A Guide to Requesting a Medical Exception for 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.

Please see Important Safety Information on page 8 and accompanying full Prescribing Information.
How to Request a Medical Exception for Gamifant (emapalumab-lzsg)

Understanding medical exceptions
There are occasions when a benefits investigation determines that Gamifant is not covered by a health plan. In other instances, the coverage may be denied for a certain patient. Under these circumstances, it is likely that your facility will need to request a medical exception (ME) in order for your patient to receive Gamifant. An ME communicates a physician's request, based on a patient's individual circumstances, to use a certain medication that is nonpreferred or not covered by the patient's health plan. MEs can also be referred to as formulary exceptions. Health plans may require that you complete a form to request an ME (see sample), submit a letter of medical necessity (see page 3), or both.

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 page 8 and accompanying full Prescribing Information.
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 page 8 and accompanying full Prescribing Information.
Step-by-Step Guide to Completing an ME

There are 3 key steps when processing an ME. In the next sections, you will find details on each of these steps.

1. Complete a benefits investigation
   - Each health plan has different requirements for submitting an ME. You can determine the ME requirements specific to Gamifant (emapalumab-lzsg) during the benefits investigation. For more information about what to ask health plans during a benefits investigation, see Tips for Completing a Benefits Investigation in this kit.
   - Information that you can learn during the benefits investigation includes:
     - Whether a prior authorization, ME, and/or letter of medical necessity are required
     - If there are restrictions around where the treatment can be administered
     - The patient’s co-pay, coinsurance, deductible, secondary insurance, and any other out-of-pocket costs
     - Where and how to submit the claim information

2. Complete the ME request and/or letter of medical necessity

3. Submit and track your ME request

For more information on benefits investigations and prior authorization submissions, please consult the other resources in this kit.

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 page 8 and accompanying full Prescribing Information.
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%).

Please see additional Important Safety Information on page 8 and accompanying full Prescribing Information.
Adverse Reactions (continued)

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 page 8 and accompanying full Prescribing Information.
What if the ME Is Denied?

If the ME is denied, determine the reason for the denial. Review the following considerations to determine your course of action.

If the ME is denied due to inaccurate or incomplete information, revise and resubmit

- Carefully review the request to verify that the information is correct and complete and that no information has been omitted. If the reasons for the denial are not provided, consider calling the health plan for details
- If necessary, resubmit the request with all the required information
- Remember, Gamifant Patient Services (1-833-597-6530) can help you understand the process for handling an ME denial. Be sure to keep a copy of all pages of the denial letter so he or she can help more quickly

If the ME is denied due to clinical reasons, request a peer-to-peer discussion

Contact the health plan directly and arrange for the prescribing physician to speak with a clinical representative or medical director for a peer-to-peer discussion. The physician can request to speak to an individual with a similar specialty (e.g., pediatrician, neonatologist, perinatal specialist, pediatric hematologist/oncologist). A peer-to-peer discussion should include detailed information about the patient's medical history, diagnostic tests, clinical considerations, and the reason for the requested treatment. This discussion may help the health plan understand the concerns for your patient and why there is an ME request for your treatment of choice.

Sobi is available to help you navigate the ME process. Contact Gamifant Patient Services at 1-833-597-6530.

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 page 8 and accompanying full Prescribing Information.
Indication and Usage
Gamifant® (emapalumab-Izsg) 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.