

Letter of Appeal Template for Stimufend® (pegfilgrastim-fpgk)

[Instructions: Before getting started, check if the health plan has its own request form for appeals. 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]

Attn: Appeals Department

[Payer Name]

[Payer Street Address]

[Payer City, State Zip]

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

To Whom It May Concern:

This letter serves as a request for reconsideration of payment of a denied [Prior Authorization/Claim] for STIMUFEND® (pegfilgrastim-fpgk) injection, for subcutaneous use for [Patient Name] on [Date(s) of Service].

This patient has been under my care for the treatment of [patient diagnosis] with [chemotherapy (regimen)], which increases the patient's risk of infection as manifested by febrile neutropenia. You have indicated that STIMUFEND is not covered because [reason for denial].

[You may want to explain why this particular patient specifically needs STIMUFEND. Consider providing a tailored account of patient's history and medical needs, describing patient's symptoms, therapy to date, risk level of infection/febrile neutropenia associated with current chemotherapy (regimen), additional patient risk factors, and any other pertinent information, including how STIMUFEND has been effective for this specific patient, that supports this particular patient's need for STIMUFEND, specifically.]

The attached Brief Summary provides the approved clinical information for STIMUFEND. STIMUFEND has been administered as a medically necessary part of this patient's treatment.

I would appreciate reconsideration of coverage for the [Prior Authorization/Claim] for the dates of service referenced above for [Patient Name].

Thank you very much in advance for your time and consideration. Please call my office at the number listed below to discuss how we can facilitate a better patient outcome in an expedited fashion. I am happy to provide any additional needed information. My office hours are as follows: [days/times.]

Sincerely,

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

Enclosures [Attach original prior authorization or claim form, denial/Explanation of Benefits, and additional supporting documents (such as 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.