Sandoz One Source Commercial Co-Pay Program Operational Guide

For Claim Submission and Payment

INDICATIONS

ZARXIO® (FILGRASTIM-SNDZ) IS INDICATED FOR:[1]

- **Patients With Cancer Receiving Myelosuppressive Chemotherapy:** 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:** To reduce 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:** To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.
- **Patients Undergoing Autologous Peripheral Blood Progenitor Cell Collection and Therapy:** For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
- **Patients With Severe Chronic Neutropenia:** For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

ZIEXTENZO® (pegfilgrastim-bmez) IS INDICATED TO:[2]

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

ZARXIO: IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ZARXIO is contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim products.

ZIEXTENZO: IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ZIEXTENZO is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim or filgrastim.

Please see pages 10-13 for additional Important Safety Information.

Table of Contents

This guide provides important information for healthcare providers (HCPs) on the options for submitting co-pay claims and receiving co-pay payments available through Sandoz One Source

The Sandoz One Source Commercial Co-Pay Program

Patients have enough to worry about. With this in mind, we streamlined our co-pay program to make it convenient by offering the following benefits:

- **Patients can sign up any time of day or night**
- **Benefits reset automatically every year**

Commercial Co-Pay Program

Patients may receive their first and subsequent doses of ZIEXTENZO or ZARXIO at no cost.

$0 out-of-pocket for first dose or cycle

$0 out-of-pocket for subsequent doses or cycles

- **For eligible,* commercially insured patients**
- **No income requirements**
- **Virtual co-pay card ensures that patients have immediate access to their benefits**

The Sandoz One Source Commercial Co-Pay Program supports eligible,* commercially insured patients with their out-of-pocket co-pay costs for ZIEXTENZO and ZARXIO.

Patient Assistance Program

Provides patient financial assistance for patients in need who meet certain requirements*

Program Enrollment

Now, it's so SIMPLE to enroll and use the Sandoz One Source Commercial Co-Pay Program:

1. ENROLL
Instruct your patients to enroll in co-pay online at ZARXIO.com or ZIEXTENZO.com.

2. CONFIRM
Patient can choose which benefit they will use. The ZARXIO Commercial Co-Pay card may be used for either medical or pharmacy benefits.

3. PROCESS
Medical benefits
- Patients show their physical co-pay card or on their phone, just once, then all pharmacies will have their information (eg, secondary, tertiary, etc)
- Submit claim
- Receive remittance and payment

Pharmacy benefits
- Get one-time registration of co-pay card with pharmacy
- Patient provides co-pay card information to their pharmacy for processing

*Terms and Conditions: Prescription must be for an approved indication. This program is not health insurance. Eligibile patients must be enrolled in commercial insurnace that covers ZARXIO or ZIEXTENZO; cash-paying or uninsured patients are not eligible. Patients are not eligible if prescription for ZARXIO® or ZIEXTENZO is paid, in whole or in part, by any state or federally funded programs, including but not limited to Medicare (including Part D, even in the coverage gap) or Medicaid, Medigap, VA, DOD, or TriCare, or private indemnity plans that do not cover prescription drugs, or HMO insurance plans that reimburse the patient for the entire cost of their prescription drugs, or where prohibited by law. Co-pay program may not be combined with any other rebate, coupon, or offer. Co-pay program has no cash value. Sandoz reserves the right to rescind, revoke, or amend this offer without further notice.

ZARXIO® (filgrastim-sndz) | ZIEXTENZO® (pegfilgrastim-bmez)

Submitting Medical Claims Through Sandoz One Source Commercial Co-Pay Program

Methods of claims submission

The Sandoz One Source Commercial Co-Pay Program has 3 methods of submitting claims:

Fax

Submit claims using paper claims form
Fax: 833-664-7127.

Submit claims through your office billing software.

Online

(Alternate) Submit claims through the Sandoz One Source Claims Portal (SDS).

FAX: SUBMIT CLAIMS USING PAPER CLAIMS FORM

A co-pay claim form is submitted after the patient is approved and enrolled in the **Sandoz One Source Commercial Co-Pay Program**.

Two types of paper claim forms can be submitted to the program: the **CMS-1500 claim form** and the **UB04 claim form**. These forms can be filled out and faxed to [1-844-726-3695]. Examples of these forms are provided for your reference.

CMS-1500 CLAIM FORM

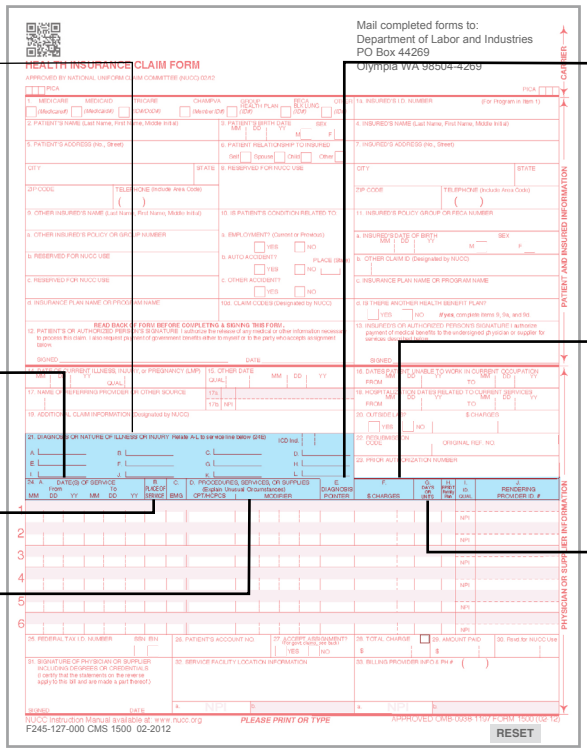
Below is an example of a **CMS-1500 claim form** with notations to help your billing office with filling out and submitting these forms. Please be sure to include a copy of the **Explanation of Benefits (EOB)** when submitting your claim.

Box 21 Diagnosis Codes
(Electronic Loop 2300, Segment HI)
Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order. Enter diagnosis code from 21A for primary diagnosis code; 21B-L for all secondary diagnosis codes.

Box 24A Date of Service
(Electronic Loop 2400, Segment DTP)

Box 24B Place of Service
(Electronic Loop 2300/2400, Segment CLM/SV) Enter the date of service and the appropriate place of service code.

Box 24D CPT/HCPCS/J-Code
(Electronic Loop 2400, Segment SV)
Indicate appropriate CPT, HCPCS codes, and modifiers, if required. If any waste product, please bill on separate line with JW modifier.



Box 24E Diagnosis Pointer
(Electronic Loop 2400, Segment SV)
Specify the diagnosis from Box 21 that corresponds to the product or procedure listed in Box 24D. Enter only 1 diagnosis pointer per line.

Box 24F Line Total Charge
(Electronic Loop 2400, Segment SV102)
Enter the total charge for each line item.

Box 24G Line Level Service Units
(Electronic Loop 2400, Segment SV)
Enter the number of service units for each line item. For example, for HCPCS Code Q5101, each unit corresponds to 1 injection of ZARXIO. One 300 mcg/0.5 mL single-dose prefilled syringe would be reported with 1 unit.

ZARXIO® (filgrastim-sndz) | ZIEXTENZO® (pegfilgrastim-bmez)

Submitting Medical Claims Through Sandoz One Source Commercial Co-Pay Program (continued)

FAX: SUBMIT CLAIMS USING PAPER CLAIMS FORM

UB04 CLAIM FORM

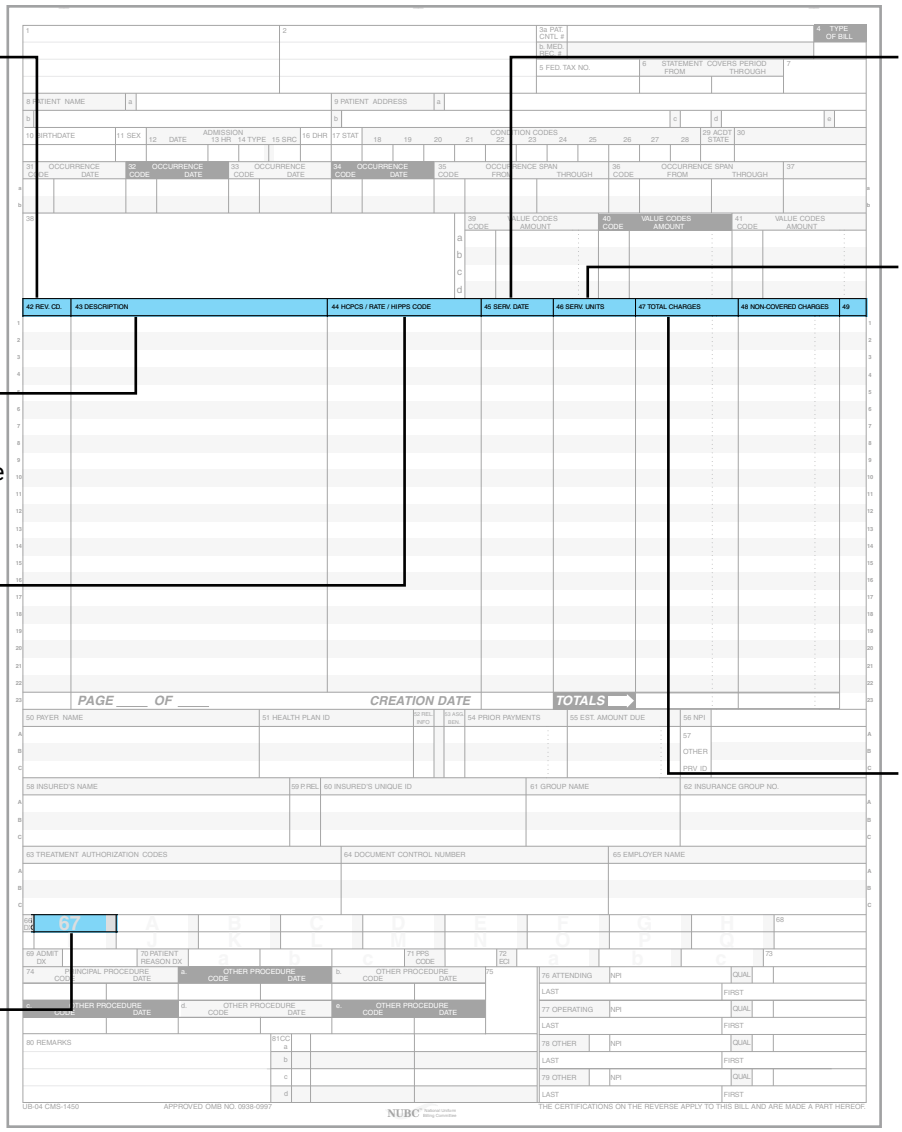
Below is an example of a **UB04 claim form** with notations to help your billing office with filling out and submitting these forms. Please be sure to include a copy of the **Explanation of Benefits (EOB)** when submitting your claim.

Box 42 Hospital Revenue Code
(Electronic Loop 2400, Segment type SV2)
List the appropriate revenue code for ZARXIO or ZIEXTENZO. Enter an appropriate revenue code for the administration service based on the cost center in which the service is performed.

Box 43 Description of CPT, HCPCS, J Code
Enter the corresponding description for the revenue code listed in Box 42.

Box 44 CPT/ HCPCS/J-Code
(Electronic Loop 2400, Segment SV2, Service Line SV201) Indicate appropriate CPT, HCPCS codes, and modifiers, if required. If any waste product, please bill on separate line with JW modifier.

Box 67 Diagnosis Code
(Electronic Loop 2300, Segment Type HI)
Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order. Use fields A-Q to report any applicable secondary diagnosis(es).



Box 45 Date of Service
(Electronic Loop 2400, Segment Type DTP)
Enter date of service.

Box 46 Service Units
(Electronic Loop 2400, Segment Type SV2 Service Line SV205) Enter the number of service units for each line item. For [HCPCS Code], each unit corresponds to [dose] of [drug name]. One [formulation] single-dose pre-filled syringe would be reported with [xx] units. For Medicare claims, on a separate line, enter the number of units discarded (if applicable), corresponding with the line item with the JW modifier.

Box 47 The Total Charge for Line
(Electronic Loop 2300, Segment type CLM, Claim Information CLM020)
Enter the total charge for each line item.

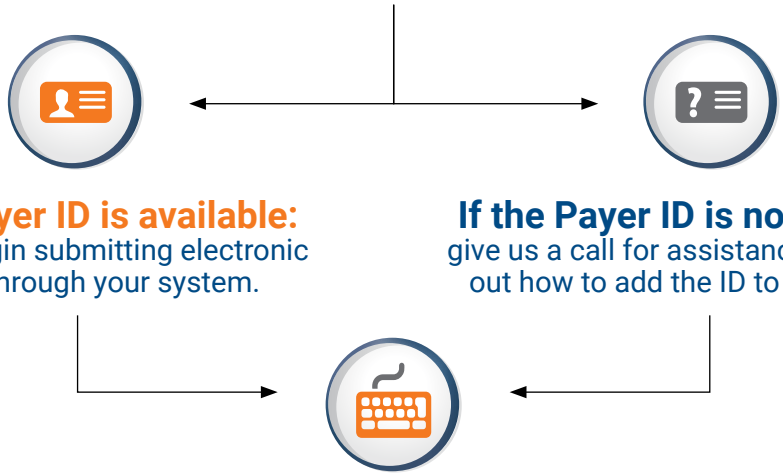
Submitting Medical Claims Through Sandoz One Source Commercial Co-Pay Program (continued)

ONLINE: SUBMIT CLAIMS THROUGH YOUR OFFICE BILLING SOFTWARE

We know that billing software can vary and that interfaces are all different. Irrespective of submission method, payment will be received in the way you have been accustomed via the designated channel you have set-up. Below are some basic steps to ensure that you can properly submit a claim through your office billing software.

Billing Software Setup

First, make sure that the Payer ID 56155 is an available Payer ID in your system.*



If the Payer ID is available:
You can begin submitting electronic claims through your system.

If the Payer ID is not available,
give us a call for assistance with figuring out how to add the ID to your system.

Once Payer ID 56155 is available in your system, please add the **Sandoz One Source Commercial Co-Pay Program** to your patients' insurance profile as a secondary or tertiary payer. Include the **Group Number 00003628**, Payer ID, and the patient's unique Member ID, or the claim will be rejected in your system.

If you do not receive remittance back, then you can ask your practice and billing vendor to allow the reception of electronic remittance advice (ERA) [EDI 835] messages from **Payer ID 56155** in order to receive claims adjudication results.

Clearinghouse Setup

The Sandoz One Source Commercial Co-pay Program and its co-pay payment partner have developed relationships with several software vendors and all major clearinghouses in order to ensure that the claims are routed properly to the program for processing.

If you are having trouble submitting claims to the program, please contact us at 1-844-726-3691.

*If your system requires a 4 digit **Relay Health Payer ID,** please use the following as appropriate: **Relay Professional Claims Payer ID:** 7821 or **Relay Institutional Claims Payer ID:** 9532.

Submitting Medical Claims Through Sandoz One Source Commercial Co-Pay Program (continued)

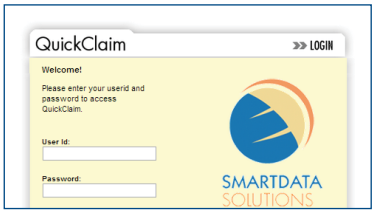
ONLINE (ALTERNATE): SUBMIT CLAIMS THROUGH THE SANDOZ ONE SOURCE CLAIMS PORTAL (SDS)

Offices that are not set up with a clearinghouse can still submit claims electronically using the online SDS portal. Any office with an internet connection can submit claims via the online portal. Sandoz One Source has chosen SDS to help process all electronic claims through the following steps:

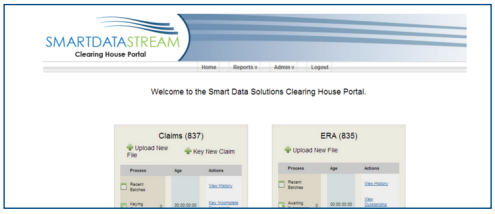
1. Register and complete account setup with SDS. Someone from your IT department, claims processing software vendor, or EDI coordinator may be able to help.
2. Navigate to https://quickclaim.smart-data-solutions.com/quickclaim/servlet/quickclaim/ and log in using your supplied credentials.
3. Once you have gained portal access, you can submit the claims for the Sandoz One Source Commercial Co-Pay Program via the following means:
   - **Direct File Upload to the Portal**
   - **Manual Claim Entry**

Direct File Upload

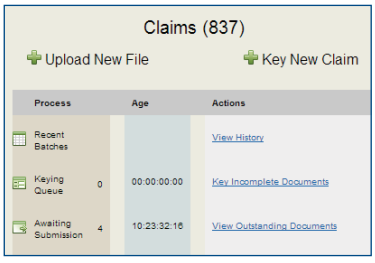
Healthcare provider (HCP) offices or institutional billing centers may upload a file directly to the SDS portal for processing in batch or as a single claim. These files must be in the EDI 837 format and you may do so by following the steps below:



1. Log into the portal.

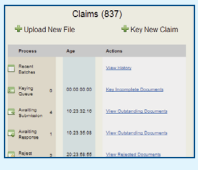


2. Select "Upload New File" under your transaction type (Claims (837)).



3. Select "Upload New File" to add a claim file to the portal.

4. Select file to insert and submit.



You may check the status of your claims file through this portal as well as submit a request to the payer for the status of an individual claim. You should expect to receive a check referencing specific patient identification unless you have registered for electronic funds transfer (EFT). Please see page 9 for additional information.

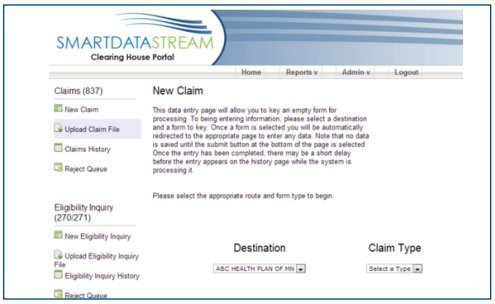
Submitting Medical Claims Through Sandoz One Source Commercial Co-Pay Program (continued)

Manual Claim Entry

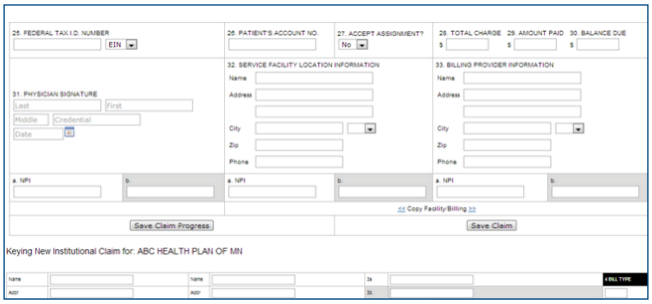
If you would like to key in the claim directly into the portal, it would be possible to do so using the data entry screens.

1. Log into the portal.

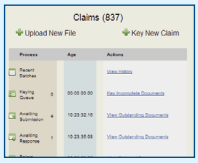
2. Select "Key New Claim" under your transaction type (Claims (837)).



3. Create a new claim by selecting the claim type and destination.



4. Once you have keyed in the claim, select "Save Claim" at the bottom of the editor.



You may check the status of your claims file through this portal as well as submit a request to the payer for the status of an individual claim. You should expect to receive a check referencing specific patient identification unless you have registered for electronic funds transfer (EFT). Please see page 9 for additional information.

Leveraging the Pharmacy Benefit

In certain cases, the HCP may send the prescription to a specialty pharmacy (eg, when ZARXIO (filgrastim-sndz) or ZIEXTENZO (pegfilgrastim-bmez) are covered under the patient's prescription benefits or when a patient's commercial insurance requires ZARXIO or ZIEXTENZO to be obtained through a payer-affiliated specialty pharmacy).

The patient provides co-pay card information to the specialty pharmacy to process co-pay claims. If the patient has enrolled online, have them provide their printout co-pay card or they can provide the following information verbally as well:

Pharmacy Claims Rx BIN Number	Group ID	Patient ID

Please see appropriate Sandoz details below:

Rx BIN Number: 610020	Group ID: 99992570	Patient ID: Unique to each patient

- The pharmacy processes the co-pay claim and collects any additional balance due from the patient.

When a specialty pharmacy purchases and bills for ZARXIO or ZIEXTENZO, the HCP is not responsible for billing the patient's primary insurance plan or the co-pay assistance program for ZARXIO or ZIEXTENZO.

SANDOZ one source®

ZARXIO® (filgrastim-sndz) | ZIEXTENZO® (pegfilgrastim-bmez)

ZARXIO (filgrastim-sndz) Important Safety Information (continued)

Please see page 1 for additional Important Safety Information.

WARNINGS AND PRECAUTIONS

- Splenic rupture, including fatal cases, has been reported following the administration of filgrastim products. Patients who report left upper abdominal or shoulder pain should be evaluated.
- Acute respiratory distress syndrome (ARDS) has been reported in patients receiving filgrastim products. Patients who develop fever and lung infiltrates or respiratory distress should be evaluated. Discontinue ZARXIO in patients with ARDS.
- 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 ZARXIO in patients with serious allergic reactions.
- Sickle cell crisis, in some cases fatal, has been reported with the use of filgrastim products in patients with sickle cell trait or sickle cell disease. Discontinue ZARXIO if sickle cell crisis occurs.
- 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 ZARXIO.
- Alveolar hemorrhage manifesting as pulmonary infiltrates and hemoptysis requiring hospitalization have been reported in healthy donors treated with filgrastim products undergoing peripheral blood progenitor cell (PBPC) collection mobilization. Hemoptysis resolved with discontinuation of filgrastim. The use of ZARXIO for PBPC mobilization in healthy donors is not an approved indication.
- 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, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive appropriate treatment.
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML):
  - Patients with Severe Chronic Neutropenia: Confirm the diagnosis of severe chronic neutropenia (SCN) before initiating ZARXIO therapy. Myelodysplastic syndrome (MDS) and acute myelogenous leukemia (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. 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 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 ZARXIO should be carefully considered.
  - Patients with Breast and Lung Cancer: MDS and AML have been associated with the use of filgrastim 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 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 receiving filgrastim at dosages above 5 mcg/kg/day. In patients with cancer receiving ZARXIO as an adjunct to myelosuppressive chemotherapy, to avoid the potential risks of excessive leukocytosis, it is recommended that ZARXIO therapy be discontinued if the ANC surpasses 10,000/mm^3 after the chemotherapy-induced ANC nadir has occurred. Monitor CBCs at least twice weekly during therapy.
  - Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy: During the period of administration of ZARXIO for PBPC mobilization in patients with cancer, discontinue ZARXIO if the leukocyte count rises to >100,000/mm^3.

ZARXIO® (filgrastim-sndz)

ZARXIO (filgrastim-sndz) Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

- 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 ZARXIO therapy in patients with cutaneous vasculitis. ZARXIO may be started at a reduced dose when the symptoms resolve and the ANC has decreased.
- The possibility that ZARXIO 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 ZARXIO is used to mobilize PBPC, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product. Available data is limited and inconclusive.
- The safety and efficacy of ZARXIO given simultaneously with cytotoxic chemotherapy have not been established. Do not use ZARXIO in the period 24 hours before through 24 hours after the administration of cytotoxic chemotherapy. The safety and efficacy of ZARXIO have not been evaluated in patients receiving concurrent radiation therapy. Avoid the simultaneous use of ZARXIO with chemotherapy and radiation therapy.
- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone-imaging changes on nuclear imaging.
- 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 (e.g., c-reactive protein and white blood cell count). Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue ZARXIO if aortitis is suspected.

ADVERSE REACTIONS

Most common adverse reactions in patients:

- With nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs (≥ 5% difference in incidence compared to placebo) are thrombocytopenia, nausea, pyrexia, chest pain, pain, fatigue, back pain, arthralgia, bone pain, pain in extremity, dizziness, cough, dyspnea, rash, blood lactate dehydrogenase increased and blood alkaline phosphatase increased.
- With AML (≥2% difference in incidence) are epistaxis, back pain, pain in extremity, erythema, and rash maculo-papular.
- With nonmyeloid malignancies undergoing myeloablative chemotherapy followed by BMT (≥5% difference in incidence) are rash and hypersensitivity.
- Undergoing peripheral blood progenitor cell mobilization and collection (≥5% incidence) are bone pain, pyrexia, blood alkaline phosphatase increased and headache.
- With severe chronic neutropenia (SCN) (≥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.

Please see accompanying full Prescribing Information for ZARXIO.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

ZARXIO® (filgrastim-sndz)

ZIEXTENZO (pegfilgrastim-bmez) Important Safety Information (continued)

Please see page 1 for additional Important Safety Information.

WARNINGS AND PRECAUTIONS

- Splenic Rupture
  - Splenic rupture, including fatal cases, can occur following the administration of pegfilgrastim. Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving ZIEXTENZO.
- Acute Respiratory Distress Syndrome (ARDS)
  - ARDS can occur in patients receiving pegfilgrastim. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving ZIEXTENZO, for ARDS. Discontinue ZIEXTENZO in patients with ARDS.
- Serious Allergic Reactions
  - Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim. The majority of events occurred upon initial exposure and can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue ZIEXTENZO in patients with serious allergic reactions. Do not administer ZIEXTENZO to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim.
- 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 ZIEXTENZO if sickle cell crisis occurs.
- Glomerulonephritis
  - Glomerulonephritis has occurred in patients receiving pegfilgrastim. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events resolved after dose-reduction or discontinuation of pegfilgrastim. If glomerulonephritis is suspected, evaluate for cause. If causality is likely, consider dose-reduction or interruption of ZIEXTENZO.
- Leukocytosis
  - White blood cell (WBC) counts of 100 x 10^9/L or greater have been observed in patients receiving pegfilgrastim. Monitoring of CBC during pegfilgrastim therapy is recommended.
- Thrombocytopenia:
  - Thrombocytopenia has been reported in patients receiving pegfilgrastim. Monitor platelet counts.
- Capillary Leak Syndrome (CLS)
  - CLS has been reported after G-CSF administration, including pegfilgrastim, and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency, 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 intensive care.
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells
  - The granulocyte colony-stimulating factor (G-CSF) receptor through which pegfilgrastim and filgrastim act has been found on tumor cell lines. The possibility that pegfilgrastim acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim is 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 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. 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 ZIEXTENZO 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.

ZIEXTENZO®
(pegfilgrastim-bmez)

ZIEXTENZO (pegfilgrastim-bmez) Important Safety Information (continued)

ADVERSE REACTIONS

- The most common adverse reactions are bone pain and pain in extremity.

Please see accompanying full Prescribing Information for ZIEXTENZO.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Billing and Coding Are Made Easy With Support From Sandoz One Source

ZARXIO (filgrastim-sndz) AND ZIEXTENZO (pegfilgrastim-bmez) BILLING CODES*

NDC Codes[1,2]			
Formulation	**Packaging size**	**10-digit NDC**	**11-digit NDC**
ZARXIO 300 mcg/0.5 mL	1 prefilled syringe	61314-318-01	61314-0318-01
	10 prefilled syringes (two 5-packs)	61314-318-10	61314-0318-10
ZARXIO 480 mcg/0.8 mL	1 prefilled syringe	61314-326-01	61314-0326-01
	10 prefilled syringes (two 5-packs)	61314-326-10	61314-0326-10
ZIEXTENZO 6 mg/0.6 mL	1 prefilled syringe	61314-866-01	61314-0866-01

HCPCS Code[3]	
Q5101	Injection, filgrastim-sndz, biosimilar (ZARXIO), 1 microgram
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ZIEXTENZO), 0.5 mg

CPT Code[4†]	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96365 (For ZARXIO only)	Intravenous (IV) infusion, for therapy, prophylaxis, or diagnosis (specifysubstance or drug); initial, up to 1 hour

Diagnosis Code[5]	
ICD-10-CM	Appropriate diagnosis code for the patient's condition. Allowable diagnosis codes vary by payer. Report the appropriate diagnosis code(s) to describe the patient's condition. Primary and secondary diagnosis codes may be required.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

*The coding information contained herein is for informational purposes only, and is not a guarantee of coverage or reimbursement for any product or service. This information is not intended to substitute for the physician's independent diagnosis or treatment of each patient.

† CPT codes describe the therapeutic injection.

For more information regarding ZARXIO or ZIEXTENZO reimbursement, please visit ZARXIO.com or ZIEXTENZO.com, or call 1-844-SANDOZ1 (844-726-3691).

ZARXIO® (filgrastim-sndz) | ZIEXTENZO® (pegfilgrastim-bmez)

*BI, Benefit Investigation; PA, Prior Authorization.

References 1. ZARXIO [prescribing information]. Princeton, NJ: Sandoz Inc; September 2022. **2.** ZIEXTENZO [prescribing information]. Princeton, NJ: Sandoz Inc; March 2021. **3.** NOC Codes - HCPCS Quarterly Update July 2020. Baltimore, MD: Centers for Medicare & Medicaid Services; 2020. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. Accessed July 13, 2020. **4.** American Medical Association. CPT® 2019 Professional Edition. **5.** Centers for Medicare and Medicaid Services. ICD-10-CM Official Guidelines for Coding and Reporting FY 2019. https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2019-ICD10-Coding-Guidelines-.pdf. Accessed September 3, 2019.

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