Stimufend®
pegfilgrastim-fpgk

# CODING AND REIMBURSEMENT GUIDE

## Important Safety Information

## Indication

Stimufend is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Stimufend is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

Limitations of Use

Stimufend is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

**Contraindication**

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

**Please see Important Safety Information throughout this brochure and click to see full Prescribing Information for STIMUFEND (pegfilgrastim-fpgk).**

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# Table of contents



**The content provided in this guide is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment.** It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure STIMUFEND® (pegfilgrastim-fpgk) claims are accurate, complete, and supported by documentation in the patient's medical record. Fresenius Kabi does not guarantee that payers will consider all codes appropriate for all encountered scenarios and Fresenius Kabi does not guarantee STIMUFEND coverage or reimbursement.

Please note that information specific to coding, coverage policies, and payment methodologies is subject to change and should be verified for each patient prior to treatment. The information in this guide is current as of September 2024.

**Please see Important Safety Information throughout this brochure and click to see full Prescribing Information for STIMUFEND (pegfilgrastim-fpgk).**

# KabiCare reimbursement and payment support

Call **1-833-KABICARE**
(1-833-522-4227)
Monday through Friday
8 AM-8 PM ET
(excluding holidays)

Fax **1-833-671-1010**

Visit our website at
**KabiCare.us/hcp/**

KabiCare
Patient Support Program by Fresenius Kabi

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# About the STIMUFEND Coding and Reimbursement Guide

The STIMUFEND® (pegfilgrastim-fpgk) Coding and Reimbursement Guide provides general reimbursement information for healthcare providers. Topics include coding, coverage, billing, and reimbursement for treatment with STIMUFEND, a pegfilgrastim biosimilar.

## About STIMUFEND[1]

**Indication:** Stimufend is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Stimufend is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

Limitations of Use Stimufend is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

**Dosing:** For adult patients with non-myeloid cancer receiving myelosuppressive chemotherapy, the recommended dosage of STIMUFEND is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. Do not administer STIMUFEND between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

Use weight-based dosing for pediatric patients weighing less than 45 kg. Refer to Table 1 (2.2 Administration) in the STIMUFEND full Prescribing Information for dosing for these patients.

**Administration:** STIMUFEND is administered subcutaneously via a single-dose, pre-filled syringe for manual use.

**Please see Important Safety Information throughout this brochure and click to see full Prescribing Information for STIMUFEND (pegfilgrastim-fpgk).**

## INDICATION

Stimufend is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

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Limitations of Use Stimufend is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

## IMPORTANT SAFETY INFORMATION

**Contraindication**

- STIMUFEND 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

Stimufend® pegfilgrastim-fpgk

# STIMUFEND coding overview

## Healthcare Common Procedure Coding System (HCPCS) code[2]

Healthcare Common Procedure Coding Systems (HCPCS) Q-Code assigned to STIMUFEND® for Centers for Medicare & Medicaid Services (CMS) claims processing effective for dates of service on and after **April 1, 2023.**

| HCPCS Code | Description | Sites of Service |
|---|---|---|
| **Q5127** | Injection, pegfilgrastim-fpgk, biosimilar, (STIMUFEND), 0.5 mg | • Physician office<br>• Hospital outpatient |

| Billable Units | Description | Details |
|---|---|---|
| **12** | Billable units for administration of 1 syringe | If applicable, discarded product should be reported on a separate line with Q5127 and the JW modifier |

**Please see Important Safety Information throughout this brochure and click to see full Prescribing Information for STIMUFEND (pegfilgrastim-fpgk).**

## Modifiers[3,4]

Drugs that are administered to patients enrolled in fee-for-service (FFS) Medicare Part B, administered in the hospital outpatient setting, or acquired via the 340B Drug Discount program require modifiers to be reported on claims along with the HCPCS codes. Effective January 1, 2023 (but not required until July 1, 2023), the JZ modifier will be required on the same service line as the drug CPT code when there are no discarded amounts from single-use vials or single-use packages.

| Modifier | Description | Sites of Service |
|---|---|---|
| JG* | Drug or biological acquired with 340B drug pricing program discount | Hospital outpatient |
| TB* | Drug or biological acquired with 340B drug pricing program discount; reported for informational purposes | Hospital outpatient |
| JW | To report the amount of drug or biological that is discarded and eligible for payment under the discarded drug policy | • Physician office<br>• Hospital outpatient<br>• Pharmacy |
| JZ | To report that no amount of drug was discarded and eligible for payment | • Physician office<br>• Hospital outpatient<br>• Pharmacy |

*Beginning January 1, 2018, Medicare requires hospitals to identify certain separately payable drugs or biologics that are acquired through the 340B program and furnished to a Medicare beneficiary. Use of modifier 'JG' or 'TB' may vary based on type of outpatient hospital and payment status indicator of the drug. Providers should verify the appropriate modifier to use when billing for a drug under the 340B program.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Leukocytosis**

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

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## National Drug Code (NDC)

The US Food and Drug Administration assigns a specific 10-digit number called an NDC that is unique based upon the drug's manufacturer, product, and package size. Payers often require an 11-digit NDC format of 5-4-2 on claim forms. The 10-digit NDC can be converted into an 11-digit NDC by adding a zero or asterisk after the fifth number. For example, 12345-123-12 should be reported as 12345012312.

| Product | 10-Digit NDC | 11-Digit NDC |
|---|---|---|
| **STIMUFEND® (pegfilgrastim-fpgk) 6-mg/0.6-mL single-dose, prefilled syringe** | 65219-371-10 | 65219037110 |

## Current Procedural Terminology (CPT®) code[5]

The CPT code is used to report the subcutaneous injection of STIMUFEND by a healthcare professional in a physician office or hospital outpatient clinic.

| Code | Description | Sites of Service |
|---|---|---|
| **96372** | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular | • Physician office<br>• Hospital outpatient |

## Diagnosis codes

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes represent the diagnosis related to the patient's treatment with STIMUFEND. Reimbursement varies by payer.

**Please see Important Safety Information throughout this brochure and click to see full Prescribing Information for STIMUFEND (pegfilgrastim-fpgk).**

## Revenue codes[6]

Revenue codes are used to categorize hospital services by revenue or cost center. Each service provided in the hospital has its own revenue code. Examples for STIMUFEND may include:

| Code | Description | Details |
|---|---|---|
| 0636 | Drugs requiring detailed coding | Used in combination with HCPCS drug code |
| 0510 | Clinic visit | Used in combination with CPT injection code |
| 0250 | General pharmacy | Used in combination with HCPCS drug code |



## Payment status indicator[7]

Identifies whether a service represented by a CPT or HCPCS code is payable under the Outpatient Prospective Payment System (OPPS) Ambulatory Payment Classification (APC) or another payment system. Only 1 status indicator is assigned to each CPT or HCPCS code.

| HCPCS Code | Description | Status Indicator |
|---|---|---|
| Q5127 | Injection, pegfilgrastim-fpgk, biosimilar, (STIMUFEND), 0.5 mg | K |

## IMPORTANT SAFETY INFORMATION (cont'd)

**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

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# STIMUFEND treatment approval process

## Benefits verification

Complete a thorough assessment and investigation of benefits before administering STIMUFEND® (pegfilgrastim-fpgk) to determine that the patient's coverage is in effect at the time of injection and to see if any additional information is required to obtain coverage.

## Benefits verification checklist

**Confirm the following with the patient's insurance plan:**

- ✓ The patient is actively covered
- ✓ Insurance policy effective and termination dates
- ✓ Whether the patient has a secondary insurer (in addition to primary)
- ✓ Whether the product is covered under medical benefit, pharmacy benefit, or both
- ✓ The insurance holder's name and relationship to the patient
- ✓ In-network or out-of-network coverage
- ✓ HCPCS Q-Code, CPT® code for administration, diagnosis code, and number of units covered
- ✓ Whether a prior authorization (PA) and supplemental documentation/medical record is required
- ✓ The patient's financial responsibility (co-pay, co-insurance percentage, deductible)
- ✓ The policy limits, including exclusions or documentation requirements
- ✓ If uninsured, whether the patient may be eligible for the Patient Assistance Program

› **Please contact KabiCare for assistance**

**Please see Important Safety Information throughout this brochure and click to see full Prescribing Information for STIMUFEND (pegfilgrastim-fpgk).**

## KabiCare

Fresenius Kabi created the KabiCare Patient Support Program to work closely with patients and healthcare providers to help navigate insurance, financial assistance, and medication access needs to simplify the treatment journey. KabiCare conducts a benefits assessment on behalf of the patient to confirm insurance coverage details. The information is provided to you, your practice, and your patient to aid in patient access to STIMUFEND.

Enrollment provides patients access to support programs and resources to help guide their treatment journey. Healthcare providers can upload enrollment forms as well as track progress and status of benefits via the KabiCare provider portal. If eligible, a patient will automatically be enrolled into copay as part of full enrollment into the KabiCare Patient Support Program.

To upload a patient enrollment form on-line, access the KabiCare provider portal at **kabicare.trialcard.com** and create an account.

*OR*

Access the full program enrollment form at **kabicare.us** and fax to the number on the form. To avoid delays, please be sure to include both your and your patient's signatures on the completed form.

**Forms can be faxed to 1-833-671-1010**

## IMPORTANT SAFETY INFORMATION (cont'd)

**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

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## Prior authorization (PA)

During benefit assessment, the payer may require a PA—a standard process to confirm the medical necessity of the medication. Requirements may include filling out a specific PA form or writing a letter of medical necessity, but they vary by insurer.

To see a sample letter of medical necessity, scan the QR code with your phone:

StimufendHCP.com/resources

## Please contact KabiCare for assistance

**KabiCare resources include:**

- ✓ Gathering specific payer requirements
- ✓ Sending the appropriate PA form with patient demographics populated (clinical information to come from the provider)
- ✓ Following up on submitted PA status and communicating to the HCP office
- ✓ Providing a sample letter of medical necessity, Prescribing Information, and FDA approval letter

## Copay support*


- Patients with commercial or private insurance may be eligible† for the copay program that lowers out-of-pocket costs to as little as $0/month with annual maximum
- Learn more at KabiCare.us or call 1-833-KABICARE (1-833-522-4227) Monday through Friday from 8 AM-8 PM ET (excluding holidays)

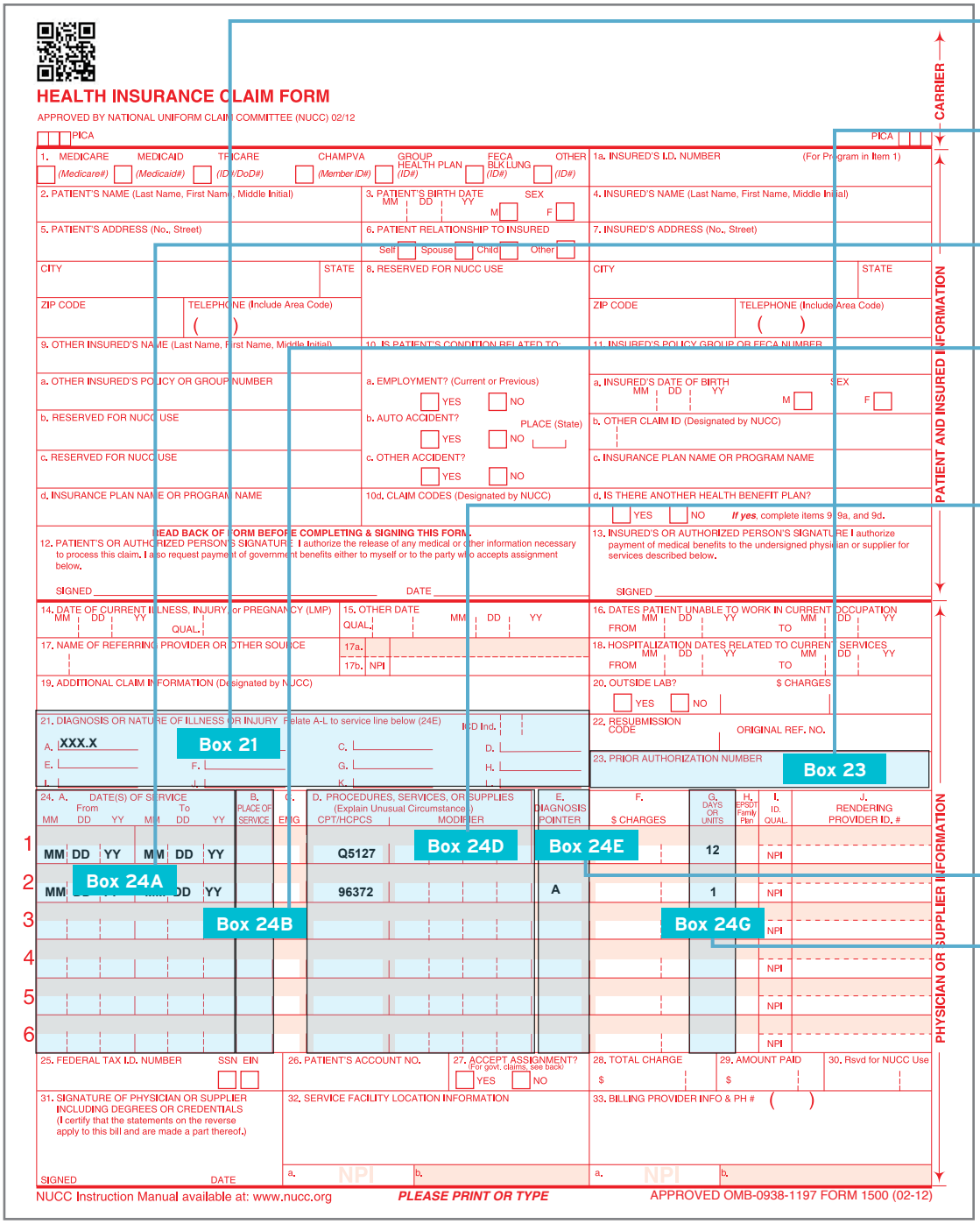
*Please see back cover for additional financial support, including patient assistance and bridge programs.
†Eligibility criteria apply. Patients are not eligible for commercial copay support if the prescription is eligible to be reimbursed, in whole or in part, by any state or federal healthcare program.

# STIMUFEND® (pegfilgrastim-fpgk) reimbursement process

## Submitting the claim form

Submit the claim form to the patient's insurance provider. Ensure the diagnosis code matches the one in the PA form, and that the claim is submitted within the acceptable timeframe after the services or medication were provided.

# Sample CMS-1500 Claim Form
## (physician office site of service)




**Box 21: Diagnosis**

Enter appropriate ICD-10-CM diagnosis code(s)

**Box 23: Prior Authorization (PA)**

Enter the PA number as obtained before services were rendered

**24A: Date(s) of Service**

Enter NDC qualifier "N4" and the NDC

**Box 24B: Place of Service**

Enter the appropriate Place of Service. Examples: 11-Physician's Office, 49-Independent Clinic

**Box 24D: Procedures, Services, or Supplies**

Enter appropriate HCPCS and CPT codes. For example:

- Drug: HCPCS Code Q5127
- Administration: 96372 for subcutaneous injection

Note: Include the JZ Modifier if no amount of drug was discarded. Discarded product should be reported on a separate line with Q5127 and the JW modifier.

**24E: Diagnosis Pointer**

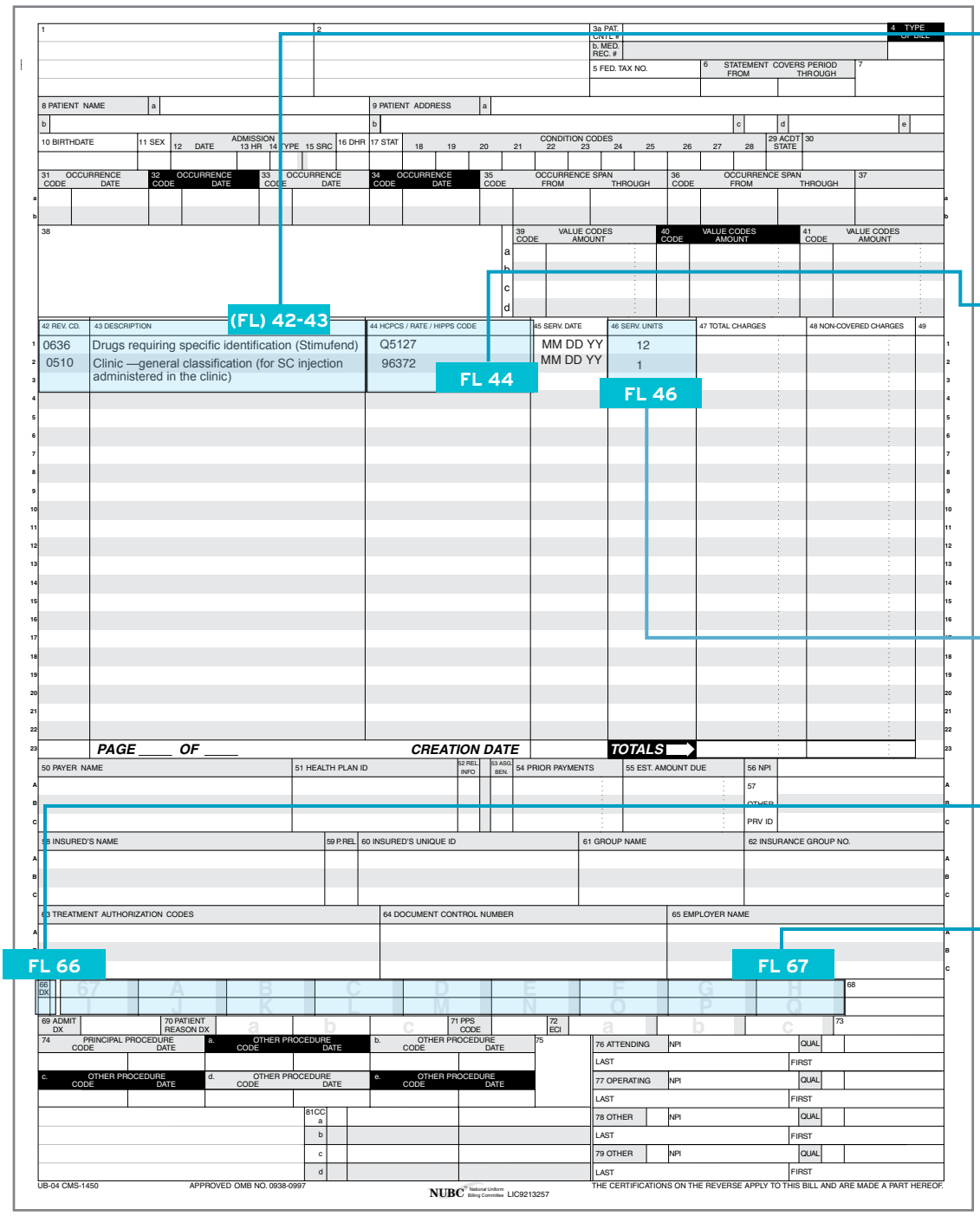
Enter the letter (A-L) from Box 21 that corresponds to the diagnosis in item 21

**Box 24G: Units**

Enter the appropriate number of units. For example, 12 billing units for administration of 1 syringe of STIMUFEND (pegfilgrastim-fpgk) 0.5 mg

These sample claim forms are for informational purposes only and are not intended to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare provider to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure STIMUFEND® (pegfilgrastim-fpgk) claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee STIMUFEND coverage or reimbursement.

# Sample CMS-1450 (UB-04) Claim Form
## (hospital outpatient site of service)




**Form Location (FL) 42-43**

Enter the appropriate revenue code and procedure description. For example:

- 0636: drugs requiring detailed coding
- 0510: clinic—general classification (for SC injection administered in the clinic)

**FL 44**

Enter appropriate HCPCS and CPT codes and modifiers. For example:

- Drug: HCPCS Code Q5127
- Administration: 96372 for subcutaneous injection

Note: Include the JZ Modifier if no amount of drug was discarded. Discarded product should be reported on a separate line with Q5127 and the JW modifier.

**FL 46**

Enter the appropriate number of units. For example, 12 billing units for administration of 1 syringe of STIMUFEND® (pegfilgrastim-fpgk) 0.5 mg

**FL 66**

Identify the type of ICD diagnosis code used (eg, enter a "0" for ICD-10-CM)

**FL 67**

Enter appropriate ICD-10-CM diagnosis code(s). For example, ICD-10-CM:D70.9 for neutropenia

## Additional documentation for filing your claim

In addition to the CMS-1500 or CMS-1450/UB-04 claim form, the payer may request the following:

- Patient medical history
- Physician clinical notes
- Letter of medical necessity (see sample at StimufendHCP.com/resources)
- PA number
- Drug-identifying information (eg, NDC)

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# Reimbursement for injectable drugs—payment rates

## Medicare[8]

When administered by a physician, injectable products will be covered under the following manner(s):

1) Medicare Fee-For-Service Part B
2) Where a Medicare Advantage Part B coverage decision has been made
3) Where a Medicare Part D coverage decision has been made

Newly approved drugs generally take about 2 quarters, or 6 months, for an ASP to be established. In lieu of an ASP, reimbursement is determined by the wholesale acquisition cost (WAC) or, if C9399 HCPCS code is used, by average wholesale price (AWP). For a new drug, CMS uses WAC data until there is a full quarter of ASP data available (with a two-quarter lag). Thus, Medicare reimbursement for a new drug may remain at WAC plus 3% for up to 9 months following the initial release of that drug.

| Sites of Service | Medicare Payment | Description |
|---|---|---|
| **Infusion centers/ physician office; hospital outpatient departments—340B and non-340B entities** | WAC + 3% of Biosimilars WAC | Newly approved FDA drug; ASP not yet established |
| | ASP + 6% of Neulasta® (pegfilgrastim) ASP | Biosimilars with an established ASP that is greater than or equal to the reference product's ASP |
| | ASP + 8% of Neulasta ASP* | Biosimilars with an established ASP that is less than the reference product's ASP |

*Biosimilars are eligible for an increased add-on payment for a 5-year period.

**Please see Important Safety Information throughout this brochure and click to see full Prescribing Information for STIMUFEND (pegfilgrastim-fpgk).**

## Sequestration

Due to across-the-board cuts in federal spending known as sequestration, Medicare covers 80% of the payment to providers, which is reduced by 2%. This affects payment for Part B–covered drugs along with payment for professional services, such as the administration of the STIMUFEND injection. Sequestration does not affect the patient's share of costs.

## Commercial payers, Medicare Advantage (Part C), and Managed Medicaid

These payers typically reimburse physicians and hospitals based on individual contracts set up between the provider and payer.

## Medicaid

Individual payment rates are determined by each Medicaid state agency. Payment plans are publicized via a fee schedule.

## IMPORTANT SAFETY INFORMATION (cont'd)

**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

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

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## Submitting for copay assistance

For patients enrolled in KabiCare, a Patient Support Guide will help providers navigate through the financial assistance process for eligible patients. Eligible patients who are not enrolled in KabiCare will be able to get copay assistance by visiting https://portal.trialcard.com/Fresenius-Kabi/kabicopay*

## Claim denials and appeals

### Denials

Review the Explanation of Benefits (EOB) provided by the payer to find out why a claim was denied. Reasons may include incorrect billing codes or member identification number, incomplete medical necessity support, transposed patient information, inaccurate number of units, incorrect modifier, incompatible site of service, or erroneous description of services provided.

### Appeals

If a claim denial cannot be overturned via a phone call to the payer, a letter of appeal may be submitted. Ensure the appeal is submitted within the filing time limit, and the reasons for the denied claim outlined in the EOB are understood. To see a sample letter of appeal, visit StimufendHCP.com/resources.

#### Preventing claim processing delays

- Provide appropriate medical record documentation to justify coding
- Include additional information required by payer when submitting a miscellaneous code
- Ensure claim was successfully submitted
- Check for changes and updates to payer coding and coverage policies

*Eligibility criteria apply. Patients are not eligible for commercial copay support if the prescription is eligible to be reimbursed, in whole or in part, by any state or federal healthcare program.

# References


1. STIMUFEND® (pegfilgrastim-fpgk) Prescribing Information. Fresenius Kabi, LLC; 2023.
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**Please see Important Safety Information throughout this brochure and click to see full Prescribing Information for STIMUFEND (pegfilgrastim-fpgk).**

# Fresenius Kabi provides comprehensive patient support

We are dedicated to providing your patients with ongoing support to help them access Fresenius Kabi medications as prescribed.

## KabiCare Program

- Centralized provider portal for submitting enrollments and tracking patient status
- Dedicated support to address access challenges, including benefits investigation/verification, prior authorization, and appeals
- Financial support, including copay assistance with out-of-pocket costs as little as $0 for commercially insured patients prescribed STIMUFEND® (pegfilgrastim-fpgk)*
- Bridge to Therapy program to avoid treatment delay (eligibility criteria apply*)

› To access the provider portal visit kabicare.trialcard.com and set up an account. To download the enrollment form, visit kabicare.us.

Additional patient support available throughout their treatment journey

- Educational resources designed for patients about disease, medication, and health and well-being
- Identifying potential treatment-related transportation and lodging benefits with patient's insurance or provide list of independent foundations†
- KabiCare clinical support can provide medication counseling and answer questions your patient may have about their Fresenius Kabi biosimilar‡

KabiCare
Patient Support Program by Fresenius Kabi

To learn more, please visit **KabiCare.us** or call **1-833-KABICARE (1-833-522-4227)**

Contact your STIMUFEND Key Account Manager to connect with a Field Reimbursement Manager, who is available to share the latest updates in payer coverage and to guide providers in securing access and coverage for patients. They can assist with billing and coding, reimbursement, and KabiCare patient support offerings.

*Eligibility criteria apply. Patients are not eligible for commercial copay assistance or Bridge to Therapy program support if the prescription is eligible to be reimbursed, in whole or in part, by any state or federal healthcare program.
†Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Fresenius Kabi has no control over these programs.
‡Clinical support is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.

**Please see Important Safety Information throughout this brochure and click to see full Prescribing Information for STIMUFEND (pegfilgrastim-fpgk).**

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