AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Gamifant® (emapalumab-lzsg) – **HLH/MAS (J9210) MEDICAL**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Max Units (per dose and over time) [HCPCS Unit]: 9250 billable units per 30 days; 1 mg = 1 billable unit

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ **Diagnosis: Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS) in known or suspected Still's disease**

Initial Authorization: 30 days

- ❑ Member has a definitive diagnosis of HLH/MAS as indicated by **BOTH** of the following **(submit documentation)**:
  - ❑ Ferritin >684 ng/mL
  - ❑ At least 2 of the following (check all that apply):
    - ❑ Platelet count $\leq 181 \times 10^9$/L
    - ❑ AST >48 U/L
    - ❑ Triglycerides >156 mg/dL
    - ❑ Fibrinogen levels ≤360 mg/dL
- ❑ Member has known or suspected diagnosis of Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA) or Adult Onset Still's Disease (AOSD)
- ❑ Member must meet **ONE** of the following **(submit documentation)**:
  - ❑ Member has had an inadequate response or intolerance to high-dose intravenous (IV) glucocorticoids **(currently or last 30 days)**
  - ❑ Member has recurrent MAS
- ❑ Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment
- ❑ Providers will monitor and consider prophylaxis in patients for Herpes Zoster, *Pneumocystis Jirovecii*, and fungal infections
- ❑ Member does **NOT** have an active infection, including clinically important localized infections that are favored by interferon-gamma neutralization (e.g., infections caused by mycobacteria, Histoplasma Capsulatum)
- ❑ Medication must **NOT** be administered concurrently with live or live attenuated vaccines

Reauthorization: 30 days. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to require therapy for treatment of HLH/MAS

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- ❑ Member must meet **ONE** of the following:
  - ❑ Member experienced a complete response (CR) as evidenced by the following:
    - ❑ Clinical resolution of MAS signs and symptoms (a visual analogue scale (VAS), of ≤1 cm [range 0 to 10 cm])
    - ❑ Member meets **ALL** the following laboratory parameter endpoints:
      - ❑ WBC count and platelet count above the lower limit of normal (LLN)
      - ❑ LDH, AST and ALT below 1.5 times the upper limit of normal (ULN)
      - ❑ Fibrinogen >100 mg/dL
      - ❑ Ferritin levels decreased ≥80% from values at screening or baseline (whichever initial value was higher) or < 2000 ng/mL, whichever was lower
- ❑ Member has had unsatisfactory improvement in clinical condition, as assessed by a healthcare provider and requires dose escalation (up to the maximum dose and frequency specified in the Dosage/Administration table below)

Treatment Day	Gamifant Dose	Dose Adjustments
Day 1	Initial Dose of 6 mg/kg	If unsatisfactory improvement in clinical condition, as assessed by a healthcare provider, the dose of Gamifant may be increased to: • A maximum cumulative dose of 10 mg/kg over 3 days **AND** the frequency may be increased to: • Every 2 days or once daily After the patient's clinical condition has improved, consider decreasing the dose to the previous level and assess whether clinical response is maintained. If the clinical condition is not stabilized while receiving the maximum dosage, consider discontinuing Gamifant.
Days 4-16	3 mg/kg every 3 days for 5 doses	
Day 19 onwards	3 mg/kg twice per week (i.e., every 3 to 4 days)	

- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., serious infections (including mycobacteria, Herpes Zoster virus, and Histoplasma Capsulatum)
- ❑ Member is receiving ongoing monitoring for adenovirus, EBV, and CMV viruses as clinically indicated

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Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.