gamifant®
emapalumab-lzsg

A Guide to Prior Authorization Submissions for Gamifant® (emapalumab-lzsg)

Please see Important Safety Information on last page and full Prescribing Information for Gamifant.

An Introduction to Submitting Prior Authorization for Gamifant (emapalumab-lzsg)

On occasion, 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 prior authorization (PA), precertification, or coverage determination.

PAs are very common for orphan drugs that treat rare diseases, such as primary HLH, because they enable health plans to ensure that drugs are being used to treat only 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 6-month or 12-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 several months before the renewal deadline to ensure that your patients can continue coverage.

Gamifant Patient Services can assist you with the PA process. After Gamifant Patient Services completes the benefit verification, your patient's Care Manager will provide you and your patient's parent/guardian with a benefit verification summary, including payer PA requirements.

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

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.

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.

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

gamifant®
emapalumab-lzsg

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 for Gamifant® (emapalumab-lzsg)** and the **Sample Letter of Medical Necessity** available on Gamifant.com.

Important Safety Information *(continued)*

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

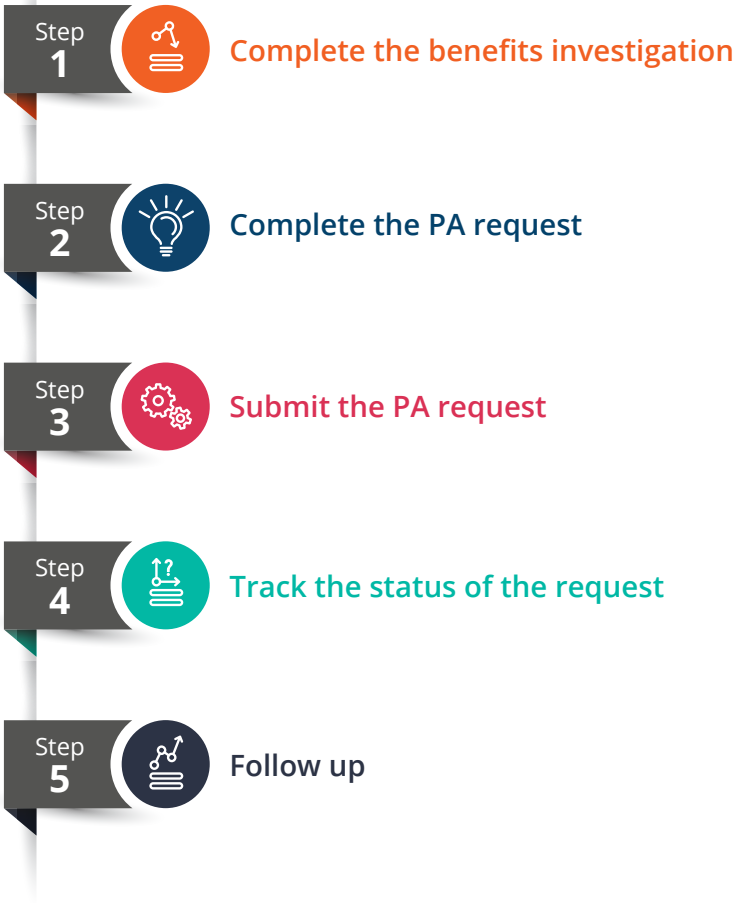
Do not administer live or live attenuated vaccines to patients receiving Gamifant and for at least 4 weeks after the last dose of Gamifant. The safety of immunization with live vaccines during or following Gamifant therapy has not been studied.

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

gamifant®
emapalumab-lzsg

The Key Steps in the PA Process

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



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.

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

gamifant®
emapalumab-lzsg

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 determine

- 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 available on Gamifant.com.

Step 2

Complete the PA request

- Make sure you have the correct PA form for that specific health plan. PAs can be denied because an incorrect form has been submitted
- Check the plan's website, as downloadable forms are often available there
- Remember to fill out the PA form completely. Missing information can cause a PA to be denied

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%).

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.

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

gamifant®
emapalumab-lzsg

How to Complete a PA *(continued)*

Step 3 — Submit the PA request

- Check the PA form and the health plan's requirements to determine the method of submitting the request (eg, email, fax, or website)
- Keep a copy of everything your facility submits with the request. There are many reasons, such as financial assistance service requests, why you may need to reference these documents
- You may want to add the insurance carrier contact information, proper submission requirements, and other notes in the **Insurance Carrier and Specialty Pharmacy Provider Contact Sheet** available on Gamifant.com

Step 4 — Track the status of the request

- Keep a thorough log of the PA submission process for each patient

Step 5 — Follow up

- Because primary HLH is a life-threatening condition requiring urgent treatment, follow up with the health plan often regarding the status of the PA request. Contact Gamifant Patient Services at 1-833-597-6530 for assistance if you have not heard from your patient's health plan.

Important Safety Information *(continued)*

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.

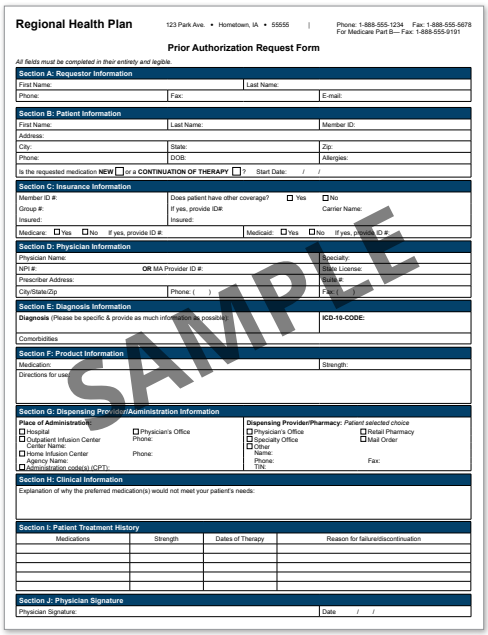
Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

gamifant®
emapalumab-lzsg

A Successful PA Begins With an Accurate and Complete Form

PA forms vary by health plan and may require more documentation than what is included on the sample in this guide. Please contact the specific health plan to obtain the correct PA form.

This sample form is intended as a guide to completing a PA form. It should not be submitted.



Regional Health Plan 123 Park Ave. • Hometown, IA • 55555 | Phone: 1-888-555-1234 Fax: 1-888-555-5678 For Medicare Part B— Fax: 1-888-555-9191

Prior Authorization Request Form

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

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

Completing and submitting the correct form is essential to streamlining the approval process—and getting your patients on therapy sooner

Since each health plan has unique requirements, it is important to identify the specific documents to submit with your PA request. Providing supplemental documentation can help increase the chance that the PA will be 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

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.

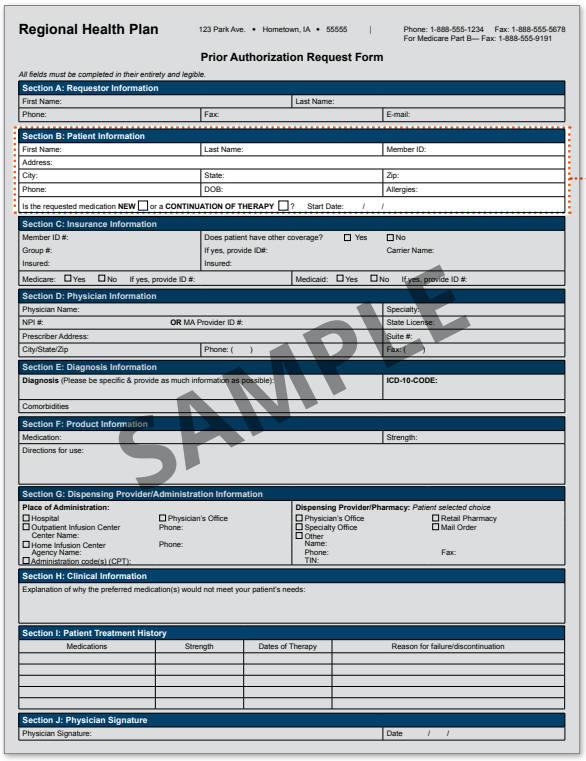
Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

gamifant®
emapalumab-lzsg

Completing the PA Form

This part of the brochure provides a section-by-section guide to completing a PA form. Although the information required may be in a different order depending on the health plan's PA form, the type of information requested on a PA form is relatively similar. Remember to check with your patient's health plan for the specific PA form.

The first part of the PA form is typically where you will include all of your relevant contact information. Be sure to complete this information accurately.



Regional Health Plan 123 Park Ave. • Hometown, IA • 55555 | Phone: 1-888-555-1234 Fax: 1-888-555-5678 For Medicare Part B— Fax: 1-888-555-9191

Prior Authorization Request Form

All 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 **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

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 (ie, 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

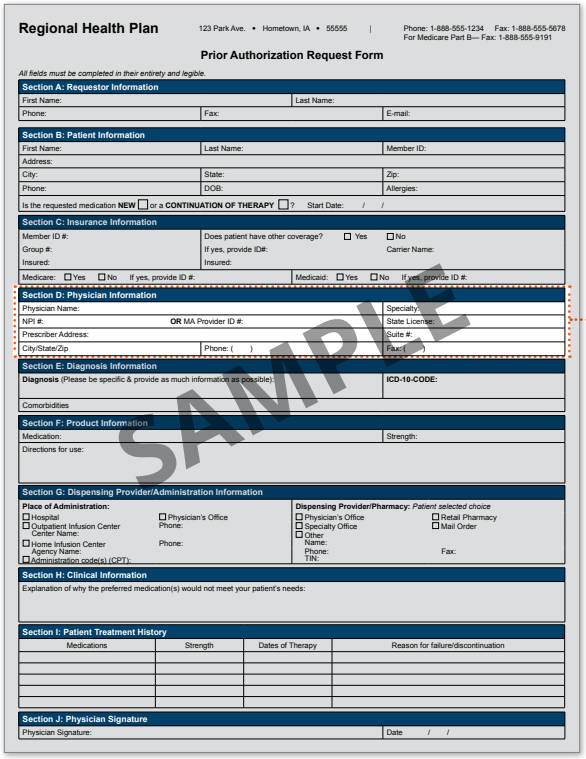
Important Safety Information *(continued)*

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.

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

Completing the PA Form *(continued)*



Regional Health Plan 123 Park Ave. • Hometown, IA • 55555 | Phone: 1-888-555-1234 Fax: 1-888-555-5678 For Medicare Part B— Fax: 1-888-555-9191

Prior Authorization Request Form

All 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 **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 Phone:
☐ Outpatient Infusion Center Center Name:
☐ Home Infusion Center Agency Name: Phone:
☐ 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

Physician information section

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

Important Safety Information *(continued)*

Adverse Reactions

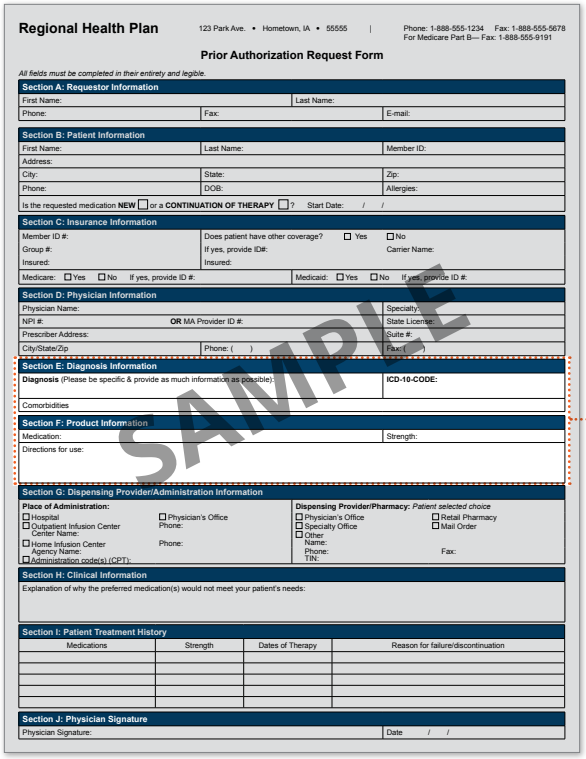
In the pivotal trial, the most commonly reported adverse reactions (≥10%) for Gamifant included infection (56%), hypertension (41%), infusion-related reactions (27%), pyrexia (24%), hypokalemia (15%), constipation (15%), rash (12%), abdominal pain (12%), CMV infection (12%), diarrhea (12%), lymphocytosis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

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.

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

gamifant®
emapalumab-lzsg

Completing the PA Form *(continued)*



Regional Health Plan 123 Park Ave. • Hometown, IA • 55555 | Phone: 1-888-555-1234 Fax: 1-888-555-5678 For Medicare Part B— Fax: 1-888-555-9191

Prior Authorization Request Form

All 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 **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 Phone:
☐ Outpatient Infusion Center Center Name:
☐ Home Infusion Center Phone:
☐ 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

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 matches the FDA-approved indication for the drug
- Include the product name Gamifant (emapalumab-lzsg), dosage, and NDC number

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

NDC Numbers[2]	Description
[NDC 72171-501-01]	One 10-mg/2-mL (5 mg/mL) single-dose vial
[NDC 72171-505-01]	One 50-mg/10-mL (5 mg/mL) single-dose vial
[NDC 66658-510-01]	[One 100-mg/20-mL (5 mg/mL) single-dose vial]

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

Important Safety Information *(continued)*

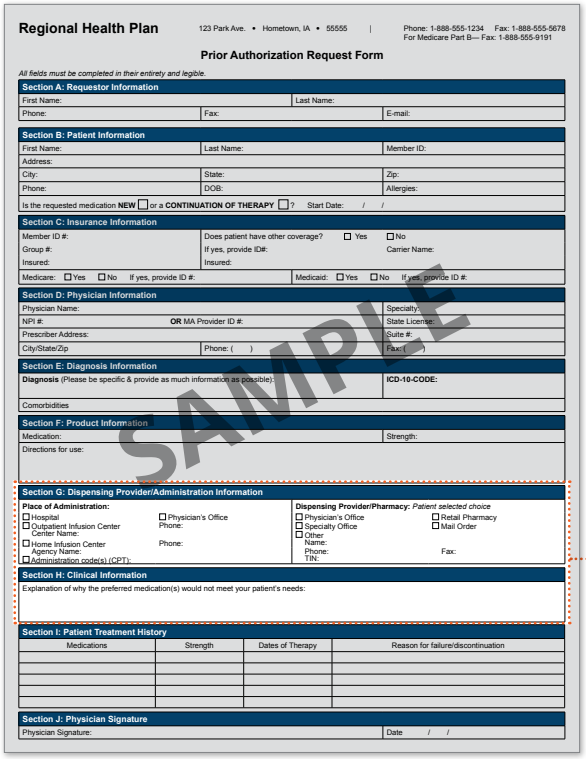
Before initiating Gamifant, patients should be evaluated for infection, including latent tuberculosis (TB). Prophylaxis for TB should be administered to patients who are at risk for TB or known to have positive purified protein derivative (PPD) test result or positive IFNγ release assay.

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

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

gamifant®
emapalumab-lzsg

Completing the PA Form *(continued)*



Regional Health Plan 123 Park Ave. • Hometown, IA • 55555 | Phone: 1-888-555-1234 Fax: 1-888-555-5678 For Medicare Part B— Fax: 1-888-555-9191

Prior Authorization Request Form

All 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 **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

Place of administration, dispensing provider/ pharmacy, and clinical information sections

- 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 information about the Place of Administration, include the name, tax ID number, and date of service.
- For the Dispensing Provider/Pharmacy section, use the information you obtained from the benefits investigation to include a specialty pharmacy that is in-network
- For the Clinical Information section, provide a detailed explanation describing why Gamifant is appropriate for your patient
  - Refer to the **Sample Letter of Medical Necessity** template available on Gamifant.com 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

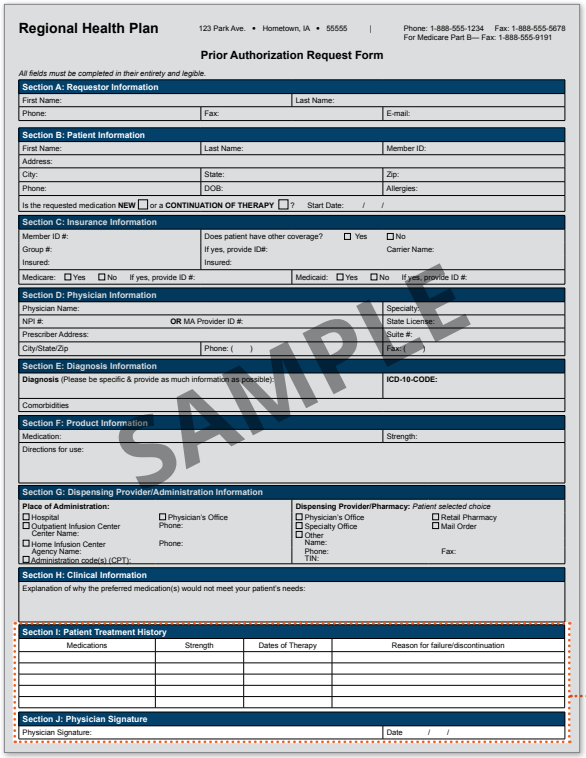
Important Safety Information *(continued)*

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.

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

Completing the PA Form *(continued)*



Regional Health Plan 123 Park Ave. • Hometown, IA • 55555 | Phone: 1-888-555-1234 Fax: 1-888-555-5678 For Medicare Part B— Fax: 1-888-555-9191

Prior Authorization Request Form

All 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 **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 Center Name: Phone:
☐ Home Infusion Center Agency Name: Phone:
☐ 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

Patient treatment history and physician signature sections

- List any medications the patient has used for treatment. 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. See the **Sample Letter of Medical Necessity** available on Gamifant.com
- Ensure that the prescribing physician's signature is on all documentation where required

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.

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

gamifant®
emapalumab-lzsg

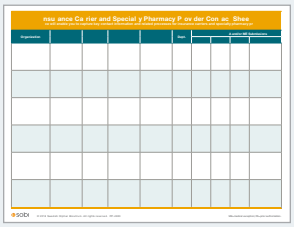
What to Do if a PA Is Denied

A PA may be denied for many reasons. One of the main reasons is incomplete or inaccurate information on the PA form. Check to ensure all information is complete and accurate. In cases where there are mistakes or omissions, resubmit the form if necessary.

It may help the PA process if a letter of medical necessity is submitted with the PA. Refer to the **Sample Letter of Medical Necessity** available on Gamifant.com to help you prepare information about why Gamifant (emapalumab-lzsg) is appropriate for your patient.

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 reason for prescribing Gamifant. 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 for Gamifant® (emapalumab-lzsg)** available on Gamifant.com.

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.



If you work with a specific individual at the insurance carrier to handle denials of PA requests, you may want to include that individual's contact information on the **Insurance Carrier and Specialty Pharmacy Provider Contact Sheet**, which can be found at Gamifant.com.

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

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%).

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.

Please see additional Important Safety Information on last page and full Prescribing Information for Gamifant.

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.

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.

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.

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.

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%).

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.

Please see the full Prescribing Information for Gamifant.

References: 1. ICD-10 Code for hemophagocytic lymphohistiocytosis D76.1. AAPC Coder website. https://coder.aapc.com/icd-10-codes/D76.1. Accessed July 15, 2020. **2.** Gamifant [prescribing information]. Waltham, MA: Sobi Inc; 2020.

sobi