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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.

Indications and Important Safety Information

INDICATIONS

Gamifant (emapalumab-lzsg) is an interferon gamma (IFNγ)-neutralizing 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.
- HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

IMPORTANT SAFETY INFORMATION

Infections

Gamifant may increase the risk of fatal and serious infections with pathogens including mycobacteria, herpes zoster virus, and histoplasma capsulatum. Do not administer Gamifant in patients with these infections until appropriate treatment has been initiated.

In patients with primary HLH receiving Gamifant in clinical trials, serious infections such as sepsis, pneumonia, bacteremia, disseminated histoplasmosis, necrotizing fasciitis, viral infections, and perforated appendicitis were observed in 32% of patients.

In patients with HLH/MAS in Still's disease receiving Gamifant in clinical trials, serious infections such as pneumonia, cytomegalovirus infection, cytomegalovirus infection reactivation, and sepsis were observed in 13% of patients.

Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating Gamifant. Administer tuberculosis prophylaxis to patients at risk for tuberculosis or known to have a positive purified protein derivative (PPD) test result.

Consider prophylaxis for herpes zoster, *Pneumocystis jirovecii*, and fungal infection while receiving Gamifant. Employ surveillance testing during treatment with Gamifant.

Closely monitor patients receiving Gamifant for signs or symptoms of infection, promptly initiate a complete diagnostic workup appropriate for an immunocompromised patient, and initiate appropriate antimicrobial therapy.

Increased Risk of Infection With Use of Live Vaccines

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 in patients with primary HLH, 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.

Infusion-related reactions in patients with HLH/MAS in Still's disease, including pyrexia, headache, paresthesia, bone pain, pruritic rash, and peripheral coldness, were reported with Gamifant treatment in 13% of patients. Infusion-related reactions were reported as mild in 8% of patients and as moderate in 5% of patients.

Monitor patients for infusion-related reactions, which can be severe. Interrupt the infusion for infusion reactions and institute appropriate medical management before continuing infusion at a slower rate.

Adverse Reactions

Primary HLH

Serious adverse reactions were reported in 53% of patients. The most common serious adverse reactions (≥3%) included infections, gastrointestinal hemorrhage, and multiple organ dysfunction. Fatal adverse reactions occurred in 2 (6%) of patients and included septic shock and gastrointestinal hemorrhage.

The most common adverse reactions were (≥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%).

HLH/MAS

Serious adverse reactions were reported in 12 patients (31%), with the most common serious adverse reaction being pneumonia (5%). Fatal adverse reactions occurred in two patients (5%) and included multiple organ dysfunction and circulatory shock.

The most common adverse reactions (≥10%) for Gamifant included viral infection (44%), rash (21%), anemia (18%), leukopenia (15%), thrombosis (15%), bacterial infections (13%), headache (13%), hyperglycemia (13%), infusion-related reactions (13%), abdominal pain (10%), hypertension (10%), pyrexia (10%), and thrombocytopenia (10%).

Click here for full Prescribing Information for Gamifant.

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Table of Contents

PA=prior authorization.

IMPORTANT SAFETY INFORMATION

Infections

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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 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.

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

IMPORTANT SAFETY INFORMATION (continued)

Infections (continued)

In patients with primary HLH receiving Gamifant in clinical trials, serious infections such as sepsis, pneumonia, bacteremia, disseminated histoplasmosis, necrotizing fasciitis, viral infections, and perforated appendicitis were observed in 32% of patients.

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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

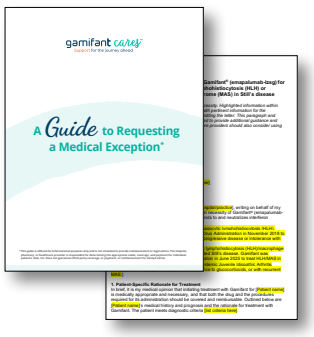
SITE-OF-CARE RESTRICTIONS FOR INFUSED TREATMENTS

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**.



IMPORTANT SAFETY INFORMATION (continued)

Infections (continued)

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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

IMPORTANT SAFETY INFORMATION (continued)

Infections (continued)

Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating Gamifant. Administer tuberculosis prophylaxis to patients at risk for tuberculosis or known to have a positive purified protein derivative (PPD) test result.

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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.

IMPORTANT SAFETY INFORMATION (continued)

Infections (continued)

Consider prophylaxis for herpes zoster, *Pneumocystis jirovecii*, and fungal infection while receiving Gamifant. Employ surveillance testing during treatment with Gamifant.

Closely monitor patients receiving Gamifant for signs or symptoms of infection, promptly initiate a complete diagnostic workup appropriate for an immunocompromised patient, and initiate appropriate antimicrobial therapy.

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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.

IMPORTANT SAFETY INFORMATION (continued)

Increased Risk of Infection With Use of Live Vaccines

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

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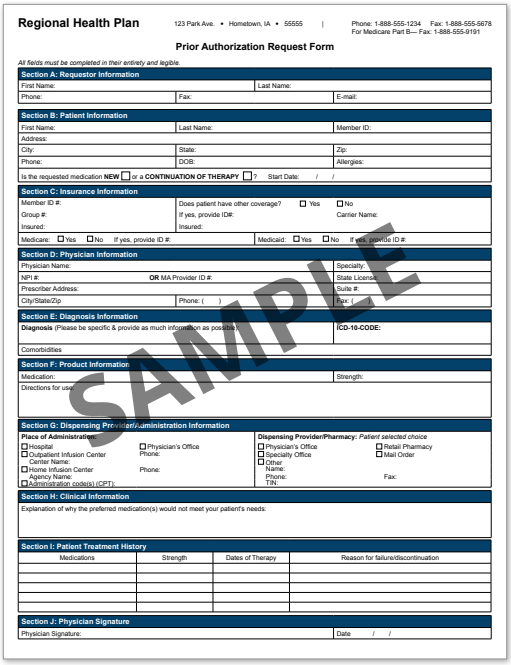
A *Successful* PA Begins With an Accurate and Complete Submission

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.

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

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

IMPORTANT SAFETY INFORMATION (continued)

Infusion-Related Reactions

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

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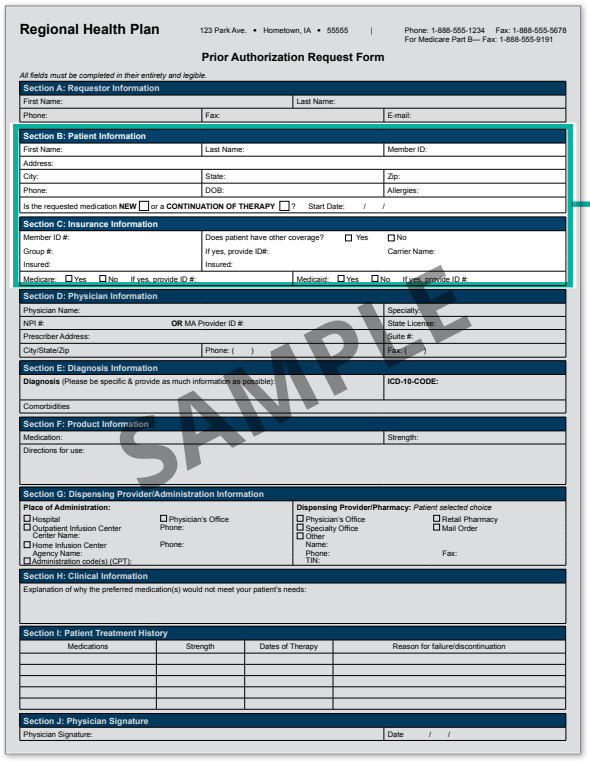
Completing the PA Form

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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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:**
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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
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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 the patient's 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.

IMPORTANT SAFETY INFORMATION (continued)

Infusion-Related Reactions (continued)

Infusion-related reactions in patients with HLH/MAS in Still's disease, including pyrexia, headache, paresthesia, bone pain, pruritic rash, and peripheral coldness, were reported with Gamifant treatment in 13% of patients. Infusion-related reactions were reported as mild in 8% of patients and as moderate in 5% of patients.

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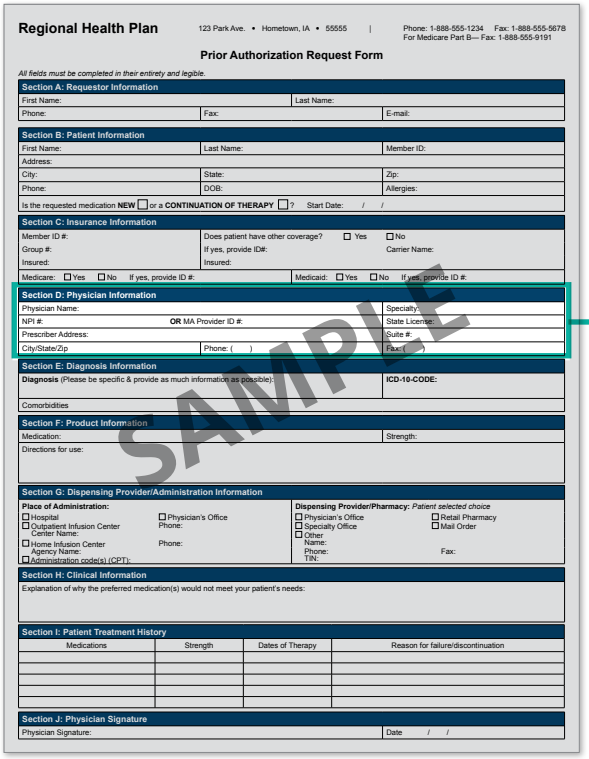
Completing the PA Form (continued)



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City: | State: | Zip:
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Section C: Insurance Information
Member ID #: | Does patient have other coverage? ☐ Yes ☐ No
Group #: | If yes, provide ID#: | Carrier Name:
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Section J: Physician Signature
Physician Signature: | Date / /

SAMPLE

Physician Information section

- Complete the physician information section, which includes the prescribing physician, specialty, and office location.
- 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.

IMPORTANT SAFETY INFORMATION (continued)

Infusion-Related Reactions (continued)

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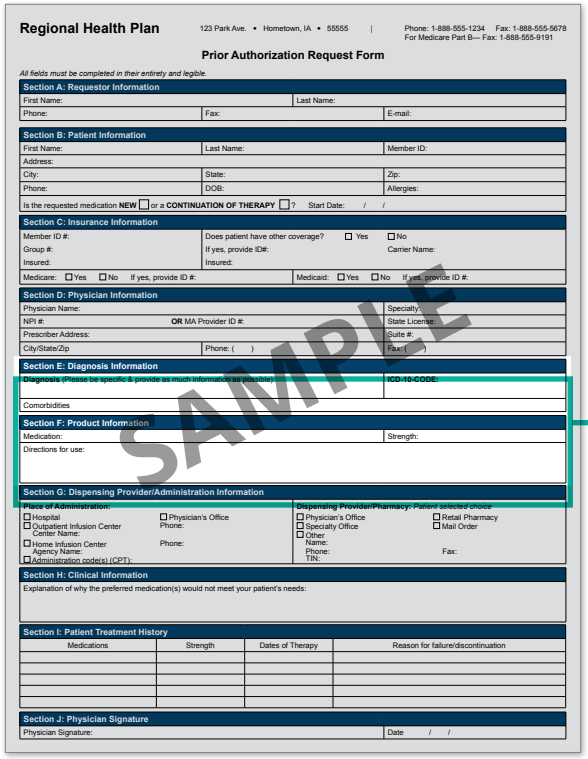

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SAMPLE

Diagnosis and Product Information sections

- Provide a detailed diagnosis and relevant *ICD-10-CM* code(s) so the health plan understands why the medication is being requested.
- Ensure that both the *ICD-10-CM* code(s) 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 Codes[1]	Description
D76.1	Hemophagocytic lymphohistiocytosis
D76.2	Hemophagocytic syndrome, infection-associated
M06.1	Adult-onset Still's disease
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.20	Juvenile rheumatoid arthritis with systemic onset, unspecified site

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

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

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.

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

Primary HLH

Serious adverse reactions were reported in 53% of patients. The most common serious adverse reactions (≥3%) included infections, gastrointestinal hemorrhage, and multiple organ dysfunction. Fatal adverse reactions occurred in 2 (6%) of patients and included septic shock and gastrointestinal hemorrhage.

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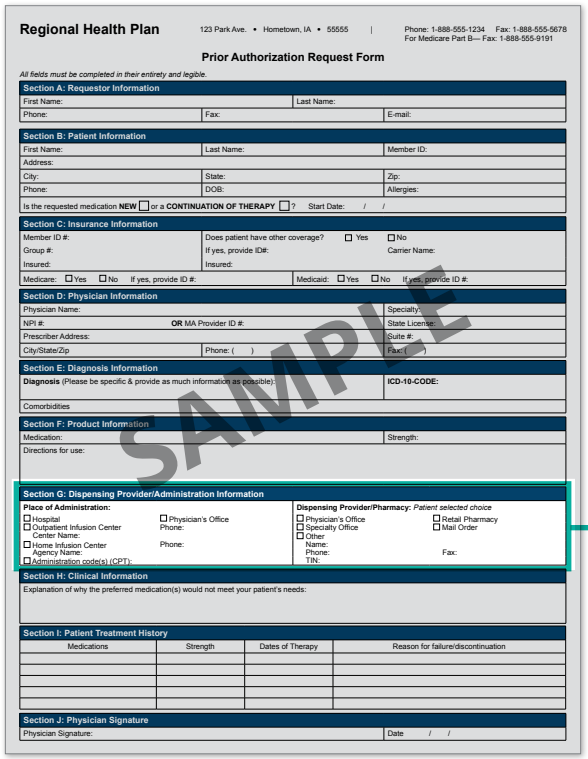
Completing the PA Form (continued)



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☐ 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

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, administration code(s), and phone number.
- 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.

IMPORTANT SAFETY INFORMATION (continued)

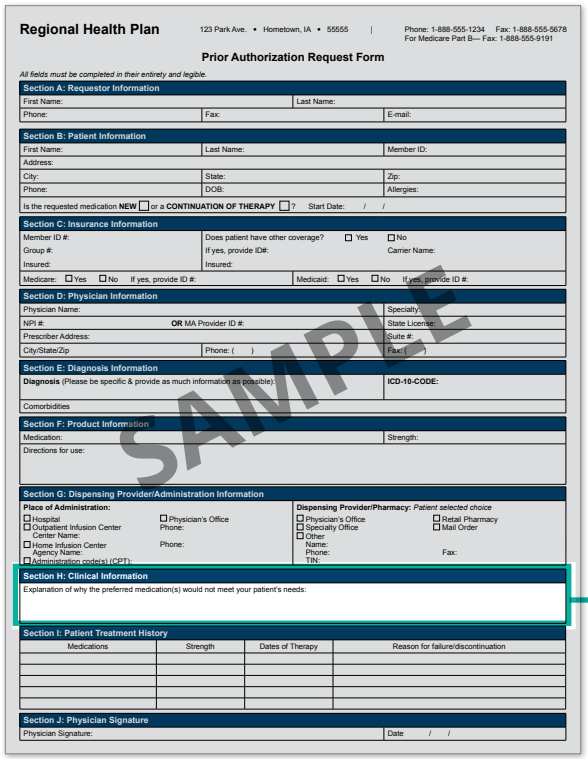
Adverse Reactions (continued)

Primary HLH (continued)

The most common adverse reactions were (≥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%).

Please see additional Important Safety Information on page 2. Click here for full Prescribing Information for Gamifant.

Completing the PA Form (continued)



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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:
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Section H: Clinical Information
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Section J: Physician Signature
Physician Signature: | Date / /

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.

IMPORTANT SAFETY INFORMATION (continued)

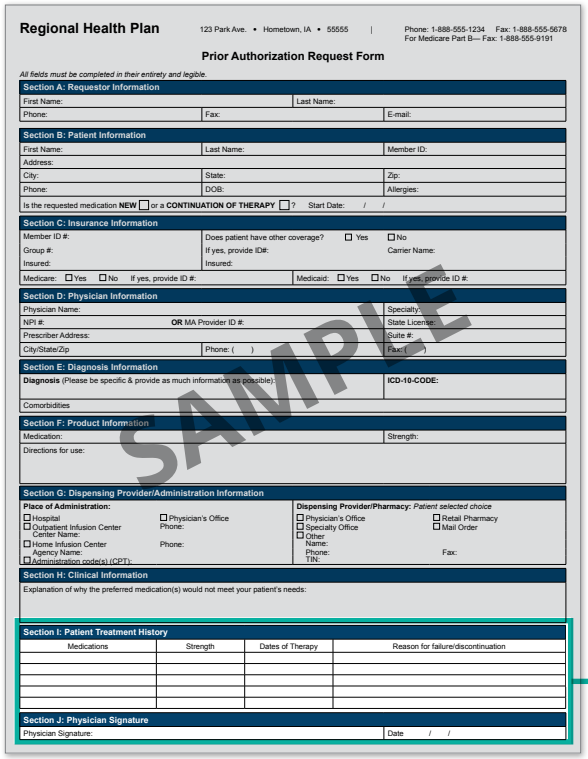
Adverse Reactions (continued)

HLH/MAS

Serious adverse reactions were reported in 12 patients (31%), with the most common serious adverse reaction being pneumonia (5%). Fatal adverse reactions occurred in two patients (5%) and included multiple organ dysfunction and circulatory shock.

Please see additional Important Safety Information on page 2. Click here for full Prescribing Information for Gamifant.

Completing the PA Form (continued)



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Prior Authorization Request Form

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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:
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:**
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Section F: Product Information
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Agency Name:
☐ Administration code(s) (CPT):
Dispensing Provider/Pharmacy: *Patient selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Office ☐ Mail Order
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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.

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions (continued)

HLH/MAS (continued)

The most common adverse reactions (≥10%) for Gamifant included viral infection (44%), rash (21%), anemia (18%), leukopenia (15%), thrombosis (15%), bacterial infections (13%), headache (13%), hyperglycemia (13%), infusion-related reactions (13%), abdominal pain (10%), hypertension (10%), pyrexia (10%), and thrombocytopenia (10%).

Please see additional Important Safety Information on page 2. Click here for full Prescribing Information for Gamifant.

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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 both indicated diseases, 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.

FOR MORE INFORMATION ON HOW SOBI CAN SUPPORT PATIENTS, PLEASE CONTACT GAMIFANT CARES.

Gamifant Cares offers access and reimbursement support to help patients access Gamifant. Gamifant Cares provides information regarding patient insurance coverage 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, visit **GamifantCares.com** or call **Gamifant Cares** at **1-833-597-6530**
Monday through Friday, 8:30 AM to 7 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.

References: 1. ICD-10-CM tabular list of diseases and injuries. Centers for Disease Control and Prevention. Published April 2022. Accessed May 6, 2025. https://ftp.cdc.gov/pub/health_statistics/nchs/Publications/ICD10CM/2022/icd10cm-tabular-2022-April-1.pdf **2.** Gamifant (emapalumab-lzsg) prescribing information. Stockholm, Sweden: Sobi, Inc. 2025. **3.** Healthcare Common Procedure Coding System (HCPCS) application summaries for drugs, biologicals and radiopharmaceuticals. Centers for Medicare & Medicaid Services. Published May 14, 2019. Accessed May 16, 2025. https://www.cms.gov/files/document/2019-hcpcs-application-summary-may-14-2019-drugs-and-biologicals.pdf

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