, refer to **A Guide to Requesting a Medical Exception** and the **Sample Letter of Medical Necessity**.



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The *Key Steps* in the PA Process

The next several pages provide you with step-by-step instructions on how to process a PA submission.

STEP 1:
Complete the benefits investigation

STEP 2:
Complete and submit the PA request

STEP 3:
Obtain PA determination

STEP 4:
Review PA approval

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How to *Complete* a PA

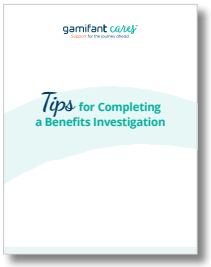
STEP 1:
Complete the benefits investigation

To determine whether your patient has health plan coverage for Gamifant® (emapalumab-lzsg), you will need to complete a benefits investigation. This will help identify

- If a PA is required
- If the health plan has a Gamifant-specific coverage policy
- If the health plan has restrictions on where the drug can be administered
- If any patient cost sharing is required

Tips to Completing a Benefits Investigation

For assistance with the benefits investigation for Gamifant, refer to the **Tips for Completing a Benefits Investigation** guide.



How to *Complete* a PA *(continued)*

STEP 2:
Complete and submit the PA request

- Check if there is a specific PA submission process for Gamifant® (emapalumab-lzsg). Some plans use a portal, specific PA form, or call-in process for PA submissions.
- Ensure all required fields of the PA request are filled out. Incomplete and/or incorrect information can cause a PA to be denied.
- Confirm that the PA submission includes the correct site of care where Gamifant will be administered.
- Ensure your PA submission explicitly states the section in the clinical information where your patient fulfills the Gamifant approval criteria. Be specific, as many payers will not identify this information on their own.
  - It is recommended to create a summary document explaining where in the submitted clinical document the payer can find evidence of your patient meeting the required criteria.
- If there is an expedited review/request process, consider submitting your request as urgent for a quicker review/determination.
- Keep a copy of everything your facility submits with the request.

STEP 3:
Obtain PA determination

- Follow up with the health plan frequently to ensure that the status of the PA request reflects the need for an urgent review.
- Once the payer makes their determination, ensure you save a copy for your records.

STEP 4:
Review PA approval

- Verify that the dates of approval will cover the dates of service for your patient's use.
- Check that the dosage or amount approved in the PA will cover your patient's use.
- Confirm if there is an approved starting dose.
- If a patient is switching from one site of care to another (eg, inpatient to outpatient), a new benefits investigation is needed as the PA process may be different.
- Once you have received the PA decision, ensure that your care team is aware of the outcome.
- If anything should change with the patient, confirm with the payer if another PA is needed.

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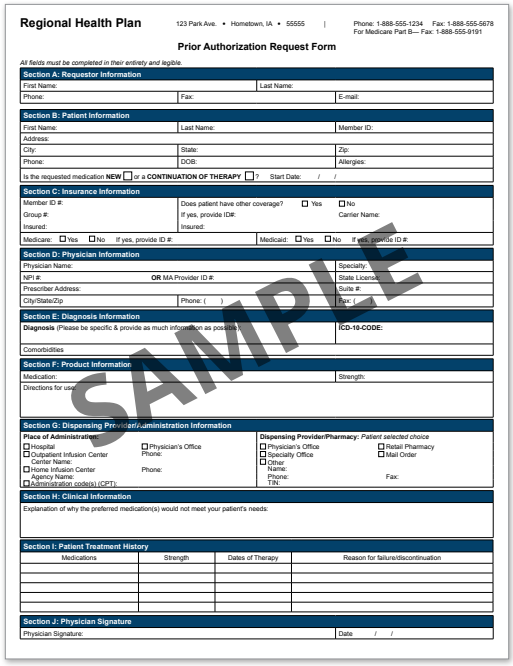
A *Successful* PA Begins With an Accurate and Complete Submission

PA submission methods vary by health plan and may require more documentation than what is included on the sample in this guide. Please contact the patient's insurance to obtain their specific PA submission process for Gamifant® (emapalumab-lzsg).

The references to this sample form are intended to help serve as a guide to completing a PA form.



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Prior Authorization Request Form

All fields must be completed in their entirety and legible.

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First Name: Last Name:
Phone: Fax: E-mail:

Section B: Patient Information
First Name: Last Name: Member ID:
Address:
City: State: Zip:
Phone: DOB: Allergies:
Is the requested medication **NEW** ☐ or a **CONTINUATION OF THERAPY** ☐? Start Date: / /

Section C: Insurance Information
Member ID #: Does patient have other coverage? ☐ Yes ☐ No
Group #: If yes, provide ID#: Carrier Name:
Insured: Insured:
Medicare: ☐ Yes ☐ No If yes, provide ID #: Medicaid: ☐ Yes ☐ No If yes, provide ID #:

Section D: Physician Information
Physician Name: Specialty:
NPI #: **OR** MA Provider ID #: State License:
Prescriber Address: Suite #:
City/State/Zip Phone: ( ) Fax: ( )

Section E: Diagnosis Information
Diagnosis (Please be specific & provide as much information as possible) **ICD-10-CODE:**
Comorbidities

Section F: Product Information
Medication: Strength:
Directions for use:

Section G: Dispensing Provider/Administration Information
Place of Administration:
☐ Hospital ☐ Physician's Office
☐ Outpatient Infusion Center Phone:
Center Name:
☐ Home Infusion Center Phone:
Agency Name:
☐ Administration code(s) (CPT):
Dispensing Provider/Pharmacy: *Patient selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Office ☐ Mail Order
☐ Other
Name:
Phone: Fax:
TIN:

Section H: Clinical Information
Explanation of why the preferred medication(s) would not meet your patient's needs:

Section I: Patient Treatment History

Medications	Strength	Dates of Therapy	Reason for failure/discontinuation

Section J: Physician Signature
Physician Signature: Date / /

SAMPLE

SUBMITTING AN ACCURATE AND COMPLETE PA REQUEST IS ESSENTIAL TO HELP GET YOUR PATIENT ON THERAPY SOONER

Since each health plan has its own requirements, it is important to identify the specific documents to submit with your PA request. Providing supplemental documentation may help get the PA approved and get your patient started on treatment as soon as possible.

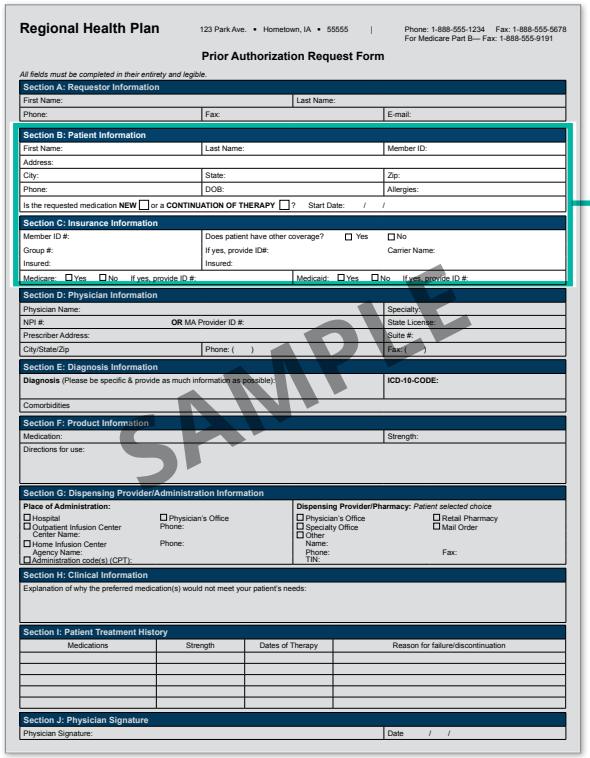
In general, a health plan may require the following additional items with your PA submission:

- Completed PA form (forms vary by health plan)
- Peer-reviewed literature
- Relevant patient medical history to inform the treatment recommendation

Completing the PA Form

Check with your patient's health plan for their specific PA form.

This part of the brochure provides a section-by-section guide to completing a PA form. The PA form required by each payer may be organized in a different way but the type of information requested on all PA forms is relatively similar. Be sure to complete all sections accurately.



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Address:
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Group #: | If yes, provide ID#: | Carrier Name:
Insured: | Insured:
Medicare: ☐ Yes ☐ No If yes, provide ID #: | Medicaid: ☐ Yes ☐ No If yes, provide ID #:

Section D: Physician Information
Physician Name: | Specialty:
NPI #: **OR** MA Provider ID #: | State License:
Prescriber Address: | Suite #:
City/State/Zip | Phone: ( ) | Fax: ( )

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Directions for use:

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☐ Outpatient Infusion Center Center Name:
☐ Home Infusion Center Phone:
Agency Name:
☐ Administration code(s) (CPT):
Dispensing Provider/Pharmacy: *Patient selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Office ☐ Mail Order
☐ Other
Name:
Phone: Fax:
TIN:

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Section I: Patient Treatment History

Medications	Strength	Dates of Therapy	Reason for failure/discontinuation

Section J: Physician Signature
Physician Signature: | Date / /

SAMPLE

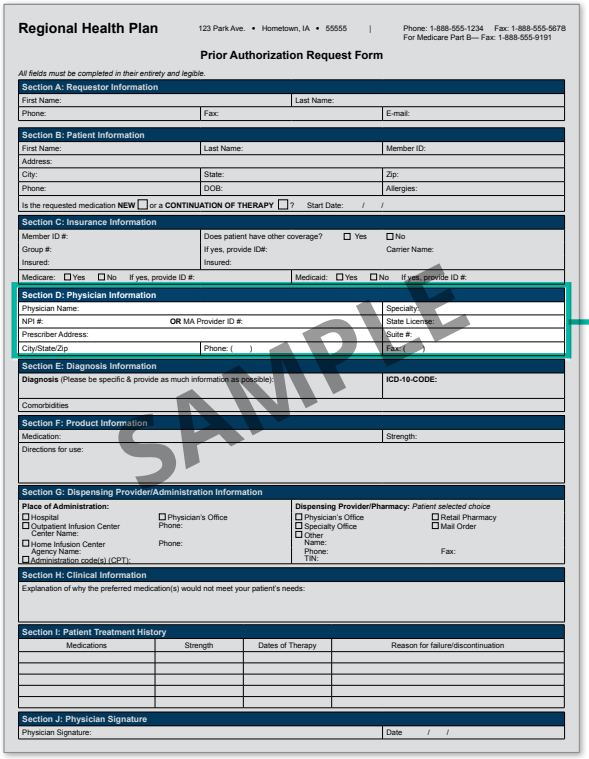
Patient and Insurance Information sections

- Make sure to list the patient's name exactly as it appears on his or her insurance card. It is important to check for possible name changes and make sure all the documents match.
- Please note that in some instances, the patient may have separate medical and pharmacy benefit cards.
  - Some therapies may be covered under the medical benefit (eg, the same card you would use to charge for the office visit); double-check the card.
- Your patient may have more than 1 health plan. Include information for primary, secondary, and if applicable, tertiary plans.
- Include all relevant patient contact information.

Patient and insurance information should be collected during the benefits investigation.

For assistance, refer to the **Tips for Completing a Benefits Investigation** guide.

Completing the PA Form *(continued)*



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Phone:	Fax:	E-mail:

Section B: Patient Information

First Name:	Last Name:	Member ID:
Address:		
City:	State:	Zip:
Phone:	DOB:	Allergies:

Is the requested medication **NEW** ☐ or a **CONTINUATION OF THERAPY** ☐? Start Date: / /

Section C: Insurance Information

Member ID #:	Does patient have other coverage? ☐ Yes ☐ No	
Group #:	If yes, provide ID#:	Carrier Name:
Insured:	Insured:	

Medicare: ☐ Yes ☐ No If yes, provide ID #: Medicaid: ☐ Yes ☐ No If yes, provide ID #:

Section D: Physician Information

Physician Name:		Specialty:
NPI #:	**OR** MA Provider ID #:	State License:
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City/State/Zip	Phone: ( )	Fax: ( )

Section E: Diagnosis Information

Diagnosis (Please be specific & provide as much information as possible):	**ICD-10-CODE:**
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Section F: Product Information

Medication:	Strength:
Directions for use:	

Section G: Dispensing Provider/Administration Information

Place of Administration:
☐ Hospital ☐ Physician's Office
☐ Outpatient Infusion Center Center Name: Phone:
☐ Home Infusion Center Agency Name: Phone:
☐ Administration code(s) (CPT):

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☐ Other Name:
Phone: Fax:
TIN:

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Section I: Patient Treatment History

Medications	Strength	Dates of Therapy	Reason for failure/discontinuation

Section J: Physician Signature

Physician Signature:	Date / /

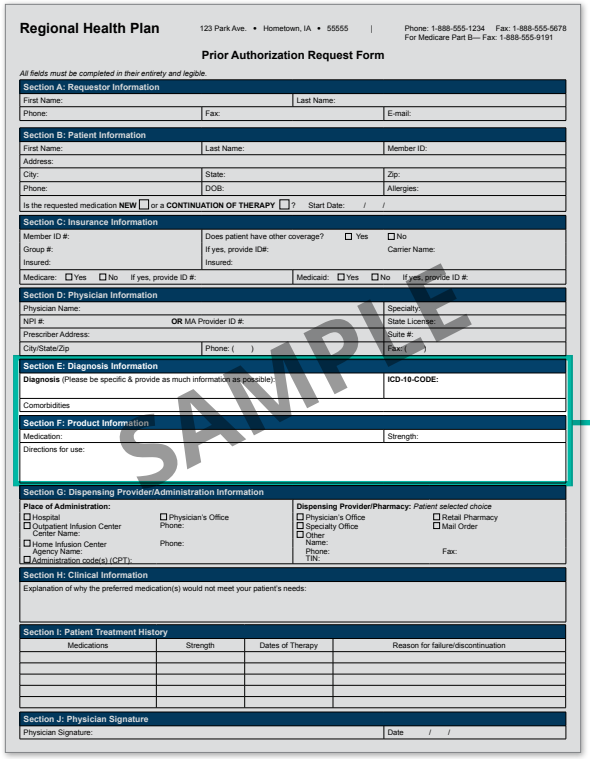
SAMPLE

Physician Information section

- Complete the physician information section, which includes the prescribing physician, diagnosis, and product information.
- Be sure to include the NPI number or Medical Assistance Provider ID number, the licensing information, and complete all other fields in this section.

NPI=National Provider Identifier.

Completing the PA Form *(continued)*



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SAMPLE

Diagnosis and Product Information sections

- Provide a detailed diagnosis and ICD-10-CM code so the health plan understands why the medication is being requested.
- Ensure that both the ICD-10-CM code and the language used to describe the diagnosis match the FDA-approved indication for the drug.
- Include the product name Gamifant® (emapalumab-lzsg), dosage, and NDC number.
- If required, include the HCPCS code.

ICD-10-CM Code[1]	Description
D76.1	Hemophagocytic lymphohistiocytosis

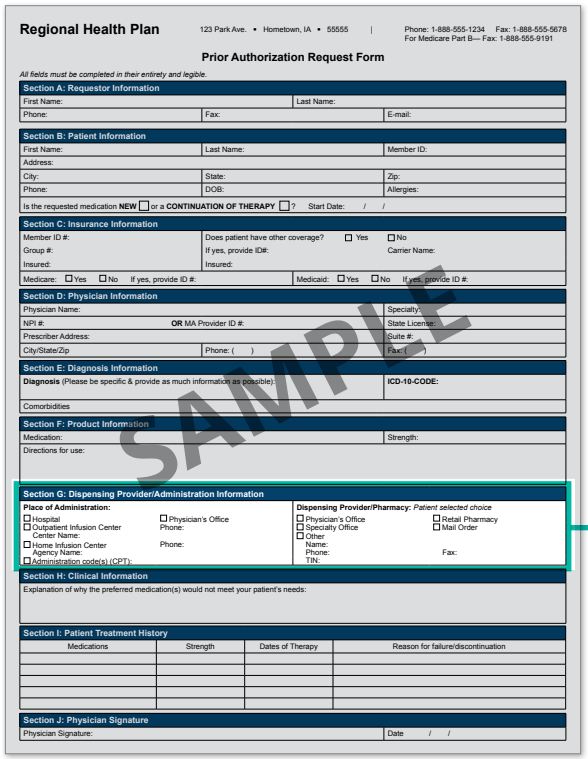
NDC Numbers[2]	Description
NDC 66658-501-01	Containing one 10 mg/2 mL (5 mg/mL) single-dose vial
NDC 66658-505-01	Containing one 50 mg/10 mL (5 mg/mL) single-dose vial
NDC 66658-510-01	Containing one 100 mg/20 mL (5 mg/mL) single-dose vial

HCPCS Code[3]	Description
J9210	Injection, emapalumab-lzsg, 1 mg

FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; NDC=National Drug Code.

For additional codes that may be useful, please see the **Summary of Relevant Codes**.

Completing the PA Form *(continued)*



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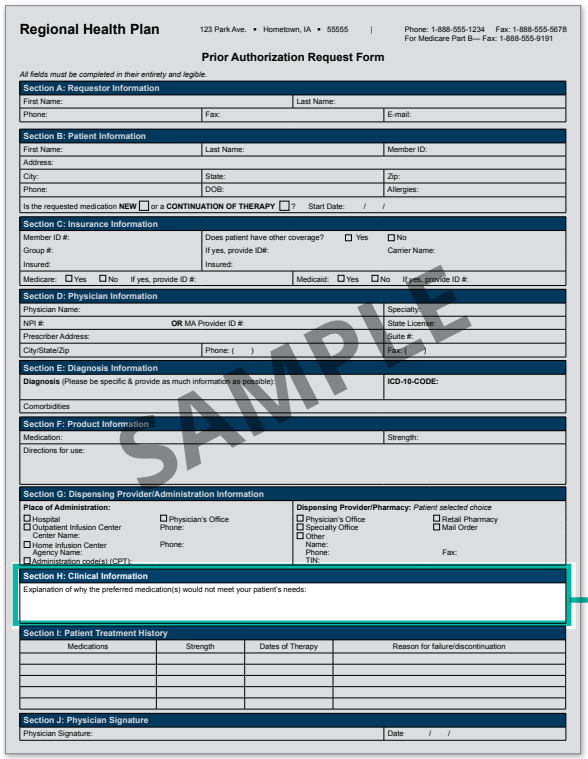
SAMPLE

Dispensing Provider/Administration Information section

- For the Place of Administration, select the type of facility where Gamifant® (emapalumab-lzsg) will be administered (eg, hospital, outpatient infusion center, physician's office). If the form asks for additional information about the Place of Administration, include the name, tax ID number, NPI, and date of service.
- For the Dispensing Provider/Pharmacy section, indicate if Gamifant will be obtained from the Gamifant specialty distributor, McKesson Plasma and Biologics, or the Gamifant specialty pharmacy, Biologics.

Completing the PA Form *(continued)*



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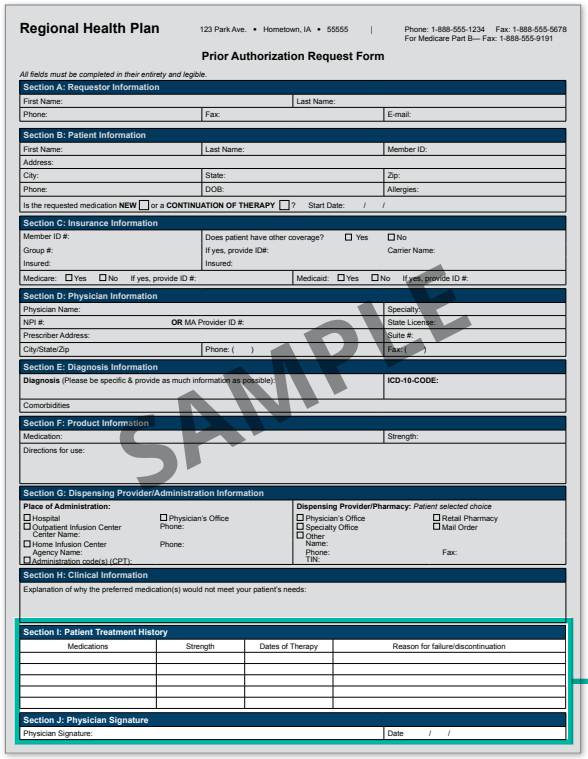
SAMPLE

Clinical Information section

- Provide a detailed explanation describing why Gamifant® (emapalumab-lzsg) is appropriate for your patient.
- Refer to the **Sample Letter of Medical Necessity** template to help with your explanation. You may need to provide additional documentation, such as the patient's medical history, clinical notes detailing the relevant diagnosis, applicable laboratory results, and peer-reviewed literature.
- Review the insurance plan's specific policy on Gamifant, or if a policy is not available, the Medical Information Checklist.

Completing the PA Form *(continued)*



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TIN:

Section H: Clinical Information
Explanation of why the preferred medication(s) would not meet your patient's needs:

Section I: Patient Treatment History

Medications	Strength	Dates of Therapy	Reason for failure/discontinuation

Section J: Physician Signature
Physician Signature: | Date / /

SAMPLE

Patient Treatment History and Physician Signature sections

- List any medications the patient has used for treatment, including any treatments that may be required by the plan before the use of Gamifant® (emapalumab-lzsg). Review the patient's benefits investigation.
- If the request is outside of the health plan's policy, a Letter of Medical Necessity may be required to help the PA process. See the **Sample Letter of Medical Necessity**.
- Ensure that the prescribing physician's signature is on all documentation where required.

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Support for the journey ahead

What to Do if a PA Is *Denied*

If a PA is denied, determine the reason for the denial. If you cannot determine the denial reason, contact the plan for more information about the denial.

One of the most common reasons a PA is denied is that information is incomplete or inaccurate. In cases where there are mistakes or omissions, resubmit the form.

When a PA is denied, the physician can appeal the decision directly. He or she can call the health plan to have a peer-to-peer discussion with a medical representative at the plan. The physician can explain the patient's background and the reasons for prescribing Gamifant® (emapalumab-lzsg). Refer to the **Guide to Denials and Appeals** for more information.

In the event a peer-to-peer discussion is not an option, you can submit an ME request. Refer to **A Guide to Requesting a Medical Exception**.

Due to the rarity of primary HLH, it is very likely that the prescribing physician will need to have a peer-to-peer discussion with the health plan to explain the disease, the patient's medical history and condition, and the rationale for prescribing Gamifant once the PA is submitted.

Contact **Gamifant Cares** at **1-833-597-6530** for assistance with the PA process.

References: 1. ICD-10-CM code for hemophagocytic lymphohistiocytosis D76.1. Codify by AAPC website. Accessed January 17, 2024. https://www.aapc.com/codes/icd-10-codes/D76.1 **2.** Gamifant [prescribing information]. Waltham, MA: Sobi, Inc; 2022. **3.** HCPCS Quarterly Update. Centers for Medicare & Medicaid Services website. Accessed January 17, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update