

## Letter of Medical Necessity Template for Stimufend® (pegfilgrastim-fpgk)

**[Instructions: Before getting started, check if the health plan has its own request form for supporting medical necessity. If not, draft the letter on your practice's letterhead. As you navigate through the template, please fill in information based on your clinical assessment for your specific patient. Be sure to also include any other pertinent information for your patient.]**

[Date]

[Medical Director Name]

[Payer Name]

[Payer Street Address]

[Payer City, State Zip]

Re: [Patient Full Name]  
[Patient Policy Number]  
[Patient Member ID]  
[Patient Date of Birth]  
[Patient Diagnosis/ICD-10]  
[Prior Authorization or Claim Number]  
[Date(s) of Service]

To Whom It May Concern:

I am writing to provide additional information to support my [Prior Authorization/Claim] for the treatment of [Patient Name] with STIMUFEND® (pegfilgrastim-fpgk) injection, for subcutaneous use.

In brief, treatment of [Patient Name] with STIMUFEND is medically appropriate and necessary and should be a covered and reimbursed service. This letter outlines [Patient Name]'s medical history, prognosis, and treatment rationale.

### Summary of Patient's History

[You may want to briefly explain why this particular patient needs STIMUFEND; consider describing patient's symptoms, therapy to date, risk level of infection/febrile neutropenia associated with current chemotherapy (regimen), additional patient risk factors, a summary of your professional opinion of the patient's likely prognosis without this specific product, and any other pertinent information.]

### Rationale for Treatment

Given the patient's history, condition, and the published data supporting use of STIMUFEND, I believe treatment of [Patient Name] with STIMUFEND is warranted, appropriate, and medically necessary.

Please call my office at the number listed below if I can provide any additional information. I look forward to receiving your timely response and approval of this [Prior Authorization/Claim].

Sincerely,

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[Physician Name]  
[Physician Street Address]  
[Physician City, State, Zip]  
[Participating Provider Number]  
[Physician Phone Number]

Enclosures [Attach additional supporting documents such as patient's treatment with patient's treatment with STIMUFEND® (pegfilgrastim-fpgk), medical history, diagnosis, lab results, STIMUFEND Brief Summary of Prescribing Information and treatment plan.]

## **Important Safety Information**

### **Contraindication**

- Stimufend (pegfilgrastim-fpgk) is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products
- Reactions have included anaphylaxis

### **Splenic Rupture**

- Splenic rupture, including fatal cases, can occur following the administration of pegfilgrastim products
- Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain

### **Acute Respiratory Distress Syndrome (ARDS)**

- ARDS can occur in patients receiving pegfilgrastim products
- Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving Stimufend
- Discontinue Stimufend in patients with ARDS

### **Serious Allergic Reactions**

- Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim products
- The majority of reported events occurred upon initial exposure and can recur within days after the discontinuation of initial anti-allergic treatment
- Permanently discontinue Stimufend in patients with serious allergic reactions

### **Use in Patients with Sickle Cell Disorders**

- In patients with sickle cell trait or disease, severe and sometimes fatal sickle cell crises can occur in patients receiving pegfilgrastim products
- Discontinue Stimufend if sickle cell crisis occurs

### **Glomerulonephritis**

- Has occurred in patients receiving pegfilgrastim products
- Diagnoses based on azotemia, hematuria, proteinuria, and renal biopsy
- Generally, events resolved after dose-reduction or discontinuation of pegfilgrastim products
- If suspected, evaluate for cause and if cause is likely, consider dose-reduction or interruption of Stimufend

#### **Leukocytosis**

- Increased white blood cell counts of  $100 \times 10^9/L$  have been observed
- Monitoring of complete blood count (CBC) during Stimufend therapy is recommended

#### **Thrombocytopenia**

- Thrombocytopenia has been reported in patients receiving pegfilgrastim products. Monitor platelet counts

#### **Capillary Leak Syndrome (CLS)**

- CLS has been reported after G-CSF administration, including pegfilgrastim products
- Characterized by hypotension, hypoalbuminemia, edema and hemoconcentration
- Episodes vary in frequency, severity and may be life-threatening if treatment is delayed
- Patients with symptoms should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care

#### **Potential for Tumor Growth Stimulatory Effects on Malignant Cells**

- G-CSF receptor has been found on tumor cell lines
- The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded.

#### **Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer**

- MDS and AML have been associated with the use of pegfilgrastim products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

#### **Aortitis**

- Aortitis has been reported in patients receiving pegfilgrastim products. It may occur as early as the first week after start of therapy
- Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count)
- Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue Stimufend if aortitis is suspected

#### **Nuclear Imaging**

- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results

**Most common adverse reactions**

- Bone pain
- Pain in extremity

Please see [Stimufend full Prescribing Information](#).

Stimufend Injection: 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only.