



# Tips for Completing a Benefits Investigation

## **Indication and Usage**

Gamifant® (emapalumab-lzsg) is an interferon gamma (IFN $\gamma$ )-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.

**Please see Important Safety Information on back cover and accompanying full Prescribing Information.**



## Understanding the Benefits Investigation

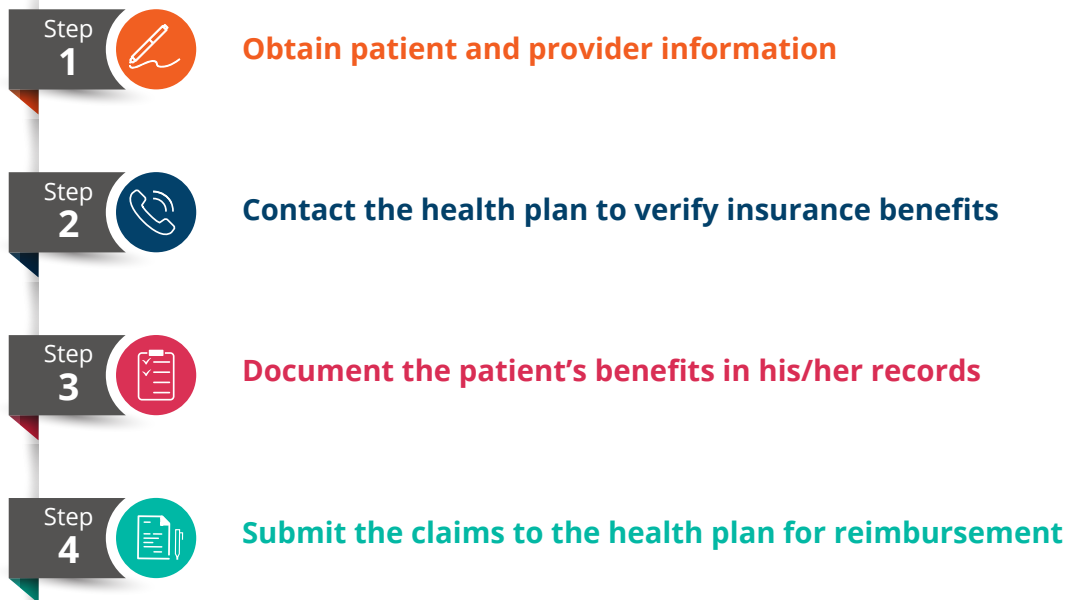
For patients prescribed Gamifant® (emapalumab-lzsg), a benefits investigation may be an important and necessary step for determining drug and ancillary procedure medical coverage. Based on the patient's benefits and his or her individual care plan, the benefits investigation will help define health plan requirements.

Additionally, the benefits investigation helps health care providers to determine benefit design, coverage requirements, and coding guidance. There are many variables associated with each patient's benefits; for example, there may be differences by state and/or by site of care (eg, whether the patient is hospitalized or is treated as an outpatient). Also, there may be patients who travel to an out-of-network facility for administration of Gamifant, which could affect their benefits coverage.

### An overview of the key steps

It is important to record specific benefit information up front so that your facility can submit the claim for reimbursement for Gamifant and for its administration correctly.

The following steps will help ensure that all the appropriate information is recorded accurately:



**Gamifant Patient Services can provide assistance throughout the benefits investigation process. Call 1-833-597-6530 for more information.**

### 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 IFN $\gamma$  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.

## Beginning the benefits investigation

Step  
1



### Obtain patient and provider information



#### Patient contact information

- Patient name
- Date of birth
- Phone number
- Address



#### Insurance information

- Policy holder name
- Policy start and end dates
- Member number
- Group number
- Primary, secondary, and tertiary health plan information (eg, commercial, Medicaid)

Obtain both medical and pharmacy benefit information from your patient's insurance cards. See the brochure called **Understanding Your Patient's Medical and Pharmacy Benefits** in this kit for more information.



#### Physician information

- Physician prescribing Gamifant  
Physician name                      NPI #                      Tax ID #
- Physician(s) administering Gamifant (if different from the prescriber)  
Physician name                      NPI #                      Tax ID #
- Site of care administering Gamifant  
Practice/facility name                      NPI #                      Site of care/place of service

NPI=National Provider Identifier.

**Please see additional Important Safety Information on back cover and accompanying full Prescribing Information.**

Step  
2



## Contact the health plan to verify insurance benefits

Record the following information related to Gamifant (emapalumab-lzsg) and its administration.



### Coverage

- Prior certification/authorization/medical exception (ME) required
- Reauthorization timing



### Patient cost

- Facility visit co-pay or coinsurance
- Drug cost co-pay or coinsurance
- Deductible

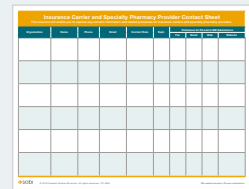
## Keep accurate records of the benefits investigation information

During a benefits investigation, documenting any communication you may have with a patient's health plan is important.

Each time your facility communicates with a health plan, be sure to record the following:

- Date
- Time
- Type of communication (phone call, email)
- Communication preference (fax, email)
- Person(s) you spoke with
- Reference number for the communication

Use the electronic **Insurance Carrier and Specialty Pharmacy Provider Contact Sheet** included in this kit to track your communications.



| Insurance Carrier | Specialty Pharmacy Provider | Contact Date | Contact Time | Contact Type | Contact Preference | Contact Person | Contact Reference Number |
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## 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.

Step  
3



### Document the patient's benefits in his/her records

Record all of the key information acquired in Step 2 in the patient's records.

Step  
4



### Submit the claims to the health plan for reimbursement

Submit the claims as soon as possible, as hemophagocytic lymphohistiocytosis (HLH) requires urgent treatment.

**Gamifant Patient Services** can help with the benefits investigation. To enroll your patient in Gamifant Patient Services, complete the Gamifant Start Form with your patient's parent/guardian and fax it to 1-866-895-7204.

Download a Gamifant Start Form at [Gamifant.com](http://Gamifant.com) or call Gamifant Patient Services at 1-833-597-6530 with questions.

Please see additional Important Safety Information on back cover and accompanying full Prescribing Information.



## Examples of benefits investigation considerations

### Remember: health plans have different coverage requirements

Each individual health plan determines its own medical policy for coverage. As there is no specific timeline for policy development, in some instances, plans may never develop a policy. However, even if a health plan has not conducted a formal coverage determination for a product, coverage may still be granted on a case-by-case basis. It is during that time when providers will usually need to complete additional requirements such as precertification/prior authorization/ME to obtain coverage for the drug and its administration services, as well as approval for the site of care.

Following are some considerations to keep in mind when conducting a benefits investigation for Gamifant (emapalumab-lzsg).

#### Preauthorization/precertification and required documentation

- Determine if preauthorization/precertification is required for Gamifant, its administration services, or other related services
- Identify which benefit the patient is covered under (ie, medical benefit or pharmacy benefit)
- Establish whether specific documentation is required before the plan will approve the product, administration-related services, and/or facility

#### Medical exception

If there is no medical policy in place, or a patient does not meet Gamifant coverage requirements in the health plan's policy, it may be possible to gain coverage through the ME process. It is important to note that the ME process tends to vary among health plans.

- Determine if there is a process for MEs and, if so, what type of documentation is required to demonstrate medical necessity
- See **A Guide to Requesting a Medical Exception for Gamifant® (emapalumab-lzsg)** found in this kit for more information

#### Observation stay

Some patients may require additional monitoring before and during the administration of Gamifant. In addition, some health plans may also cover an outpatient observation stay (for up to 48 hours).

- Determine the monitoring conditions for coverage during the benefits investigation

#### Before initiating Gamifant treatment<sup>1</sup>

Prior to initiating Gamifant, conduct testing for latent tuberculosis infections using the purified protein derivative (PPD) or interferon gamma (IFN $\gamma$ ) release assay and evaluate patients for tuberculosis risk factors. Administer tuberculosis prophylaxis to patients at risk for tuberculosis or who are known to have a positive PPD test result or positive IFN $\gamma$  release assay.

### 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.

### **During Gamifant treatment<sup>1</sup>**

Monitor for tuberculosis, adenovirus, Epstein-Barr virus, and cytomegalovirus every 2 weeks and as clinically indicated.

- Make sure to clarify the health plan's parameters for length of stay for outpatient observation

### **Out-of-network and/or out-of-state restrictions**

There may be restrictions on Gamifant for some patients when the provider and/or facility is out of network or out of state. In these cases, waivers or exceptions can be granted if it is demonstrated that Gamifant is medically necessary.

- During the benefits investigation, determine the network and/or state participation status for the physician(s) and/or facility
- Determine if there is an exception process for patients seeking care out of network and/or out of state

### **Coordinating benefits between multiple health plans**

If your patient has more than 1 health plan that provides benefit coverage, these plans will need to coordinate benefits.

- During the benefits investigation, establish which payer is primary, which is secondary, and which is tertiary
- Follow the instructions provided by each health plan regarding the order of benefits and processes for submitting claims

### **Method of health plan reimbursement**

Payer reimbursement methodology for facility and professional services may have significant variations.

- The facility and/or professional services may be subject to some form of global payment rules or prospectively set reimbursement rates (eg, diagnosis-related group [DRG]-based payment)
- The payment for Gamifant may be separate or bundled within a prospectively set rate (eg, DRG-based rate, per diem rate)
- Contact the health plan for specific rules regarding method of reimbursement

### **Patient financial responsibility**

Understanding the patient's out-of-pocket (OOP) costs is important. These costs may vary based on the specific benefit design, location of treatment, network parameters, and the number of health plans. For example, patients with more than 1 plan, such as commercial insurance and Medicaid, may have additional financial support for OOP expenses. Be sure to understand the patient's fiscal responsibility by

- Determining the patient's annual deductible, OOP maximum, and how much has been met to date
- Documenting the coinsurance and/or co-pay that will apply for Gamifant and related services
- Contacting Gamifant Patient Services at 1-833-597-6530 for additional patient financial support information

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## Adverse Reactions

In the pivotal trial, the most commonly reported adverse reactions ( $\geq 10\%$ ) 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.

**Reference:** 1. Gamifant [prescribing information]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; 2018.



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