Pfizer Oncology together™

INJECTION
Nyvepria®
pegfilgrastim-apgf

NYVEPRIA® (pegfilgrastim-apgf) Billing and Coding Guide

Please see Important Safety Information and Indication on pages 11-12 and full Prescribing Information, Patient Information, and Instructions for Use for NYVEPRIA.

Introduction

Pfizer Inc. has developed this reference guide to assist healthcare providers (HCPs) with understanding coding for NYVEPRIA® (pegfilgrastim-apgf), a pegfilgrastim biosimilar approved for use in the United States for subcutaneous injection.

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for NYVEPRIA. Coding and coverage policies change periodically and often without notice. The HCP 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 NYVEPRIA.

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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 NYVEPRIA 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

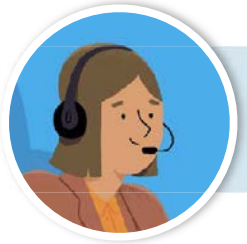
We can review the reasons for a denied claim and provide information on payer requirements. After an appeal is submitted, we can follow up with the payer until a final outcome is determined.

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

It is critical to report billing codes that accurately reflect a patient's condition, treatment, and the services that are rendered on the claim form submitted to a payer. The codes in this section may be appropriate to report services related to therapy with NYVEPRIA® (pegfilgrastim-apgf) when performed in the physician office and hospital outpatient department sites of care to Medicare Administrative Contractors (MACs), private commercial payers, and Medicaid.

Coding for NYVEPRIA

In the physician office and hospital outpatient department sites of care, Medicare, Medicaid, and private commercial payers typically recognize the following codes for reporting NYVEPRIA and its administration on claim forms.

Effective for dates of service on and after January 1, 2021, HCPCS code Q5122 may be used to report NYVEPRIA.

HCPCS Code[1]	Descriptor
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg

Modifiers may be included on claims to provide additional information. Some payers may require the modifier JB to be reported, indicating a subcutaneous route of administration. Additional modifiers may also be considered appropriate when submitting claims.

HCPCS Modifier[1,2]	Descriptor
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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NYVEPRIA National Drug Code

National Drug Codes (NDCs) are unique 10-digit, 3-segment numbers used to identify drugs.[3] State Medicaid agencies usually require 11-digit NDCs on claims, even after a unique code has been assigned.

Strength[4]	Prefilled Syringe Size	10-Digit NDC
6 mg/0.6 mL	Single-dose prefilled syringe for manual use only	0069-0324-01

NDC Conversion Example

For reimbursement purposes, some payers (eg, Medicaid) require the NDC on the claim form. For claims-reporting purposes, the Health Insurance Portability and Accountability Act (HIPAA) requires conversion of the 10-digit NDC to an 11-digit NDC by adding a leading "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 for NYVEPRIA. See placement of the red zero in the example below.

Strength	Prefilled Syringe Size	10-Digit NDC	11-Digit NDC
6 mg/0.6 mL	Single-dose prefilled syringe for manual use only	0069-0324-01	00069-0324-01

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Coding for NYVEPRIA Administration Services

Current Procedural Terminology (CPT®) codes define specific medical procedures performed by physicians or other qualified HCPs.[5] The following codes may be used to report the subcutaneous administration of NYVEPRIA:

Type of Code	*Code/Descriptor*	*Relevant Sites of Service*
CPT® code[5]	**96372:** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Physician office and hospital outpatient department

Hospital outpatient departments use revenue codes to report specific accommodations and/or ancillary charges.[6]

Type of Code	*Code/Descriptor*	*Relevant Site of Service*
Revenue code[7]	**0636:** Drugs requiring specific identification – detailed coding *Used in combination with the drug code*	Hospital outpatient department
	0500: Outpatient services – general classification *Used in combination with the administration code*	
	0510: Clinic – general classification *Used in combination with the administration code*	

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Diagnosis Coding for NYVEPRIA

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 documented in the medical record.

Reporting the medical necessity for NYVEPRIA may require a primary and secondary diagnosis, in some cases. HCPs should verify payer-specific diagnosis coding and sequencing requirements before submitting a claim, as they may vary by payer.

NYVEPRIA (pegfilgrastim-apgf) is a biosimilar that is FDA-approved 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.

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

Consult your reimbursement expert for appropriate codes.

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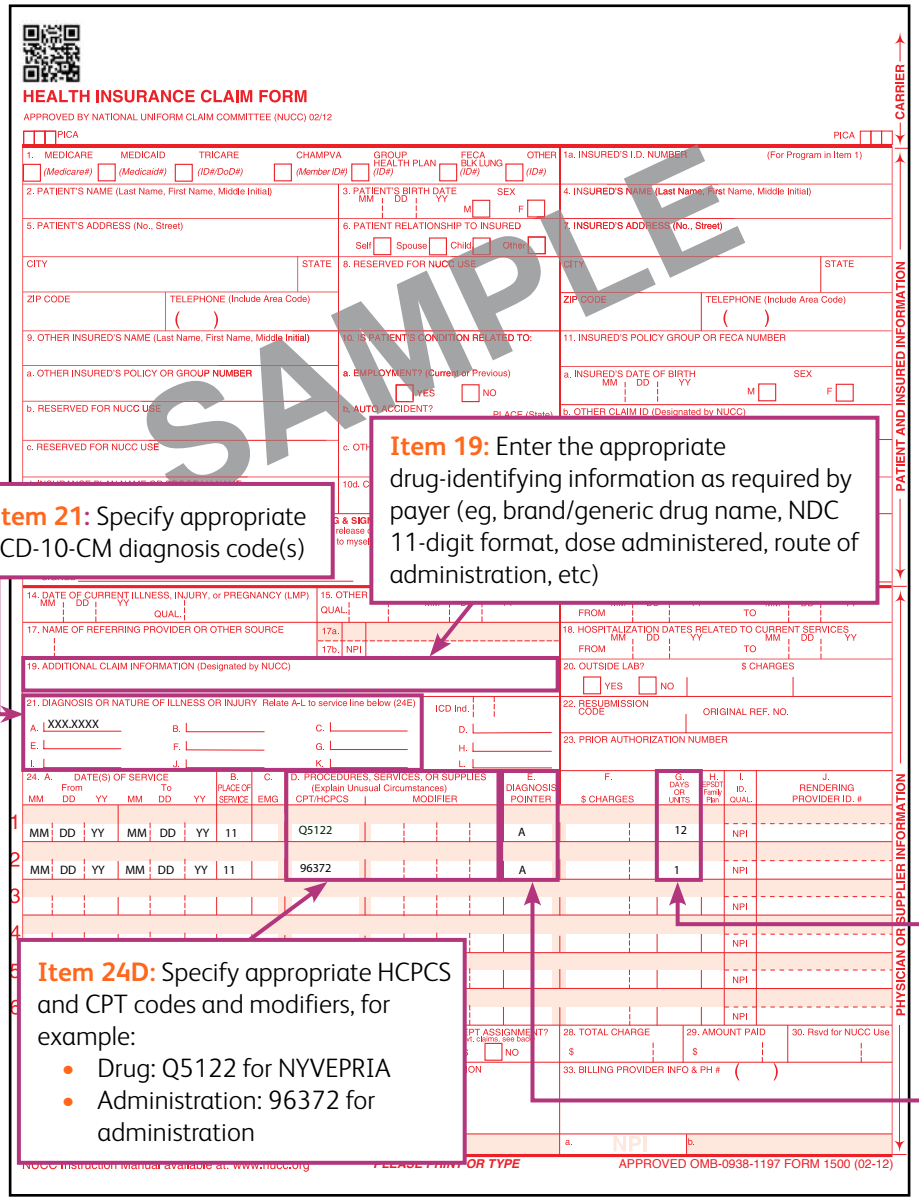
Sample Claim Form: CMS-1500, Physician Office Site of Service



This sample form is intended as a reference for the coding and billing of NYVEPRIA. 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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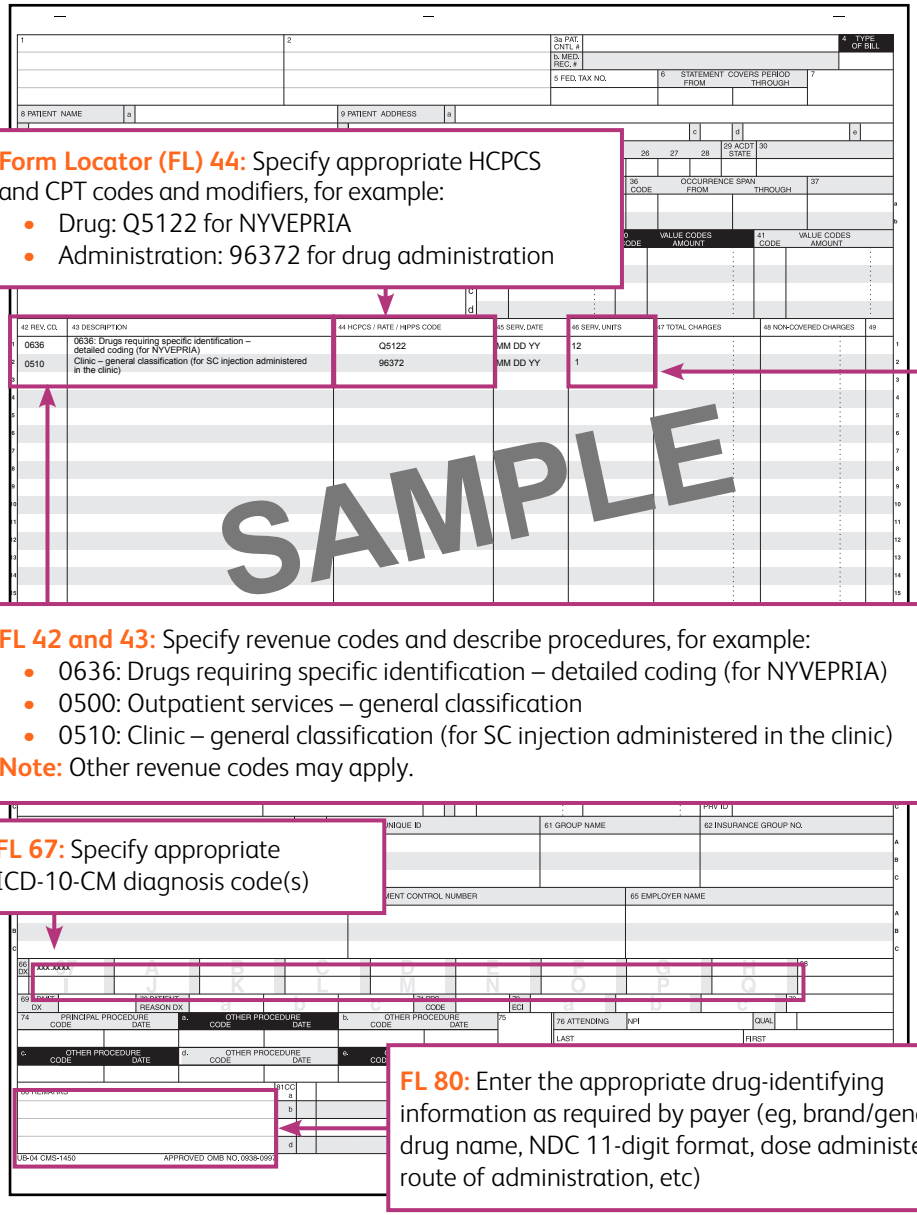
Sample Claim Form: UB-04, Hospital Outpatient Site of Service



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

- Drug: Q5122 for NYVEPRIA
- Administration: 96372 for drug administration

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

- 0636: Drugs requiring specific identification – detailed coding (for NYVEPRIA)
- 0500: Outpatient services – general classification
- 0510: Clinic – general classification (for SC injection administered in the clinic)

Note: Other revenue codes may apply.

FL 46: Specify the billing units. For example, Q5122 billing unit = 0.5 mg of pegfilgrastim-apgf biosimilar (NYVEPRIA). To report 6 mg, bill Q5122 with 12 units. To bill for the subcutaneous injection, bill 1 unit of 96372.

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

FL 80: Enter the appropriate drug-identifying information as required by payer (eg, brand/generic drug name, NDC 11-digit format, dose administered, route of administration, etc)

This sample form is intended as a reference for the coding and billing of NYVEPRIA. 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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Claims Submission Checklist

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

- ☑ **Provide the patient name, address, and insurance identification number, and review each of 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 NYVEPRIA-specific information (eg, name of drug, HCPCS code, NDC, number of units, route, and frequency of administration)**

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
2. Centers for Medicare & Medicaid Services (CMS). Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Accessed July 9, 2023. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf
3. U.S. Food and Drug Administration (FDA). National Drug Code directory. Accessed February 17, 2020. https://www.fda.gov/drugs/informationondrugs/ucm142438.htm
4. NYVEPRIA [package insert]. New York, NY: Pfizer Inc.; 2021.
5. American Medical Association. 2020 CPT Professional Edition. Current Procedural Terminology (CPT®) copyright 2019 by the American Medical Association. All rights reserved. Chicago, IL: AMA; 2019.
6. Centers for Medicare & Medicaid Services (CMS). Transmittal 167. Accessed February 17, 2020. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R167CP.pdf
7. Research Data Assistance Center (ResDAC). Revenue center code. Accessed February 17, 2020. https://www.resdac.org/sites/resdac.umn.edu/files/Revenue%20Center%20Code%20Table.txt

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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 after receiving NYVEPRIA

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 NYVEPRIA
- Discontinue NYVEPRIA 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
- Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment
- Permanently discontinue NYVEPRIA in patients with serious allergic reactions
- Do not administer NYVEPRIA to patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products

USE IN PATIENTS WITH SICKLE CELL DISORDERS

- Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving pegfilgrastim products
- Discontinue NYVEPRIA if sickle cell crisis occurs

GLOMERULONEPHRITIS

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

LEUKOCYTOSIS

- White blood cell counts of 100 x 10^9/L or greater have been observed in patients receiving pegfilgrastim products
- Monitoring of complete blood count (CBC) during NYVEPRIA 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 granulocyte-colony stimulating factor (G-CSF) administration, including pegfilgrastim 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 a need for intensive care

Continued on the next page

Please see full Prescribing Information, Patient Information, and Instructions for Use for NYVEPRIA.

IMPORTANT SAFETY INFORMATION (Continued)

POTENTIAL FOR TUMOR GROWTH STIMULATORY EFFECTS ON MALIGNANT CELLS

- The G-CSF receptor through which pegfilgrastim and filgrastim products act has been found on tumor cell lines
- The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded

MYELODYSPLASTIC SYNDROME (MDS) AND ACUTE MYELOID LEUKEMIA (AML) IN PATIENTS WITH BREAST AND LUNG CANCER

- MDS and AML have been associated with the use of pegfilgrastim products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer
- Monitor patients for signs and symptoms of MDS/AML in these settings

AORTITIS

- Aortitis has been reported in patients receiving pegfilgrastim products. It may occur as early as the first week after start of therapy
- Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count)
- Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue NYVEPRIA 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

INDICATION

NYVEPRIA 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

Limitations of Use

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

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