

A Guide to Prior Authorization Submissions*

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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 personalized support and resources to help patients and their families throughout treatment with 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 and help with navigating and understanding the insurance process
- Provide financial assistance information
- Identify potential financial assistance options that may be available to help eligible patients with financial needs
- Provide educational materials and nursing support through the Sobi Nurse Case Manager program

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





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



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**.







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





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 fulfils 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.











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.

Regional Health Plan	123 Park Ave. • Homet	own, IA • 55555	Phone: 1-888-555-1234 Fax: 1-888-555- For Medicare Part B— Fax: 1-888-555-919
	Prior Authorizat	ion Request For	m
I fields must be completed in their entirety and	f legible.		
Section A: Requestor Information			
First Name: Phone:	Fax	Last Name:	E-meil:
Phone.	Pax.		E-mail
Section B: Patient Information			
First Name:	Last Name:		Member ID:
Address:			
City:	State:		Zip:
Phone:	DOB:		Allergies:
Is the requested medication NEW C or a COM	NTINUATION OF THERAPY	? Start Date: /	1
Section C: Insurance Information			
Member ID #:	Does patient have other	coverage? Yes	N 8
Group #:	If yes, provide ID#:	tes	Carrier Name:
Insured:	Insured:		-
Medicare: Yes No If yes provide		Medicaid: Yes	No If yes, provide ID #
	L. #.	Medicard: U Yes	
Section D: Physician Information			
Physician Name:			Specialty:
	R MA Provider ID #:		State License:
Prescriber Address:			Suite #:
City/State/Zip	Phone: ()		Fac (
Comorbidites Section F: Product Information			
Medication:			Strength:
Directions for use			
Section G: Dispensing Provider/Admin	istration Information		
Place of Administration:	vsician's Office	Dispensing Provider/F	Pharmacy: Patient selected choice
Outpatient Infusion Center Phone	E Contraction	Specialty Office	Mail Order
Center Name: Home Infusion Center Phone		Other Name:	
Agency Name: Administration code(s) (CPT):		Phone: TIN	Fax:
		1 000	
Section H: Clinical Information			
Explanation of why the preferred medication(s)) would not meet your patient's n	eeds:	
Section I: Patient Treatment History			
Medications	Strength Dates of	Therapy	Reason for failure/discontinuation
Section J: Physician Signature Physician Signature			Date / /

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.

Regional Health Plan	123 Park Ave. • Horneti	own, IA • 55555	Phone: 1-888-555-1234 Fax: 1-888-555- For Medicare Part B— Fax: 1-888-555-919	
	Prior Authorizat	ion Request Fo		
Ill fields must be completed in their entirety and	legible.			
Section A: Requestor Information				
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 CON	TINUATION OF THERAPY	? Start Date: /	1	
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	D#:	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 mu	ch information as possible):		ICD-10-CODE:	
Comorbidities				
Section F: Product Information		*		
Medication:			Strength:	
Directions for use:				
Section G: Dispensing Provider/Admin	stration Information			
Place of Administration:			Pharmacy: Patient selected choice	
Outpatient Infusion Center Phone	sician's Office	Physician's Office	Retail Pharmacy Mail Order	
Center Name: Home Infusion Center Phone		Other Name:		
Agency Name:		Phone: TIN:	Fax:	
Administration code(s) (CPT):		UN:		_
Section H: Clinical Information Explanation of why the preferred medication(s)	unuld not must usue patient's a	and a		
explanation of why the presence medication(s)	wood not meet your patients n	eous.		
Section I: Patient Treatment History				
Medications	Strength Dates of	Therapy	Reason for failure/discontinuation	
				-
				-
Section J: Physician Signature				=

O 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 **<u>Tips for Completing a Benefits Investigation</u>** guide.





Regional Health Plan	123 Park Ave. • Home	town, IA • 55555	Phone: 1-888-555-1234 Fax: 1-888-555-5678 For Medicare Part B— Fax: 1-888-555-9191
	Prior Authoriza	tion Request	Form
All fields must be completed in their entirety and leg			
Section A: Requestor Information			
First Name:		Last Name:	
Phone:	Fax:		E-mail:
Section B: Patient Information			
First Name:	Last Name:		Member ID:
Address:	1		
City: Phone:	State: DOB:		Zip: Allergies:
Is the requested medication NEW or a CONTIN			Allergies.
	UATION OF THERAPY	? Start Date:	<u> </u>
Section C: Insurance Information	0		
Member ID #: Group #:	Does patient have other If yes, provide ID#:	r coverage?	Yes No Carrier Name:
Insured:	Insured:		Contract Manna.
Medicare: Yes No If yes, provide ID #		Medicaid: Yes	s No If yes, provide ID #:
Section D: Physician Information			
Physician Name:			Specialty
NPI#: OR M	Provider ID #:		State License:
Prescriber Address:			Suite #:
City/State/Zip	Phone: ()		Fax:()
Section E: Diagnosis Information			
Diagnosis (Please be specific & provide as much	nformation as possible):		ICD-10-CODE:
Comorbidities			
Section F: Product Information			Strength:
Directions for use:			Strength:
Section G: Dispensing Provider/Administr	ation Information		
Place of Administration:			ider/Pharmacy: Patient selected choice
Hospital Outpatient Infusion Center Physic Phone:	an's Office	Physician's Off Specialty Office	ce Retail Pharmacy
Center Name:		Other Name:	
Agency Name:		Phone: TIN:	Fax:
Administration code(s) (CPT):		TIN.	
Section H: Clinical Information Explanation of why the preferred medication(s) wo	del entre entre entre entre tre :		
	and more your publit si		
Section I: Patient Treatment History			
Medications SI	rength Dates of	f Therapy	Reason for failure/discontinuation
Section J: Physician Signature			
Physician Signature:			Date / /

• Physician Information section

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





Regional Health Plan	123 Park Ave. • Hometo	wn, IA • 55555	Phone: 1-888-555-1234 Fax: 1-888-555-567 For Medicare Part B— Fax: 1-888-555-9191
	Prior Authorizati	on Request For	
All fields must be completed in their entirety and			
Section A: Requestor Information			
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 CON	TINUATION OF THERAPY	? Start Date: /	1
Section C: Insurance Information			
Member ID #:	Does patient have other of	coverage? 🔲 Yes	□ No
Group #:	If yes, provide ID#:		Carrier Name:
Insured:	Insured:		
Medicare: Yes No If yes, provide II	D#:	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: ()
Comorbidities Section F: Product Information			
Medication:			Strength:
Directions for use:			1
Section G: Dispensing Provider/Admini	stration Information		
Outpatient Infusion Center Phone: Center Name:		Dispensing Provider/P Dispensing Provider/P Specialty Office Other Name:	harmacy: Patient selected choice Retail Pharmacy Mail Order
Home Infusion Center Phone: Agency Name: Administration code(s) (CPT):		Phone: TIN:	Fax:
Section H: Clinical Information			
Explanation of why the preferred medication(s)	would not meet your patient's ne	eeds:	
Section I: Patient Treatment History			
Medications	Strength Dates of	Therapy	Reason for failure/discontinuation
	Janua Gr		
Section J: Physician Signature Physician Signature:			Date / /

• 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 **<u>Summary of Relevant Codes</u>**.





Regional Health Plan	123 Park Ave. • Home	town, IA • 55555	Phone: 1-888-555-1234 Fax: 1-888-55 For Medicare Part B— Fax: 1-888-555-9	
	Prior Authoriza	tion Request Fo		
All fields must be completed in their entirety and i				
Section A: Requestor Information				
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 CON	TINUATION OF THERAPY	? Start Date: /	1	
Section C: Insurance Information		-		=
Member ID #:	Does patient have other	r coverage? Yes	No	
Group #:	If yes, provide ID#:		Carrier Name:	
Insured:	Insured:		4	
Medicare: Yes No If ves. provide II		Medicaid: Yes	No If yes, provide ID #:	_
Section D: Physician Information				
Physician Name:			Specialty:	
	MA Provider ID #:		State License:	
Prescriber Address:			Suite #:	_
City/State/Zip	Phone: ()		Fax:(_
Section E: Diagnosis Information				=
Diagnosis (Please be specific & provide as mu	th information as possible)		ICD.40-CODE:	
Comorbidities				
Section F: Product Information				
Medication:			Strength:	
Directions for use:				
Section G: Dispensing Provider/Admini	stration Information			
Place of Administration:			r/Pharmacy: Patient selected choice	
Hospital Outpatient Infusion Center Physical Physical	ician's Office	Physician's Office	Retail Pharmacy Mail Order	
Center Name:		C Other		
Agency Name:		Name: Phone:	Fax:	
Administration code(s) (CPT):		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				

-O 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.





		iown, IA • 55555	Phone: 1-888-555-1234 Fax: 1-888-55 For Medicare Part B— Fax: 1-888-555-91	5-5678 191
	Prior Authorizat	tion Request For	m	
Il fields must be completed in their entirety and	l legible.			
Section A: Requestor Information				
First Name:	1-	Last Name:	1	
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 COM	TINUATION OF THERAPY	? Start Date: /	1	
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:	
	R MA Provider ID #:		State License:	
Prescriber Address:			Suite #:	
City/State/Zip	Phone: ()		Fax:(
Section E: Diagnosis Information				
Diagnosis (Please be specific & provide as ma	uch information as possible):		ICD-10-CODE:	
Comorbidities				
Section F: Product Information				
Medication: Directions for use:			Strength:	
Directions for use.				
Section C: Disponsing Drovider/Admin	istration Information			
Section G: Dispensing Provider/Admin	istration Information	Dispansing Provider(6	Pharmacu: Patient related choice	
Place of Administration:	ysician's Office	Physician's Office	Pharmacy: Patient selected choice	
Place of Administration: Hospital Outpatient Infusion Center Phone	ysician's Office	Physician's Office	Pharmacy: Patient selected choice	
Place of Administration: Hospital Outpatient Infusion Center Phone Center Name: Home Infusion Center Phone	ysician's Office a:	Physician's Office Specialty Office Other Name:	Retail Pharmacy Mail Order	
Place of Administration: Hospital Phy Outpatient Infusion Center Phone Center Name:	ysician's Office a:	Physician's Office Specialty Office Other		
Place of Administration: Displaid Pro- Outpatient Infusion Center Phone Center Name: Home Infusion Center Phone Agency Name:	ysician's Office a:	Physician's Office Specialty Office Other Name: Phone:	Retail Pharmacy Mail Order	
Place of Administration: Dispital Dispital Dim Outpatient Infusion Center Phone Center Name: Home Infusion Center Phone Agency Name: Administration code(s) (CPT):	ysician's Office 5: 2:	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order	
Place of Administration:	ysician's Office 5: 2:	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order	
Place of Administration:	ysician's Office 5: 2:	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order	
Jacopial Jioppial Ji	ysician's Office 5: 2:	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order	
Place of Administration:	vsician's Office 2: 2:) would not meet your patient's r	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order	
Izec of Administration: Orophat Orophat	vsician's Office 2: 2:) would not meet your patient's r	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order Fax:	
Isee of Administration: Isopata Grapha Guipata Guipata	vsician's Office 2: 2:) would not meet your patient's r	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order Fax:	
Place of Administration: locipatial locipatial locipatian Infusion Center Phone Center Name: Agency Name: Cadministration codets I (CPT): Section II: Clinical Information Explanation of why the preferred medication(s) Section II: Pattent Treatment History	vsician's Office 2: 2:) would not meet your patient's r	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order Fax:	
Izec of Administration: Orophat Orophat	vsician's Office 2: 2:) would not meet your patient's r	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order Fax:	
Izec of Administration: Orophat Orophat	vsician's Office 2: 2:) would not meet your patient's r	Physician's Office Specialty Office Other Name: Phone: TIN:	Retail Pharmacy Mail Order Fax:	

For the 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.





Regional Health Plan	123 Park Ave. • Horneto	wn, IA • 55555	Phone: 1-888-555-1234 Fax: 1-888-555-5678 For Medicare Part B— Fax: 1-888-555-9191
	Prior Authorizat	ion Request For	
All fields must be completed in their entirety and			
Section A: Requestor Information			
First Name:		Last Name:	E-mail:
Phone:	Fax:		E-mail:
Section B: Patient Information			
First Name: Address:	Last Name:		Member ID:
City:	State:		Zip:
Phone:	DOB:		Allergies:
Is the requested medication NEW or a CON	TINUATION OF THERAPY	? Start Date: /	1
Section C: Insurance Information			
Member ID #:	Does patient have other	coverage? 🔲 Yes	□ No
Group #:	If yes, provide ID#:		Carrier Name:
Insured: Medicare: Yes No If yes, provide I	Insured:	Medicaid: Yes	No If yes, provide ID #:
	u #.	medicalo: Li tês L	and injest provide in #:
Section D: Physician Information Physician Name:			Specialty:
	MA Provider ID #:		State License:
Prescriber Address:			Suite #:
City/State/Zip	Phone: ()		Fax:(
Section E: Diagnosis Information			
Diagnosis (Please be specific & provide as mu	ch information as possible):		ICD-10-CODE:
Comorbidities			
Section F: Product Information			
Medication:			Strength:
Directions for use:			
Section G: Dispensing Provider/Admini	stration Information		
Place of Administration:			Pharmacy: Patient selected choice
Hospital Outpatient Infusion Center Phone Center Name:	sician's Office	Physician's Office	Retail Pharmacy Mail Order
Center Name: Home Infusion Center Phone		Other Name:	
Agency Name: Administration code(s) (CPT):		Phone: TIN:	Fax:
Section H: Clinical Information			
Explanation of why the preferred medication(s)	would not meet your patient's n	eeds:	
Section I: Patient Treatment History			
Section I: Patient Treatment History Medications	Strength Dates of	Therapy	Reason for failure/discontinuation
	Strength Dates of	Therapy	Reason for failure/discontinuation
	Strength Dates of	Therapy	Reason for failure/discontinuation
	Strength Dates of	Therapy	Reason for failure/discontinuation
	Strength Dates of	Therapy	Reason for failure/discontinuation

• 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 <u>Sample Letter of</u> <u>Medical Necessity</u>.
- Ensure that the prescribing physician's signature is on all documentation where required.





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 <u>A Guide to</u> <u>Requesting a Medical Exception</u>.



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 rationale for prescribing Gamifant once the PA is submitted.



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

IMPORTANT INFORMATION: Any coding, coverage, or billing 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 billing 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.

References: 1. ICD-10 Code for hemophagocytic lymphohistiocytosis D76.1. AAPC Coder website. Accessed April 4, 2023. https://coder.aapc.com/ 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 April 4, 2023. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update



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