



# A *Guide* to Denials and Appeals\*

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## Why a Request May Be Denied by a Health Plan

A prior authorization (PA) may be denied for many reasons. The 2 most common reasons for a denial are **incomplete and/or inaccurate information** on the submission and **clinical issues**.

If the reason for the denial is not provided, call the health plan for more information. Always keep a copy of the denial letter with the patient's chart as it may be referenced in the future.

### REASONS FOR ADMINISTRATIVE AND CLINICAL DENIALS



#### ADMINISTRATIVE DENIALS

Administrative denials are due to inaccurate or incomplete information, or an incorrect submission method. Be sure to confirm the health plan's specific PA submission method (eg, form, website, portal).



#### CLINICAL DENIALS

Clinical denials suggest that the health plan may have determined that the patient's medical condition does not meet the payer's medical criteria or meet the product label for Gamifant® (emapalumab-lzsg). This may be because

- The patient does not meet medical necessity criteria
- The patient diagnosis does not qualify
- The requested starting dose is higher than the payer's starting dose
- There is no clinical evidence to show that the patient has been evaluated for infection (eg, latent tuberculosis)



## Next Steps When a PA Is *Denied*

### ADMINISTRATIVE DENIAL

**Denied due to inaccurate or incomplete information, or incorrect submission method**

#### Next steps



- Carefully review the request to verify that the information is correct and complete and that no information has been omitted.
- If the wrong PA submission method was used, revise and resubmit.
- If necessary, resubmit the request with all the required information and use the proper PA submission method.
- An administrative denial may require an appeal rather than a resubmission.

### CLINICAL DENIAL

**Denied due to clinical issues**

#### Next steps



- Submit an appeal or request a peer-to-peer discussion.
  - The timeframe of an insurance's response to an appeal may vary. Choose the method that meets your patient's needs.
  - Ensure that clear clinical evidence is included in the PA submission to show that the medical criteria has been met or that the patient meets the product label.
  - It may be helpful to include a detailed explanation of where the applicable clinical evidence can be found in the submitted clinical information.



**Proactively contacting** the health plan after submitting a PA to have a peer-to-peer discussion regarding the patient, clinical issues, and the reasons for prescribing Gamifant® (emapalumab-lzsg) may assist the health plan in understanding your treatment option.



## Levels of Appeal

If a health plan denies a PA, you may be asked to submit an appeal to the health plan.

### FIRST LEVEL:

#### First-level Appeal: Letter of appeal or peer-to-peer discussion



A Letter of Medical Necessity may be submitted to the health plan to overturn a denial. Refer to the **Sample Letter of Medical Necessity** as an example.

To expedite the appeal, you may consider contacting the health plan and arranging for the prescribing physician to have a peer-to-peer discussion with a clinical representative or medical director at the plan.

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Due to the rarity of both indicated diseases, the prescribing physician may 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® (emapalumab-lzsg).

### SECOND LEVEL:

#### Second-level Appeal: Medical review



The appeal is reviewed by a medical director at the health plan who has not been involved with the claim decision.

### THIRD LEVEL:

#### Third-level Appeal: External review



The external review is conducted by an independent, third-party reviewer working with a board-certified physician in the same field as the patient's physician.



**If an appeal is denied at any level,** consider submitting an appeal at the next level or contacting the payer to request a peer-to-peer discussion.



## Considerations for an Appeal

When submitting an appeal, it may be helpful to have a peer-to-peer discussion regarding the patient, clinical issues, and the reasons for prescribing Gamifant® (emapalumab-lzsg) to assist the health plan in better understanding treatment options. For this discussion or for appeals in general, it may be helpful to include

- Background on your patient's condition
- An explanation about why, in your opinion, Gamifant is the appropriate choice for your patient, including
  - Clinical validation supporting Gamifant treatment for your patient and cite any relevant literature
  - Patient-specific reasons for selecting Gamifant, such as the expected effect of treatment
  - Specific criteria your patient meets that is listed in the health plan's medical policy (if available). For any unmet criteria, explain why the patient should be exempted.

You may also provide additional documentation supporting your decision to strengthen your request, which may include

- General medical history, listing comorbidities, medication history, and any other relevant patient information
- Letters from other healthcare professionals (such as geneticists, rheumatologists, or hematologists) supporting your choice for Gamifant
- Relevant clinical information regarding your treatment choice, such as the product's Prescribing Information. Refer to the **Gamifant Clinical Overview** for more information.
- A **Patient Appeal Letter**. Refer your patients to the Patient Appeal Letter for a template.
- Other relevant patient information

**Be sure to follow up on the status of the appeal until a determination is made.**

### 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](https://GamifantCares.com) or call **Gamifant Cares** at **1-833-597-6530**  
Monday through Friday, 8:30 AM to 7 PM ET.

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