Pfizer Oncology together™

INJECTION
Nivestym®
filgrastim-aafi
Pfizer

NIVESTYM® (filgrastim-aafi) Billing and Coding Guide

Please see Important Safety Information and Indications on pages 13-15 and click here for full Prescribing Information and Patient Information.

Introduction

Pfizer Inc. has developed this reference guide to assist healthcare providers (HCPs) with understanding coding for NIVESTYM (filgrastim-aafi), a filgrastim biosimilar approved for use in the United States for intravenous or subcutaneous use.

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for NIVESTYM. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for treatment of his/her patients. The information provided should not be considered a guarantee of coverage or reimbursement for NIVESTYM.

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Making your patients' support needs a priority. Together.

At Pfizer Oncology Together, patient support is at the core of everything we do. We've gathered resources and developed tools to help patients and their loved ones throughout NIVESTYM treatment. From helping to identify financial assistance options to connecting patients to resources for emotional support, your patients' needs are our priority.*

Benefits Verification

We can help determine a patient's coverage and out-of-pocket costs.

Prior Authorization (PA) Assistance

We can coordinate with a patient's insurer to determine the PA requirements. After a PA request is submitted, we can follow up with the payer until a final outcome is determined.

Appeals Assistance

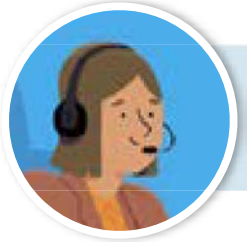
We can review the reasons for a denied claim and provide information on payer requirements. After an appeal is submitted, we can follow up with the payer until a final outcome is determined.

Billing and Coding Assistance for Injectable Products

For your patient claim submissions, we provide easy access to sample forms and template letters, along with billing and coding information for physician office and hospital outpatient settings of care.

Patient Financial Assistance

We can help patients understand their benefits and connect them with financial assistance resources.



FOR LIVE, PERSONALIZED SUPPORT
Call **1-877-744-5675** (Monday–Friday 8 AM–8 PM ET)

VISIT
PfizerOncologyTogether.com

*Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.

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Coding Overview

In the physician office and hospital outpatient department sites of care, Medicare Administrative Contractors (MACs), private commercial payers, and Medicaid may recognize the following codes for reporting NIVESTYM on claim forms.

Coding for NIVESTYM

Effective for dates of service on or after October 1, 2018, the Centers for Medicare & Medicaid Services (CMS) has assigned a new product-specific Healthcare Common Procedure Coding System (HCPCS) code for NIVESTYM.[1]

HCPCS Code[1]	Descriptor
Q5110	Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram

Modifiers may be included on claims to provide additional information. Some payers may require modifiers JA or JB to be reported, indicating the route of administration. The JW modifier is used to report the amount of the drug that is unused after administration to a patient. For Medicare and some payers, the unused amount should be reported on a separate line of the claim form, and the claim should include the drug code, modifier, and number of units discarded.[2] Additional modifiers may also be considered appropriate when submitting claims.

HCPCS Modifier[1,2]	Descriptor
JA	Intravenous administration
JB	Subcutaneous administration
JW[a]	Drug amount discarded/not administered to any patient
JZ[a]	Zero drug amount discarded/not administered to any patient

[a]Use of the JZ modifier (in situations where it applies) is required on Medicare claims with a date of service on or after 7/1/2023. An applicable claim without modifier JW or JZ may be rejected beginning on 10/1/2023.

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NIVESTYM National Drug Codes

National Drug Codes (NDCs) are unique 10-digit, 3-segment numbers used to identify drugs.[3]

Strength[4]	Vial/Prefilled Syringe Size	10-Digit NDC
Single Unit of Use		
300 mcg/0.5 mL	1 prefilled syringe	0069-0291-01
480 mcg/0.8 mL	1 prefilled syringe	0069-0292-01
300 mcg/mL[5]	1 single-dose vial	0069-0293-01
480 mcg/1.6 mL[5]	1 single-dose vial	0069-0294-01
Packs of 10		
300 mcg/0.5 mL	Pack containing 10 prefilled syringes	0069-0291-10
480 mcg/0.8 mL	Pack containing 10 prefilled syringes	0069-0292-10
300 mcg/mL	Pack containing 10 single-dose vials	0069-0293-10
480 mcg/1.6 mL	Pack containing 10 single-dose vials	0069-0294-10

NDC Conversion Example

For reimbursement purposes, some payers may require the HCP to include NDCs on the claim form. For claims-reporting purposes, some payers may also require HCPs to convert the 10-digit NDC to an 11-digit NDC by adding a "0" (zero) where appropriate to create a 5-4-2 configuration. The zero is added in front of the first segment of numbers when the 10-digit format is the 4-4-2 configuration. See placement of the red zero in the example below.

Strength	Vial/Prefilled Syringe Size	10-Digit NDC	11-Digit NDC
Single Unit of Use			
300 mcg/0.5 mL	1 prefilled syringe	0069-0291-01	00069-0291-01

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Coding for NIVESTYM Administration Services

Current Procedural Terminology (CPT®) codes define specific medical procedures performed by physicians.[6]
The following codes may be used to report the administration of NIVESTYM:

Type of Code	*Code/Descriptor*	*Relevant Sites of Service*
Administration: CPT® codes[6]	**96365:** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour (Used for an IV infusion lasting greater than 15 min)	Physician office and hospital outpatient department
	96367: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure) (Used for an IV infusion lasting greater than 15 min)	
	96372: Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular	
	96374: Therapeutic, prophylactic, or diagnostic injection; intravenous push, single or initial substance/drug (Used for a short IV infusion lasting 15 min or less)	
	96375: Therapeutic, prophylactic, or diagnostic injection; each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure) (Used for a short IV infusion lasting 15 min or less)	
	96379: Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion (Used for a continuous IV infusion)	

Hospital outpatient departments use revenue codes to report specific accommodations and/or ancillary charges.[7]

Type of Code	*Code/Descriptor*	*Relevant Sites of Service*
Revenue codes[8]	**0636:** Drugs requiring specific identification – detailed coding (For NIVESTYM)	Hospital outpatient department
	0260: IV therapy – general classification (For IV injection administered in the hospital outpatient department)	
	0510: Clinic – general classification (For IV injection administered in the clinic)	

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Diagnosis Coding for NIVESTYM

NIVESTYM (filgrastim-aafi) is an FDA-approved biosimilar.

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code set should be used, as appropriate, to report the patient-specific diagnosis.

Reporting the medical necessity for NIVESTYM may require a primary as well as secondary diagnosis, in some cases. HCPs should verify payer-specific coding requirements before submitting a claim and the order of required codes (eg, primary, secondary, etc), as these may vary by payer. ICD-10-CM codes may include, but are not limited to, the following codes listed below:

ICD-10-CM Code[9]	*Code/Descriptor*
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.40	Acute promyelocytic leukemia, not having achieved remission
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality, not having achieved remission
C92.62	Acute myeloid leukemia with 11q23-abnormality, in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C00.0–C96.9	(Other nonmyeloid malignancy, as applicable)
D70.0	Congenital agranulocytosis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.3	Neutropenia due to infection
D70.4	Cyclic neutropenia
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
Z48.290	Encounter for aftercare following bone marrow transplant
Z94.81	Bone marrow transplant status

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NIVESTYM Billing Units

The NIVESTYM HCPCS code Q5110 is described as "Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram." Each dose increment of 1 microgram equals 1 billing unit. For example, a 300 mcg/mL vial of NIVESTYM represents 300 billing units of Q5110. See the chart below correlating a vial and syringe of NIVESTYM administered with the number of billing units based on the description of Q5110.

Strength	*Vial/Prefilled Syringe Size*	*Number of Q5110 Billing Units (1 mcg filgrastim-aafi biosimilar per 1 billing unit) Equivalent to the Micrograms of NIVESTYM in Each Vial/ Prefilled Syringe*
300 mcg/mL	1 mL single-dose vial	300 units
300 mcg/0.5 mL	1 prefilled syringe	300 units
480 mcg/0.8 mL	1 prefilled syringe	480 units
480 mcg/1.6 mL	1.6 mL single-dose vial	480 units

Claims Submission Checklist

The following may be considered to assist with submitting claims completely and accurately, which is important for timely claims processing, for appropriate payment, and to avoid denied claims.

- ☑ **Provide the patient name, address, and insurance identification number, and review these for accuracy**
- ☑ **Include the HCP's name, National Provider Identifier (NPI), and payer-specific provider ID (if applicable)**
- ☑ **Indicate the appropriate place of service code (2-digit code) for where the treatment was provided**
- ☑ **Check to ensure that ICD-10-CM diagnosis codes, CPT procedure codes, and modifiers (if applicable) are consistent with information included in the patient's medical record**
- ☑ **Review the NIVESTYM-specific information (eg, name of drug, HCPCS code, NDC, number of units, route, and frequency of administration)**

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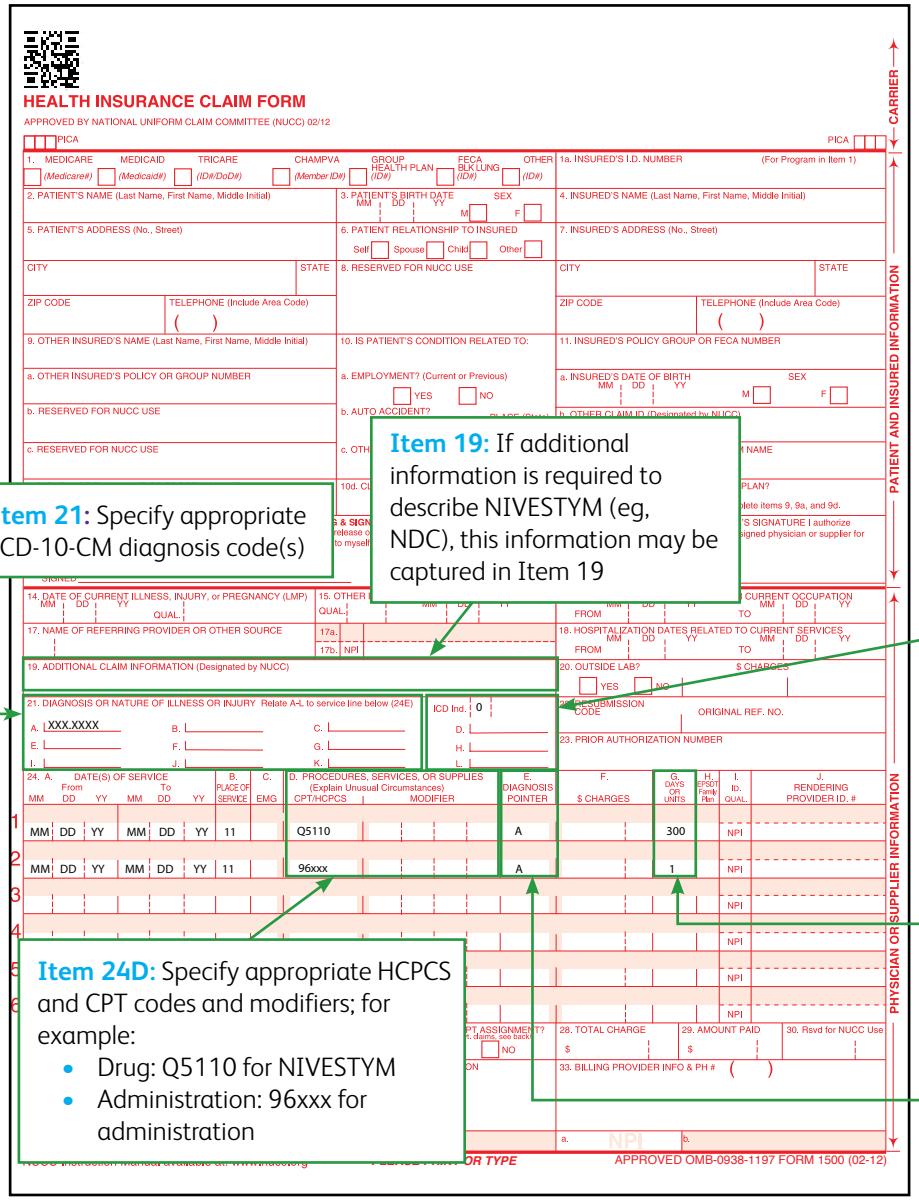
Sample Claim Form: CMS-1500, Physician Office Site of Service



This sample form is intended as a reference for the coding and billing of NIVESTYM. This form is not intended to be directive and the use of the recommended codes does not guarantee reimbursement. HCPs may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.

Item 21: Specify appropriate ICD-10-CM diagnosis code(s)

Item 19: If additional information is required to describe NIVESTYM (eg, NDC), this information may be captured in Item 19

Item 21: Identify the type of ICD diagnosis code used (eg, enter a "0" for ICD-10-CM)

Item 24G: Specify the billing units. For example, 1 billing unit = **1** mcg of filgrastim-aafi biosimilar (NIVESTYM) for HCPCS code Q5110. To bill 300 mcg of NIVESTYM, enter 300 billing units. To bill 1 96xxx for drug administration, enter 1 billing unit

Item 24D: Specify appropriate HCPCS and CPT codes and modifiers; for example:

- Drug: Q5110 for NIVESTYM
- Administration: 96xxx for administration

Item 24E: Enter reference to the diagnosis for the CPT and HCPCS codes from Item 21

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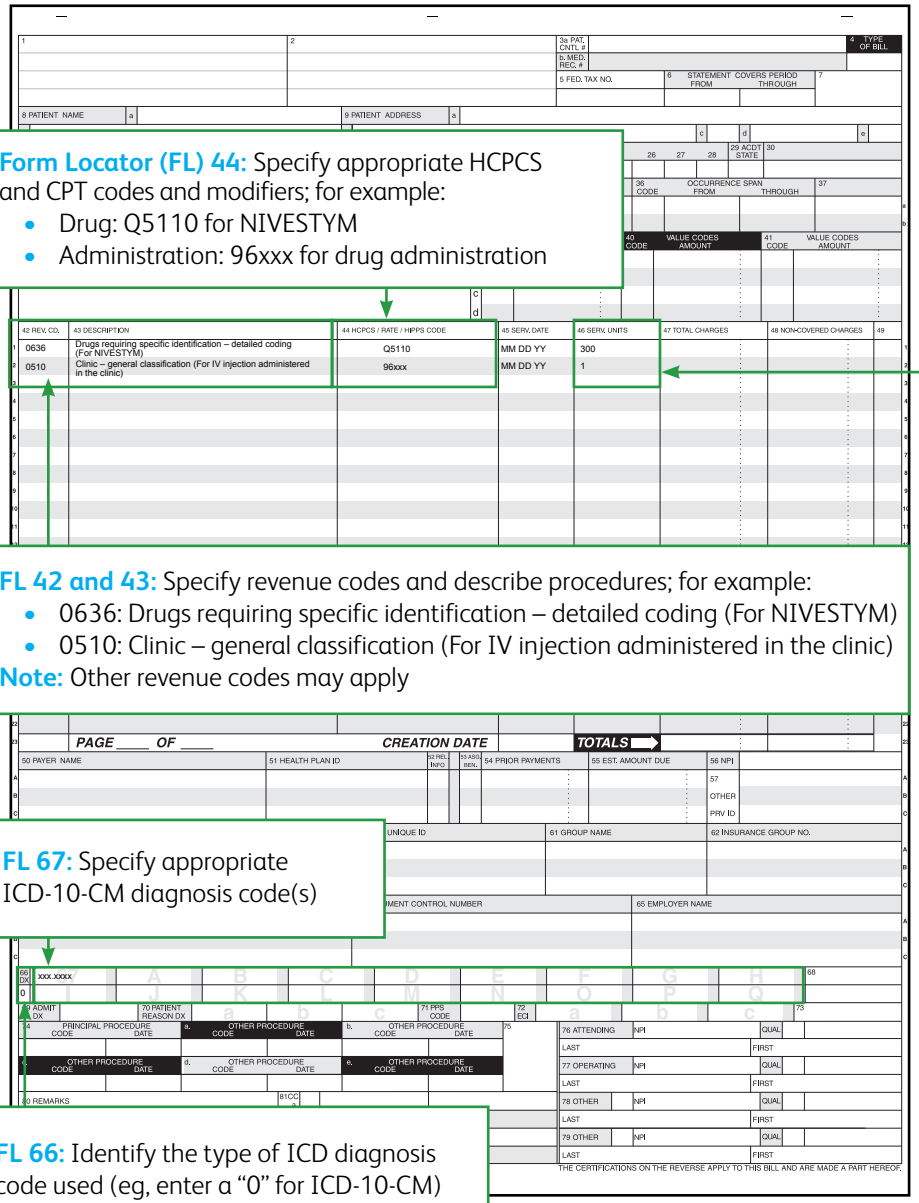
Sample Claim Form: UB-04, Hospital Outpatient Site of Service



Form Locator (FL) 44: Specify appropriate HCPCS and CPT codes and modifiers; for example:

- Drug: Q5110 for NIVESTYM
- Administration: 96xxx for drug administration

FL 42 and 43: Specify revenue codes and describe procedures; for example:

- 0636: Drugs requiring specific identification – detailed coding (For NIVESTYM)
- 0510: Clinic – general classification (For IV injection administered in the clinic)

Note: Other revenue codes may apply

FL 67: Specify appropriate ICD-10-CM diagnosis code(s)

FL 66: Identify the type of ICD diagnosis code used (eg, enter a "0" for ICD-10-CM)

FL 46: Specify the billing units. For example, 1 billing unit = **1** mcg of filgrastim-aafi biosimilar (NIVESTYM) for HCPCS code Q5110. To bill 300 mcg of NIVESTYM, enter 300 billing units. To bill 1 96xxx for drug administration, enter 1 billing unit

This sample form is intended as a reference for the coding and billing of NIVESTYM. This form is not intended to be directive and the use of the recommended codes does not guarantee reimbursement. HCPs may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patients, and services rendered.

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References

1. Centers for Medicare & Medicaid Services (CMS). July 2023 Alpha-Numeric HCPCS File. Accessed June 29, 2023. https://www.cms.gov/files/zip/july-2023-alpha-numeric-hcpcs-file.zip
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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NIVESTYM® is contraindicated in patients with a history of serious allergic reactions to human granulocyte-colony stimulating factors (G-CSF), such as filgrastim products or pegfilgrastim products.

WARNINGS AND PRECAUTIONS

Splenic Rupture

Splenic rupture, including fatal cases, has been reported following the administration of filgrastim products. Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

Acute Respiratory Distress Syndrome

Acute respiratory distress syndrome (ARDS) has been reported in patients receiving filgrastim products. Evaluate patients who develop fever and lung infiltrates or respiratory distress for ARDS. Discontinue NIVESTYM® in patients with ARDS.

Serious Allergic Reactions

Serious allergic reactions, including anaphylaxis, have been reported in patients receiving filgrastim products. The majority of reported events occurred upon initial exposure. Provide symptomatic treatment for allergic reactions. Allergic reactions, including anaphylaxis, in patients receiving filgrastim products can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue NIVESTYM® in patients with serious allergic reactions. NIVESTYM® is contraindicated in patients with a history of serious allergic reactions to human G-CSF such as filgrastim or pegfilgrastim.

Sickle Cell Disorders

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving filgrastim products. Discontinue NIVESTYM® if sickle cell crisis occurs.

Glomerulonephritis

Glomerulonephritis has occurred in patients receiving filgrastim products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after dose reduction or discontinuation of filgrastim products. If glomerulonephritis is suspected, evaluate for cause. If causality is likely, consider dose-reduction or interruption of NIVESTYM®.

Alveolar Hemorrhage and Hemoptysis

Alveolar hemorrhage manifesting as pulmonary infiltrates and hemoptysis requiring hospitalization has been reported in healthy donors treated with filgrastim products for peripheral blood progenitor cell (PBPC) mobilization. Hemoptysis resolved with discontinuation of filgrastim products. The use of NIVESTYM® for PBPC mobilization in healthy donors is not an approved indication.

Capillary Leak Syndrome

Capillary leak syndrome (CLS) has been reported after G-CSF administration, including filgrastim products, and is characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration. Episodes vary in frequency and severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of CLS should be closely monitored and receive standard symptomatic treatment, which may include the need for intensive care.

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML)

Patients With Severe Chronic Neutropenia (SCN)

Confirm the diagnosis of SCN before initiating NIVESTYM® therapy. MDS and AML have been reported to occur in the natural history of congenital neutropenia without cytokine therapy. Cytogenetic abnormalities, transformation to MDS, and AML have also been observed in patients treated with filgrastim products for SCN. Based on available data including a post-marketing surveillance study, the risk of developing MDS and AML appears to be confined to the subset of patients with congenital neutropenia. Abnormal cytogenetics and MDS have been associated with the eventual development of myeloid leukemia. The effect of filgrastim products on the development of abnormal cytogenetics and the effect of continued filgrastim product administration in patients with abnormal cytogenetics or MDS are unknown. Monitor patients for signs and symptoms of MDS/AML in these settings. If a patient with SCN develops abnormal cytogenetics or myelodysplasia, the risks and benefits of continuing NIVESTYM® should be carefully considered.

Patients with Breast and Lung Cancer

MDS and AML have been associated with the use of filgrastim 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.

Please see full Prescribing Information and Patient Information.

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IMPORTANT SAFETY INFORMATION (Continued)

WARNINGS AND PRECAUTIONS (Continued)

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

Leukocytosis
Patients With Cancer Receiving Myelosuppressive Chemotherapy:
White blood cell counts of 100,000/mm^3 or greater were observed in approximately 2% of patients who received filgrastim at dosages above 5 mcg/kg/day. In patients with cancer receiving NIVESTYM® as an adjunct to myelosuppressive chemotherapy, to avoid the potential risks of excessive leukocytosis, it is recommended that NIVESTYM® therapy be discontinued if the absolute neutrophil count (ANC) surpasses 10,000/mm^3 after the chemotherapy-induced ANC nadir has occurred. Monitor CBCs at least twice weekly during therapy. Dosages of NIVESTYM® that increase the ANC beyond 10,000/mm^3 may not result in any additional clinical benefit. In patients with cancer receiving myelosuppressive chemotherapy, discontinuation of filgrastim therapy usually resulted in a 50% decrease in circulating neutrophils within 1 to 2 days, with a return to pretreatment levels in 1 to 7 days.

Peripheral Blood Progenitor Cell Collection and Therapy:
During the period of administration of NIVESTYM® for PBPC mobilization in patients with cancer, discontinue NIVESTYM® if the leukocyte count rises to >100,000/mm^3.

Cutaneous Vasculitis
Cutaneous vasculitis has been reported in patients treated with filgrastim products. In most cases, the severity of cutaneous vasculitis was moderate or severe. Most of the reports involved patients with SCN receiving long-term filgrastim therapy. Hold NIVESTYM® therapy in patients with cutaneous vasculitis. NIVESTYM® may be started at a reduced dose when the symptoms resolve and the ANC has decreased.

Potential Effect on Malignant Cells
NIVESTYM® is a leukocyte growth factor that primarily stimulates neutrophils. The G-CSF receptor through which NIVESTYM® acts has also been found on tumor cell lines. The possibility that NIVESTYM® acts as a growth factor for any tumor type cannot be excluded. The safety of filgrastim products in chronic myeloid leukemia (CML) and myelodysplasia has not been established.

When NIVESTYM® is used to mobilize PBPC, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product. The effect of reinfusion of tumor cells has not been well studied, and the limited data available are inconclusive.

Simultaneous Use With Chemotherapy and Radiation Not Recommended
The safety and efficacy of NIVESTYM® given simultaneously with cytotoxic chemotherapy have not been established. Because of the potential sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy, do not use NIVESTYM® in the period of 24 hours before through 24 hours after the administration of cytotoxic chemotherapy.

The safety and efficacy of NIVESTYM® have not been evaluated in patients receiving concurrent radiation therapy. Avoid the simultaneous use of NIVESTYM® with chemotherapy and radiation therapy.

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.

Aortitis
Aortitis has been reported in patients receiving filgrastim 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 (eg, c-reactive protein and white blood cell count). Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue NIVESTYM® if aortitis is suspected.

ADVERSE REACTIONS
The most common adverse reactions in patients:

- with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs (≥5% difference in incidence compared to placebo) are anemia, constipation, diarrhea, oral pain, vomiting, asthenia, malaise, peripheral edema, decreased hemoglobin, decreased appetite, oropharyngeal pain, and alopecia
- with AML (≥2% difference in incidence) are epistaxis, back pain, pain in extremity, erythema, maculopapular rash, diarrhea, constipation, and transfusion reaction
- with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) (≥5% difference in incidence) are rash, hypersensitivity, thrombocytopenia, anemia, hypertension, sepsis, bronchitis, and insomnia

Please see full Prescribing Information and Patient Information.

Continued on the next page

IMPORTANT SAFETY INFORMATION (Continued)

ADVERSE REACTIONS (Continued)

- undergoing peripheral blood progenitor cell mobilization and collection (≥5 % incidence) are bone pain, pyrexia, increased blood alkaline phosphatase, and headache
- with severe chronic neutropenia (≥5 % difference in incidence) are arthralgia, bone pain, back pain, muscle spasms, musculoskeletal pain, pain in extremity, splenomegaly, anemia, upper respiratory tract infection, urinary tract infection, epistaxis, chest pain, diarrhea, hypoesthesia, and alopecia

INDICATIONS

Patients With Cancer Receiving Myelosuppressive Chemotherapy

- NIVESTYM® is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

Patients With Acute Myeloid Leukemia Receiving Induction or Consolidation Chemotherapy

- NIVESTYM® is indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)

Patients With Cancer Undergoing Bone Marrow Transplantation

- NIVESTYM® is indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, eg, febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by BMT

Patients Undergoing Autologous Peripheral Blood Progenitor Cell Collection and Therapy

- NIVESTYM® is indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

Patients With Severe Chronic Neutropenia

- NIVESTYM® is indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

This product's labeling may have been updated. For the most recent prescribing information, please visit www.pfizer.com.

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