Stimufend®
pegfilgrastim-fpgk

**STIMUFEND® (pegfilgrastim-fpgk)**
**Injection for subcutaneous use**

# Billing & Coding Guide

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

FRESENIUS KABI

# STIMUFEND® (pegfilgrastim-fpgk) Billing and Coding Guide

## The STIMUFEND® Billing and Coding Guide provides general reimbursement information for healthcare providers.

**Topics include billing, coding, coverage, and reimbursement for treatment with STIMUFEND®.**

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® 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.

## INDICATIONS AND USAGE[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.

For patients with hematopoietic subsyndrome of acute radiation syndrome, the recommended dose of STIMUFEND® is two doses, 6 mg each, administered subcutaneously one week apart.

For dosing in 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. Administer the first dose as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray. Administer the second dose one week after the first dose.

Obtain a baseline complete blood count (CBC). Do not delay administration of STIMUFEND® if a CBC is not readily available. Estimate a patient's absorbed radiation dose (i.e., level of radiation exposure) based on information from public health authorities, biodosimetry if available, or clinical findings such as time to onset of vomiting or lymphocyte depletion kinetics.

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

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### 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



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## 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 | Billable Units |
|---|---|---|---|
| **Q5127** | Injection, pegfilgrastim-fpgk, biosimilar, (STIMUFEND®), 0.5 mg | • Physician office<br>• Hospital outpatient | 12<br>(Billable units for administration of 1 syringe) |

Details: 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. Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment.

**Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing, coding, and KabiCare patient support offerings.**

# MODIFIERS

| Summary of Code Modifiers | | | | |
|---|---|---|---|---|
| **Modifier** | **Description[3]** | **Indication and Placement[4,5]** | **CMS-1500 (Item 24D)** | **CMS-1450 (Box 44)** |
| JW | Drug amount discarded/not administered to any patient | Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial. | ✓ Required by Medicare | ✓ Required by Medicare |
| JZ | Zero drug amount discarded/not administered to any patient | To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage). | ✓ Required by Medicare | ✓ Required by Medicare |
| TB* | Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities | TB modifier is used to identify drugs or biologicals acquired through the 340B Drug Pricing Program for informational purposes.<br>The TB modifier is required for all 340B covered entities, including hospital-based and non-hospital-based entities, for claims with dates of service beginning on or after January 1, 2025.<br>TB modifier to be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs. | N/A | ✓ Required by Medicare |

* CMS is requiring all 340B covered entities, including hospital-based and non-hospital-based entities, that submit claims for separately payable Part B drugs and biologicals to discontinue the use of modifier "JG" on claim lines for drugs acquired through the 340B Drug Pricing Program after December 31, 2024.

## Important Safety Information (continued)

**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

**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)



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# NDC Numbers and CPT Codes

## What codes do I use to bill for STIMUFEND® (pegfilgrastim-fpgk)?

- A new prescription is required for STIMUFEND®.
- To ensure your patient will receive STIMUFEND®, please select the appropriate dosing from the Enrollment and Prescription Form or when prescribing electronically.

## National Drug Code (NDC)[1]

Electronic data exchange standards usually require the use of an 11-digit NDC. Check with the payer to confirm the correct code required when billing to STIMUFEND®.

| Dosage Form | Description | 10-digit NDC Code | 11-digit NDC Code |
|---|---|---|---|
| Subcutaneous Injection | 6 mg/0.6 mL, single-dose prefilled syringe | 65219-371-10 | 65219-0371-10 |

## Current Procedural Terminology (CPT) Code[6]

CPT codes are the standard coding system for reporting medical procedures and services under both public and private health insurance plans.

| Type | Code | Description |
|---|---|---|
| CPT Code | 96372 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular. |

All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement. Medicare requires detailed documentation to support a complex infusion code claim.

## 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.

## Revenue codes[7]

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:

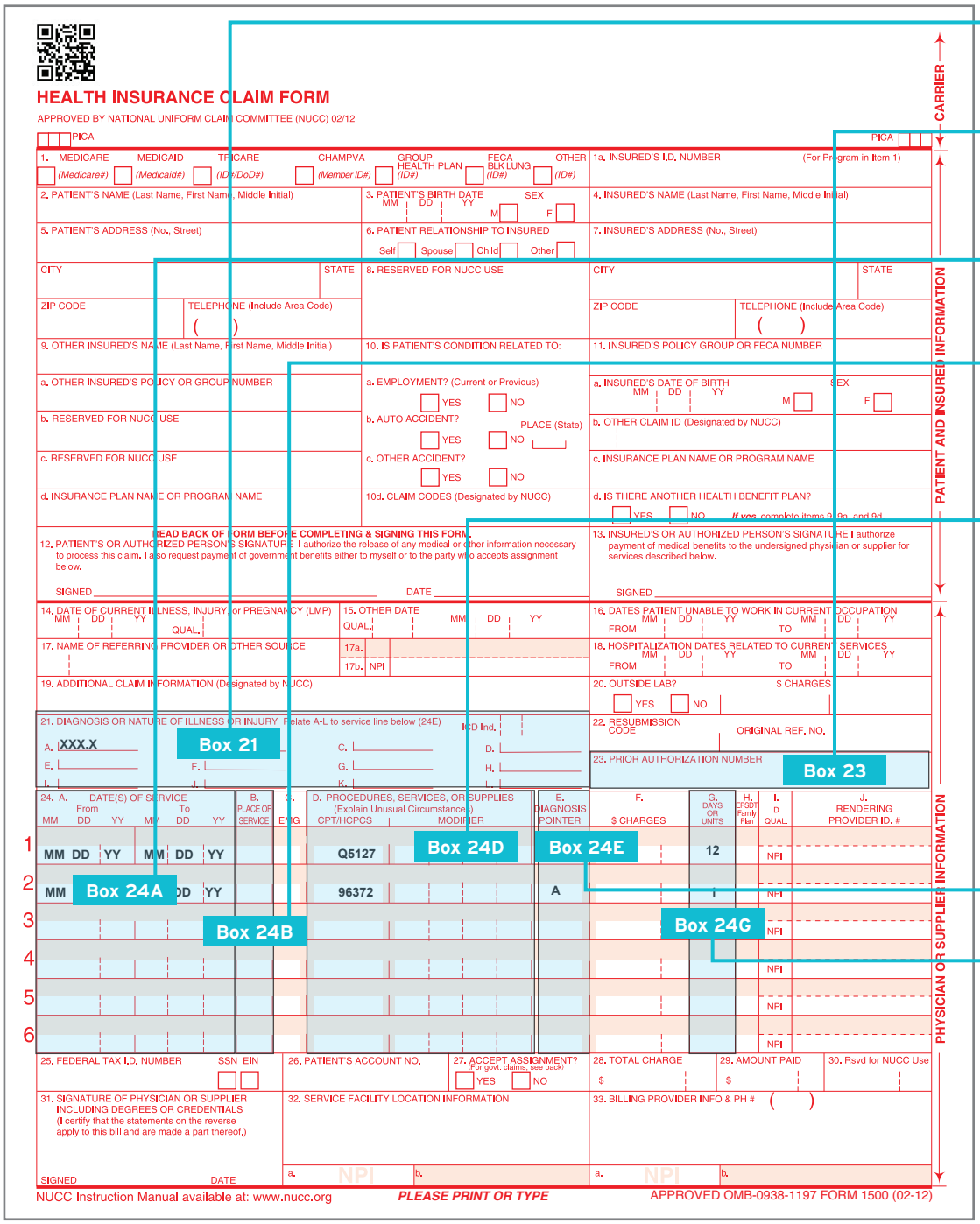
| Code | Description | Details |
|---|---|---|
| **0636** | Drugs requiring detailed coding | Used in combination with HCPCS drug code |
| **0510** | Clinic visit | Used in combination with CPT injection code |
| **0250** | General pharmacy | Used in combination with HCPCS drug code |

## Payment status indicator[8]

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 |

# Sample CMS-1500 Claim Form
## (physician office site of service)[9]




**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.



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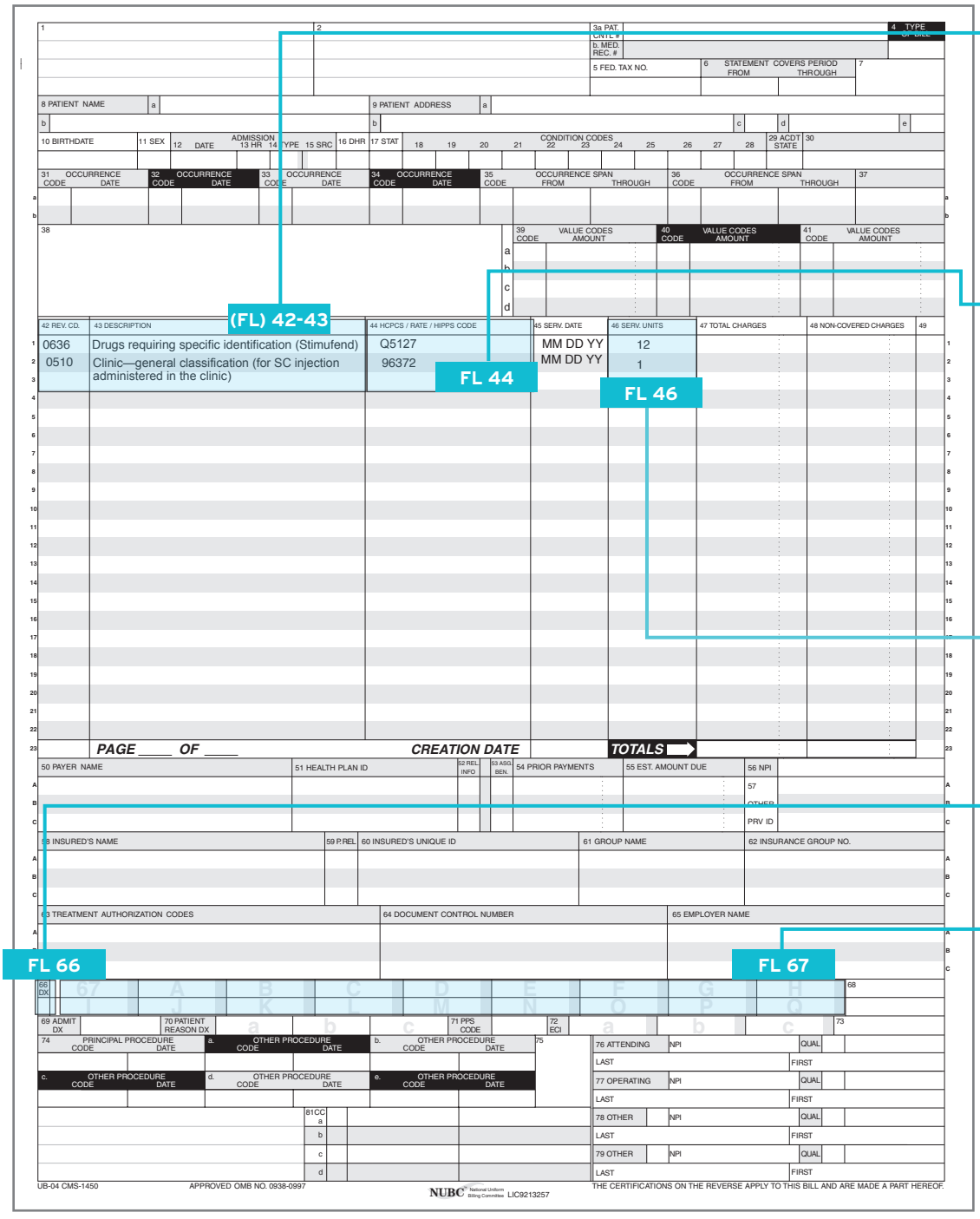
# Sample CMS-1450 (UB-04) Claim Form
## (hospital outpatient site of service)[10]




**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 (e.g., 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 (e.g., NDC)

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# KabiCare Reimbursement and Payment Support

## KabiCare supports obtaining access for your patients

### Enrollment Support

- **Case Management Support** – KabiCare helps your team navigate insurance processes and provides information related to your patient's insurance coverage. After enrollment is complete and insurance is confirmed, your patient will receive a phone call from KabiCare to review their benefits and discuss other KabiCare resources that may be available.
- **Provider Access** – Centralized provider portal for submitting enrollments and checking patient status.

### Insurance Support

- **Bridge to Therapy** – The Bridge to Therapy Program provides commercially insured patients access to treatment without delay while they are waiting for insurance approval. Eligibility criteria apply.*
- **Benefits Investigation** – Once your patient is enrolled, KabiCare conducts the benefits investigation 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.
- **Prior Authorization Support** – If a prior authorization is needed, KabiCare will provide the appropriate forms to the office for completion and will help follow up on the status.
- **Billing & Coding Support** – KabiCare offers reimbursement resources to help you submit claims and understand eligibility for reimbursement.†
- **Claims Appeals Support** – Should a claim or prior authorization be denied, KabiCare will provide the appropriate appeal documentation and the information required to contest the denial similar to the prior authorization process. Visit KabiCare.us for a Sample Letter of Medical Necessity and Sample Letter of Appeal.

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

† Terms and conditions apply.

‡ 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 provided by KabiCare is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.

# KabiCare Contact Information

## Financial Support

- **Commercial Copay Support** – If your patient has commercial or private insurance, they may be eligible* for the copay program that lowers their out-of-pocket costs to as little as $0/month for treatment with an annual maximum.
- **Patient Assistance Program** – If your patient does not have insurance or their plan does not cover their medication, they may be eligible for additional assistance through the Patient Assistance Program or through independent nonprofit assistance programs. Eligibility criteria apply.‡

## Clinical Support

- **Clinical Support** – KabiCare clinical support can provide medication counseling, offer self-injection training for applicable products, and answer questions your patient may have about their Fresenius Kabi biosimilar.§
- **Transportation & Lodging** – KabiCare will look into potential transportation and lodging benefits that may be offered by your patient's insurance. A list of independent foundations‡ are provided to patients when treatment-related transportation and lodging assistance are needed.

KabiCare
Patient Support Program by Fresenius Kabi

**Call 1-833-KABICARE**
(1-833-522-4227)
Monday through Friday
8 a.m. to 8 p.m. ET
(excluding holidays)

Fax 1-833-302-1420

Visit our website at KabiCare.us

To learn more about the KabiCare patient support program, please scan the QR code:

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

# STIMUFEND® (pegfilgrastim-fpgk) 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 (copay, coinsurance 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**

Important Safety Information (continued)

- 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



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# Notes

## Important Safety Information (continued)

**Indications and Usage**

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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.

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

Stimufend®
pegfilgrastim-fpgk

# STIMUFEND® (pegfilgrastim-fpgk) offers resources to help your patients start and stay on prescribed therapy

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

**Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing, coding, and KabiCare patient support offerings.**

**References: 1.** STIMUFEND® (pegfilgrastim-fpgk) Prescribing Information. Fresenius Kabi, LLC; 2023. **2.** CMS.gov. Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding recommendations. Updated October 1, 2022. Accessed. August 27, 2024. https://www.cms.gov/files/document/2022-hcpcs-application-summary-quarter-4-2022-drugs-and-biologicals-updated-02/01/2023.pdf **3.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update: January 2025 Alpha-Numeric HCPCS Files [zip file]. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update. Page last modified December 17, 2024. Accessed January 10, 2025 **4.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17: Drugs and Biologicals. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf. Revised February 15, 2024. Accessed January 10, 2025 **5.** Centers for Medicare & Medicaid Services. Medicare Part B inflation rebate guidance: Use of the 340B Modifier. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf. Accessed January 10, 2025 **6.** American Medical Association. CPT® 2021 Professional Edition. Chicago, IL: American Medical Association; 2020. **7.** Research Data Assistance Center. Revenue center code. Updated 2020. Accessed August 27, 2024. https://resdac.org/sites/datadocumentation.resdac.org/files/Revenue%20Center%20Code%20Code%20Book%20%28FFS%29.txt **8.** CMS.gov. April 2023 update of the hospital outpatient prospective payment system (OPPS). Updated March 10, 2023. Accessed February 25, 2025. https://www.cms.gov/files/document/mm13136-hospital-outpatient-prospective-payment-system-april-2023-update.pdf **9.** Medicare claims processing manual, Chapter 26 - Completing and Processing Form CMS-1500 Data Set. cms.gov. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf. Accessed January 15, 2025. **10.** Medicare claims processing manual, Chapter 25 - Completing and Processing the Form CMS-1450 Data Set. cms.gov. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25pdf.pdf. Accessed January 15, 2025.

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