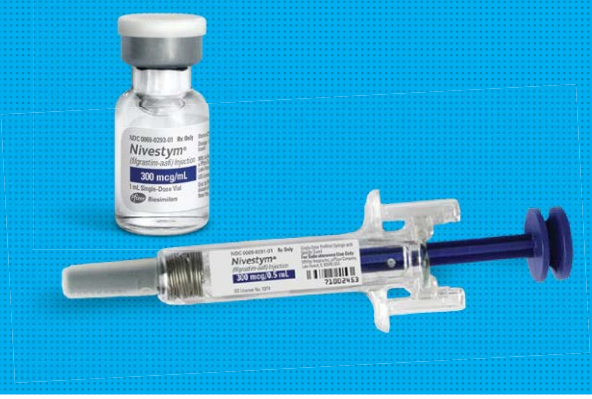
The first FDA-approved biosimilar* to Neupogen® (filgrastim) available in both prefilled syringes and single-dose vials[1]

NIVESTYM® (filgrastim-aafi) product and reimbursement information for your practice



NIVESTYM Injection for Subcutaneous or Intravenous Use

Ordering NIVESTYM—What You Need to Know						
Unit of Sale	**300 mcg/0.5 mL PFS**	**300 mcg/0.5 mL PFS**	**480 mcg/0.8 mL PFS**	**480 mcg/0.8 mL PFS**	**300 mcg/mL SDV**	**480 mcg/1.6 mL SDV**
Unit of Sale NDC	0069-0291-01	0069-0291-10	0069-0292-01	0069-0292-10	0069-0293-10	0069-0294-10
Unit of Sale Quantity	1 syringe	1 (10 syringes)	1 syringe	1 (10 syringes)	1 (10 vials)	1 (10 vials)
Unit of Sale List Price†	$219.00	$2,190.00	$350.40	$3,504.00	$2,190.00	$3,504.00

HCPCS Code[2]	Descriptor
Q5110	Injection, filgrastim-aafi, biosimilar, (NIVESTYM), 1 microgram

PFS=prefilled syringe; SDV=single-dose vial.

*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar and the reference product.[1]

†As of May 2021.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

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.

(CONTINUED ON NEXT PAGE)

Please see Important Safety Information and Indications throughout and full Prescribing Information, including Patient Information, available at NivestymHCP.com.

INJECTION
Nivestym®
filgrastim-aafi
Pfizer

IMPORTANT SAFETY INFORMATION AND INDICATIONS (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

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.

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.

(CONTINUED ON NEXT PAGE)

IMPORTANT SAFETY INFORMATION AND INDICATIONS (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

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
- 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

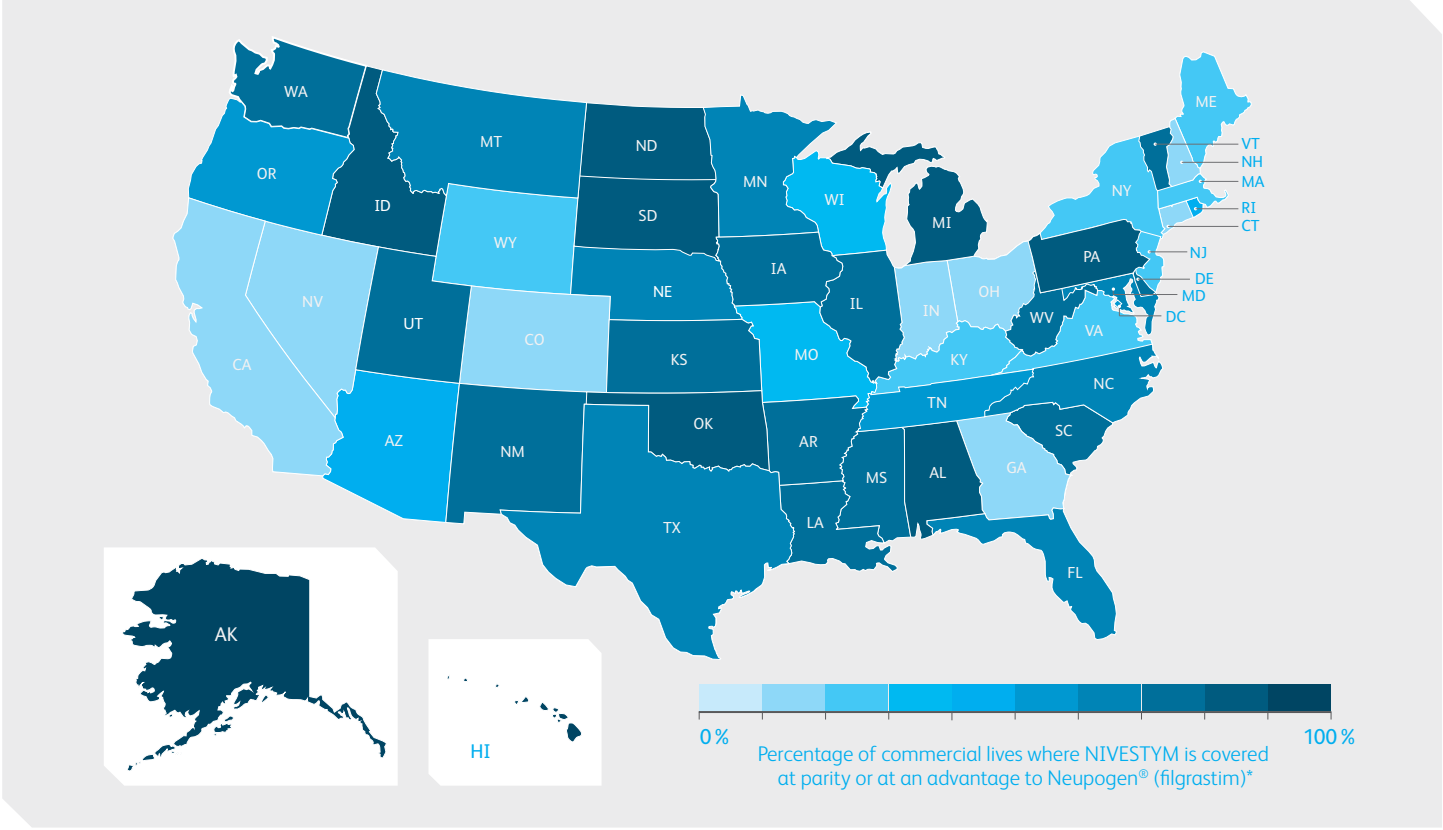
- NIVESTYM® is indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

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.

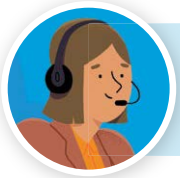
NIVESTYM Payer Coverage Nationwide[3]



77%
of Medicare lives covered, including managed Medicare[3†]

49%
of commercially insured patients have access to NIVESTYM nationwide[3†]

*As of May 2021. Includes Medicare and commercial lives.
†The information provided in this communication is not a guarantee of coverage or payment (partial or full). Actual benefits are determined by each plan administrator with its respective policy and procedures. Nothing herein may be construed as an endorsement, approval, recommendation, or warranty of any kind by any plan or insurer.



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

VISIT
PfizerOncologyTogether.com

References: 1. NIVESTYM [prescribing information]. New York, NY: Pfizer Inc.; May 2021. **2.** HCPCS Codes Level II - 2020 Complete Reference. https://hcpcs.codes/q-codes/Q5110/. Accessed May 14, 2021. **3.** Data on file. Pfizer Inc.; New York, NY.

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