

Tipo for Completing a Benefits Investigation*

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Importance of the Benefits Investigation for Gamifant® (emapalumab-lzsg)

For patients prescribed Gamifant, a benefits investigation is an important and necessary step for determining drug coverage. Based on the patient's benefits and his or her individual care plan, the benefits investigation will help to identify any health plan requirements.

Additionally, the benefits investigation may help healthcare providers to determine coverage and coding requirements. There are many variables associated with the benefits set forth in each health plan. 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.



Gamifant is most likely to be covered under the medical benefit

- Medical benefits typically cover drugs, such as Gamifant, that are infused by a healthcare provider at a facility, such as a hospital.
- However, health plan requirements differ. Some plans may cover Gamifant under the pharmacy benefit.
- A benefits investigation will help evaluate whether the health plan will cover Gamifant through the medical or pharmacy benefit.





An Overview of the Key Steps

It is important to understand and document the specific benefit information about a patient's insurance plan up front so that your facility can correctly submit the claim for reimbursement for Gamifant® (emapalumab-lzsg) and for its administration.

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



STEP 1:

Obtain patient and provider information



STEP 2:

Contact the health plan to verify insurance benefits



STEP 3:

Document the patient's benefits in his/her records



STEP 4:

Submit prior authorization (PA) request for urgent review (if necessary)



STEP 5:

Submit the claims to the health plan for reimbursement and communicate the PA decision with other departments



Gamifant Cares can provide assistance with the benefits investigation and PA process. Call **1-833-597-6530** for more 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 in those situations that providers usually need to complete additional requirements, such as precertification/PA/medical exception (ME), to obtain coverage for the drug and its administration services, as well as approval for the site of care.

The following are some considerations to keep in mind when conducting a benefits investigation for Gamifant® (emapalumab-lzsg). To determine if a preauthorization/precertification or ME is required, refer to the payer's website or call the payer directly.

Preauthorization/ precertification and required documentation	 Determine if preauthorization/precertification is required for Gamifant, its administration services, or other related services and if an urgent review is necessary. Establish whether specific documentation is required before the plan will approve the product, administration-related services, and/or facility. See <u>A Guide to Prior Authorization Submissions</u> for more information.
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 <u>A Guide to Requesting a Medical Exception</u> for more information.
Observation period	 Determine the monitoring conditions for coverage during the benefits investigation. Some plans may require proof of screening as part of the clinical criteria. Remember to clarify the health plan's parameters for length of stay for outpatient observation.





EXAMPLES OF BENEFITS INVESTIGATION CONSIDERATIONS (continued)

Out-of-network and/or out-of-state restrictions	There may be restrictions on Gamifant® (emapalumab-lzsg) 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. • Ask the health plan 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. Confirm whether a PA is required by either or both plans.
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 and if an outlier payment can be requested.
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 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 copay that will apply for Gamifant and related services Contact Gamifant Cares at 1-833-597-6530 for information about financial assistance options for eligible patients.

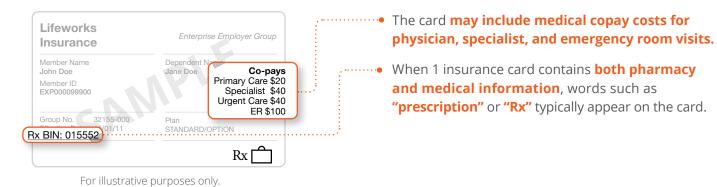




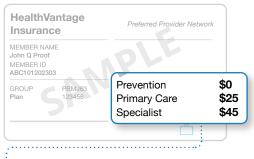
Identifying a Patient's Medical and Pharmacy Benefits

When conducting a benefits investigation, it is important to include all of the information provided by the patient about their insurance. This includes the medical and pharmacy benefit information that is supplied on insurance cards.

SOME PATIENTS HAVE 1 CARD FOR BOTH THE PHARMACY BENEFIT AND THE MEDICAL BENEFIT



SOME PATIENTS WITH SEPARATE PHARMACY BENEFITS AND MEDICAL BENEFITS HAVE 2 CARDS



 Patient copays for office and emergency room visits indicate the medical benefit.



 Rx identification numbers provide the pharmacy benefit information.



Remember that patients can have more than 1 insurance plan.

Be sure to ask the patient for all of his or her insurance cards. Make a copy of the front and back of each card for your patient records.





Beginning the Benefits Investigation

STEP 1:

Obtain patient and provider information



Be sure to gather the following information:

Patient contact information	Insurance information
• Name	Policyholder name
Date of birth	Policy start and end dates
Phone number	Member number
• Address	Group number
	 Primary, secondary, and tertiary health plan information, if applicable (eg, commercial, Medicaid, etc)

Physician information		
Physician prescribing Gamifant® (emapalumab-lzsg)	Physician(s) administering Gamifant (if different from the prescriber)	Site of care administering Gamifant
NameNPI numberTax ID number	Name(s)NPI number(s)Tax ID number(s)	Practice/facility nameNPI numberSite of care/place of service



Keep accurate records of the benefits investigation information.

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

- Date, time, and method of communication (eg, phone call or email)
- Name(s), title(s), and department(s)/role(s) of the person(s) you communicated with
- Reference number for the communication





STEP 2:

Contact the health plan to verify insurance benefits



- Call the provider services number on the back of the medical insurance card and ask if Gamifant® (emapalumab-lzsg) is covered under the medical benefit. If not, call the number for the pharmacy benefit provider on the back of the appropriate card and ask if Gamifant is covered under the pharmacy benefit.
- Ask the plan if a PA is required, and if so, how to submit it for an urgent review.
- Ask if the plan has a published policy for Gamifant, and if so, where it may be found.
 - If the plan has a Gamifant policy, be sure to review it after the call to identify which criteria apply to your patient so you can accurately complete the PA request, if necessary.
 - If there is no Gamifant policy, review the Medical Information Checklist for a summary of the most commonly requested clinical documentation required by payers, which may help you complete a PA request, if necessary.
- Confirm that the prescriber and facility are in network.
- Verify if there are any dispensing requirements for Gamifant when using a specialty pharmacy or buy-and-bill.
- If Gamifant is covered under the medical benefit, verify the patient's deductible and OOP responsibility. If Gamifant is covered under the pharmacy benefit, verify any copay the patient may have.
- Confirm billing requirements for Gamifant.
- Ask about the method of reimbursement for Gamifant (See "Examples of Benefits Investigation Considerations" on pages 4-5 for more details).
- Verify with the plan that either the Gamifant specialty distributor, McKesson Plasma and Biologics, or the Gamifant specialty pharmacy, Biologics, is in network.

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, or attach a copy of the Benefits Investigation Worksheet (please see pages 10-12).



For more detailed information and a worksheet you can use to help keep track of the answers to these questions, please see pages 10-12 or contact **Gamifant Cares** at **1-833-597-6530** for assistance.





STEP 4:

Submit PA request for urgent review (if necessary)



Using the responses regarding the PA from Step 2 and information gathered from the plan's Gamifant® (emapalumab-lzsg) policy, if applicable,

- Complete and submit the PA request according to the plan's preferred method
- Follow up with the plan on the PA determination until a resolution is reached. For additional information about submitting a PA request, please see **A Guide to Prior Authorization Submissions**
- Share the PA approval or denial with the appropriate healthcare professional

STEP 5:

Submit the claims to the health plan for reimbursement and communicate the PA decision with other departments



Submit the claims per the payer's preferred method as soon as possible, as hemophagocytic lymphohistiocytosis (HLH) requires urgent treatment.

It is important to reverify your patient's benefits prior to each administration of Gamifant, especially if it is administered at a different site of care.



Gamifant Cares can help with the benefits investigation. To enroll your patient in Gamifant Cares, complete the Patient Enrollment Form with your patient or his/her parent/caregiver and fax it to 1-866-895-7204.

Download a Patient Enrollment Form at **Gamifant.com** or call Gamifant Cares at **1-833-597-6530** with questions.





Benefits Investigation Worksheet

	lling the health plan to find out how Gamifant® (emap ring information:	alumab-lzsg) is covered, be sure that you have
O Prescrib		Patient ID Copies of all insurance cards g physician name, NPI number, and Tax ID
		agnosis code ONDC OCPT® code
Pieuse see	the Summary of Relevant Codes for diagnosis code, Ch	r code, and NDC.
STEPS TO	VERIFY INSURANCE BENEFITS	
		Notes
Step 1	Call the provider services number on the back of the medical insurance card and ask if Gamifant is covered under the medical benefit. If not, call the number for the pharmacy benefit provider on the back of the appropriate card and ask if Gamifant is covered under the pharmacy benefit.	
Step 2	Ask if a PA is required, and if so, how to submit it.	
Step 3	 Ask if the plan has a published policy for Gamifant, and if so, where it may be found. If the plan has a Gamifant policy, be sure to review it after the call to identify which criteria apply to your patient so you can accurately complete the PA request, if necessary. Criteria are generally separated between criteria for Gamifant to be medically necessary for the patient and criteria for the patient to start on Gamifant. Some policies require proof that the patient has been evaluated for infection, including latent tuberculosis, prior to approval. If this applies to your patient, make sure to include clinical evidence that the patient has been evaluated in the PA submission. 	

CPT=Current Procedural Terminology; NDC=National Drug Code.





STEPS TO VERIFY INSURANCE BENEFITS (continued)

		Notes
Step 4	Confirm that the prescriber and facility are in network.	
Step 5	Verify if there are any dispensing requirements for Gamifant® (emapalumab-lzsg).	
Step 6	If Gamifant is covered under the medical benefit, verify the patient's deductible and OOP responsibility. If Gamifant is covered under the pharmacy benefit, verify any copay the patient may have.	
Step 7	Confirm billing requirements for Gamifant.	
Step 8	 Ask about the method of reimbursement for Gamifant. Are the facility and/or professional services subject to some form of global payment rules or prospectively set reimbursement rates (eg, DRG-based payment)? Is the payment for Gamifant separate or bundled within a prospectively set rate (eg, DRG-based rate or per diem rate)? 	

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STEPS TO VERIFY INSURANCE BENEFITS (continued)

		Notes
Step 9	Verify with the plan that either the Gamifant® (emapalumab-lzsg) specialty distributor, McKesson Plasma and Biologics, or the Gamifant specialty pharmacy, Biologics, is in network.	
Step 10	Once benefits have been verified, complete the PA submission according to the plan's preferred method, if applicable.	

If the patient has multiple insurance plans, please repeat this exercise with each plan.



Gamifant Cares offers access and reimbursement support to help patients access Gamifant. Gamifant Cares provides information regarding patient healthcare coverage options and financial assistance information that may be available to help patients with financial needs. Gamifant Cares can:

- Evaluate a patient's insurance coverage, including benefits investigation, PA, and appeal support
- Provide a Benefit Investigation Summary and, if applicable, any PA requirements
- Identify potential financial assistance options that may be available to help patients with financial needs
- Answer logistical questions and provide information and confirmation around the specialty pharmacy fulfillment process

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

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.

