

# Sandoz One Source Commercial Co-Pay Program Operational Guide

## For Claim Submission and Payment

### INDICATIONS

#### ZARXIO® (FILGRASTIM-SNDZ) IS INDICATED FOR:<sup>1</sup>

- **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:** 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:** 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:<sup>2</sup>

- 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 page 10-13 for additional Important Safety Information.

**SANDOZ** A Novartis Division

 **ZARXIO®**  
(filgrastim-sndz)

 **ZIEXTENZO®**  
(pegfilgrastim-bmez)

# 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

Sandoz One Source Commercial Co-Pay Program	3
Submitting MEDICAL CLAIMS Through Sandoz One Source	4
Leveraging the Pharmacy Benefit	9
Important Safety Information	10
Billing and Coding	14
Additional Sandoz One Source Patient Support Services	15



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



# The Sandoz One Source Commercial Co-Pay Program



Sandoz One Source is a comprehensive reimbursement and patient support program for patients treated with ZARXIO or ZIEXTENZO

## 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.

## Contact Sandoz One Source at 1-844-SANDOZ1

(1-844-726-3691) for program details and eligibility requirements

## Program Enrollment

There  
are

**3**

ways to enroll in the  
Sandoz One Source  
Commercial Co-Pay Program:

- 1 Instruct your patients to enroll in the program online at [ZARXIO.com](http://ZARXIO.com) or [ZIEXTENZO.com](http://ZIEXTENZO.com).
- 2 Submit an online Sandoz One Source enrollment form and choose co-pay assistance.
- 3 Download and fax the Sandoz One Source enrollment form to 1-844-726-3695 and choose co-pay assistance.

\*Terms and Conditions: Maximum benefit of \$10,000 annually. Prescription must be for an approved indication. This program is not health insurance. Eligible patients must be enrolled in commercial insurance 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.

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

 **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.

### 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.

The form is a redacted version of a CMS-1500 claim form. The following boxes are labeled with their respective submission instructions:

- Box 21 Diagnosis Codes:** Located in the upper left section of the form, this box is where diagnosis codes are entered.
- Box 24E Diagnosis Pointer:** Located in the upper right section, this box is where the diagnosis from Box 21 is mapped to a procedure in Box 24D.
- Box 24A Date of Service:** Located in the middle left section, this box is where the date of service is entered.
- Box 24B Place of Service:** Located in the middle left section, this box is where the place of service code is entered.
- Box 24D CPT/HCPCS/J-Code:** Located in the middle right section, this box is where CPT, HCPCS, and J-Code are entered.
- Box 24F Line Total Charge:** Located in the middle right section, this box is where the total charge for each line item is entered.
- Box 24G Line Level Service Units:** Located in the bottom right section, this box is where the number of service units for each line item is entered.

##### 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.

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



# 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).

1	2	3A PAT. CNTL # 3B MED. BILL#	3C	34 FED. TAX NO.	35 STATEMENT COVERS PERIOD FROM _____ THROUGH _____	36	37	38	39	40	41	42	43	44	45	46	47	48	49																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																							
4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													
10	11 BIRTHDATE	12 SEX	13 DATE	14 ADMISSION TYPE	15 SRC	16 DHR	17 STAT	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
11	31 OCCURRENCE CODE DATE	32 OCCURRENCE CODE DATE	33 OCCURRENCE CODE DATE	34 OCCURRENCE CODE DATE	35 OCCURRENCE CODE DATE	36 OCCURRENCE SPAN FROM _____ THROUGH _____	37 OCCURRENCE SPAN FROM _____ THROUGH _____	38 CODE	39 CODE	40 CODE	41 CODE	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100	101	102	103	104	105	106	107	108	109	110	111	112	113	114	115	116	117	118	119	120	121	122	123	124	125	126	127	128	129	130	131	132	133	134	135	136	137	138	139	140	141	142	143	144	145	146	147	148	149	150	151	152	153	154	155	156	157	158	159	160	161	162	163	164	165	166	167	168	169	170	171	172	173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188	189	190	191	192	193	194	195	196	197	198	199	200	201	202	203	204	205	206	207	208	209	210	211	212	213	214	215	216	217	218	219	220	221	222	223	224	225	226	227	228	229	230	231	232	233	234	235	236	237	238	239	240	241	242	243	244	245	246	247	248	249	250	251	252	253	254	255	256	257	258	259	260	261	262	263	264	265	266	267	268	269	270	271	272	273	274	275	276	277	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294	295	296	297	298	299	300	301	302	303	304	305	306	307	308	309	310	311	312	313	314	315	316	317	318	319	320	321	322	323	324	325	326	327	328	329	330	331	332	333	334	335	336	337	338	339	340	341	342	343	344	345	346	347	348	349	350	351	352	353	354	355	356	357	358	359	360	361	362	363	364	365	366	367	368	369	370	371	372	373	374	375	376	377	378	379	380	381	382	383	384	385	386	387	388	389	390	391	392	393	394	395	396	397	398	399	400	401	402	403	404	405	406	407	408	409	410	411	412	413	414	415	416	417	418	419	420	421	422	423	424	425	426	427	428	429	430	431	432	433	434	435	436	437	438	439	440	441	442	443	444	445	446	447	448	449	450	451	452	453	454	455	456	457	458	459	460	461	462	463	464	465	466	467	468	469	470	471	472	473	474	475	476	477	478	479	480	481	482	483	484	485	486	487	488	489	490	491	492	493	494	495	496	497	498	499	500	501	502	503	504	505	506	507	508	509	510	511	512	513	514	515	516	517	518	519	520	521	522	523	524	525	526	527	528	529	530	531	532	533	534	535	536	537	538	539	540	541	542	543	544	545	546	547	548	549	550	551	552	553	554	555	556	557	558	559	560	561	562	563	564	565	566	567	568	569	570	571	572	573	574	575	576	577	578	579	580	581	582	583	584	585	586	587	588	589	590	591	592	593	594	595	596	597	598	599	600	601	602	603	604	605	606	607	608	609	610	611	612	613	614	615	616	617	618	619	620	621	622	623	624	625	626	627	628	629	630	631	632	633	634	635	636	637	638	639	640	641	642	643	644	645	646	647	648	649	650	651	652	653	654	655	656	657	658	659	660	661	662	663	664	665	666	667	668	669	670	671	672	673	674	675	676	677	678	679	680	681	682	683	684	685	686	687	688	689	690	691	692	693	694	695	696	697	698	699	700	701	702	703	704	705	706	707	708	709	710	711	712	713	714	715	716	717	718	719	720	721	722	723	724	725	726	727	728	729	730	731	732	733	734	735	736	737	738	739	740	741	742	743	744	745	746	747	748	749	750	751	752	753	754	755	756	757	758	759	760	761	762	763	764	765	766	767	768	769	770	771	772	773	774	775	776	777	778	779	780	781	782	783	784	785	786	787	788	789	790	791	792	793	794	795	796	797	798	799	800	801	802	803	804	805	806	807	808	809	810	811	812	813	814	815	816	817	818	819	820	821	822	823	824	825	826	827	828	829	830	831	832	833	834	835	836	837	838	839	840	841	842	843	844	845	846	847	848	849	850	851	852	853	854	855	856	857	858	859	860	861	862	863	864	865	866	867	868	869	870	871	872	873	874	875	876	877	878	879	880	881	882	883	884	885	886	887	888	889	890	891	892	893	894	895	896	897	898	899	900	901	902	903	904	905	906	907	908	909	910	911	912	913	914	915	916	917	918	919	920	921	922	923	924	925	926	927	928	929	930	931	932	933	934	935	936	937	938	939	940	941	942	943	944	945	946	947	948	949	950	951	952	953	954	955	956	957	958	959	960	961	962	963	964	965	966	967	968	969	970	971	972	973	974	975	976	977	978	979	980	981	982	983	984	985	986	987	988	989	990	991	992	993	994	995	996	997	998	999	1000

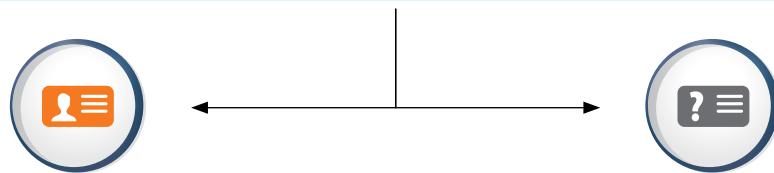
# Submitting Medical Claims Through Sandoz One Source Commercial Co-Pay Program (continued)

## 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.

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

 **ZARXIO®**  
(filgrastim-sndz)

 **ZIEXTENZO®**  
(pegfilgrastim-bmez)

# 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.

Please see page 10-13 for additional Important Safety 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.

# What You Need To Do If Your Patient is Leveraging the Pharmacy Benefit

In certain cases, the HCP may send the prescription to a specialty pharmacy (eg, when ZARXIO or ZIEXTENZO 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 HCP or patient provides patient co-pay information to the specialty pharmacy to process co-pay claims. Either the patient or the office may send over the co-pay information. 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:

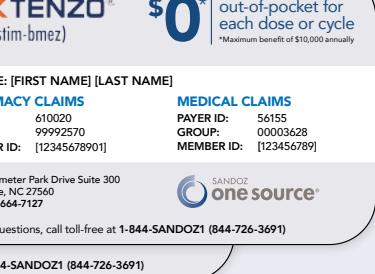
Rx BIN Number: 610020

Group ID: 99992570

Patient ID:  
Unique to each patient



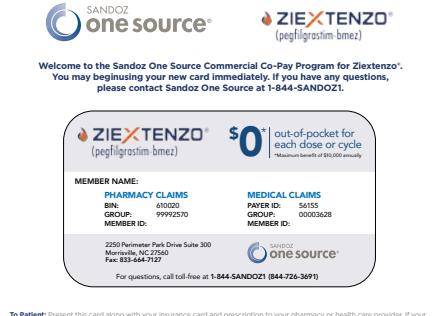
**ZARXIO®**  
(filgrastim-sndz)  
Subcutaneous or Intravenous  
300 mg/0.5 mL | 480 mg/1  
BIN: 610020  
GROUP: 99992570  
MEMBER ID: 12345678901  
2250 Perimeter Park Drive Suite 300  
Morrisville, NC 27560  
Fax: 833-664-7127  
For questions, call toll-free at 1-844-SANDOZ1 (844-726-3691)



**ZIEXTENZO®**  
(pegfilgrastim-bmez)  
\$0\* out-of-pocket for  
each dose or cycle  
\*Maximum benefit of \$10,000 annually  
MEMBER NAME: [FIRST NAME] [LAST NAME]  
**PHARMACY CLAIMS**  
BIN: 610020  
GROUP: 99992570  
MEMBER ID: 12345678901  
2250 Perimeter Park Drive Suite 300  
Morrisville, NC 27560  
Fax: 833-664-7127  
For questions, call toll-free at 1-844-SANDOZ1 (844-726-3691)



**SANDOZ one source®**  
Welcome to the Sandoz One Source Commercial Co-Pay Program for ZIEXTENZO.  
You may begin using your card immediately. If you have any questions,  
please contact Sandoz One Source at 1-844-SANDOZ1.



**SANDOZ one source®**  
**ZIEXTENZO®**  
(pegfilgrastim-bmez)  
\$0\* out-of-pocket for  
each dose or cycle  
\*Maximum benefit of \$10,000 annually  
MEMBER NAME:  
BIN: 610020  
GROUP: 99992570  
MEMBER ID: 12345678901  
2250 Perimeter Park Drive Suite 300  
Morrisville, NC 27560  
Fax: 833-664-7127  
For questions, call toll-free at 1-844-SANDOZ1 (844-726-3691)

- 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.**

**Pharmacy Claims Instructions:** Use patient's medical electronic claim to the Sandoz One Source Commercial Co-Pay Program. Use the Sandoz One Source Commercial Co-Pay Payer ID: 7820 or Institutional CHC Payer ID: 1826 in the manner in which you receive primary insurance.

**Medical Claim Instructions:** Use patient's medical electronic claim to the Sandoz One Source Commercial Co-Pay Program. Use the Sandoz One Source Commercial Co-Pay Payer ID: 7820 or Institutional CHC Payer ID: 1826 in the manner in which you receive primary insurance.

**For help processing this card, call 1-844-SANDOZ1**

**Eligibility Criteria:** Maximum benefit of \$10,000 annually. Prescription must be for an approved indication. This program is not eligible for patients with Medicare, Medicaid, cash-paying or uninsured patients are not eligible. Patients are not eligible if prescription for 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, Medicare, VA, DOD, or Tricare, or private indemnity plans that do not cover prescription drugs. HMO insurance plans that reimburse the patient for the entire cost of their prescription drugs, or where prohibited by law. Co-Pay Program may apply to out-of-pocket expenses that occurred within 120 days prior to the date of the enrollment. 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® is a registered trademark and Sandoz One Source is a trademark of Novartis AG.  
© 2019 Sandoz Inc., a Novartis Division, 100 College Road West, Princeton, NJ 08540 All rights reserved. S-294-XXXXXX 9/19

**SANDOZ**  
**one source®**

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

**ZARXIO®**  
(filgrastim-sndz)

**ZIEXTENZO®**  
(pegfilgrastim-bmez)

# ZARXIO 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.
- 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. 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.

- 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. If a patient with SCN develops abnormal cytogenetics or myelodysplasia, the risks and benefits of continuing ZARXIO should be carefully considered.
- Thrombocytopenia has been reported in patients receiving filgrastim products. Monitor platelet counts.
- Leukocytosis:
  - Patients With Cancer Receiving Myelosuppressive Chemotherapy: White blood cell counts of  $100,000/\text{mm}^3$  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  $10,000/\text{mm}^3$  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  $>100,000/\text{mm}^3$ .
- 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 was decreased.
- The possibility that filgrastim 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.

# ZARXIO Important Safety Information (continued)

## WARNINGS AND PRECAUTIONS (continued)

- 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 filgrastim products 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 ( $\geq 5\%$  difference in incidence compared to placebo) are pyrexia, pain, rash, cough, and dyspnea.
- With AML ( $\geq 2\%$  difference in incidence) are pain, epistaxis and rash.
- With nonmyeloid malignancies undergoing myeloablative chemotherapy followed by BMT ( $\geq 5\%$  difference in incidence) is rash.
- Undergoing peripheral blood progenitor cell mobilization and collection ( $\geq 5\%$  incidence) are bone pain, pyrexia and headache.
- With severe chronic neutropenia (SCN) ( $\geq 5\%$  difference in incidence) are pain, anemia, epistaxis, diarrhea, hypoesthesia and alopecia.

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](http://www.fda.gov/medwatch).

# ZIEXTENZO 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.
- 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  $100 \times 10^9/L$  or greater have been observed in patients receiving pegfilgrastim. Monitoring of CBC during pegfilgrastim therapy is recommended.
- 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.
- 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 Important Safety Information (continued)

## ADVERSE REACTIONS

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

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](http://www.fda.gov/medwatch).

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

## ZARXIO AND ZIEXTENZO BILLING CODES\*

NDC Codes <sup>1,2</sup>			
Formulation	Packaging size	10-digit NDC	11-digit NDC
<b>ZARXIO</b> 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
<b>ZARXIO</b> 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
<b>ZIEXTENZO</b> 6 mg/0.6 mL	1 prefilled syringe	61314-866-01	61314-0866-01

HCPCS Code <sup>3-5</sup>	
Q5101	Injection, filgrastim-sndz, biosimilar (ZARXIO), 1 microgram
J3590	Unclassified Biologics
J3490	Unclassified Drugs
C9058	Injection, pegfilgrastim-bmez, biosimilar, (ZIEXTENZO), 0.5 mg
Q5120 - Effective, July 1, 2020 <sup>†</sup>	Injection, pegfilgrastim-bmez, biosimilar, (ZIEXTENZO), 0.5 mg

CPT Code <sup>6‡</sup>	
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 (specify substance or drug); initial, up to 1 hour

Diagnosis Code <sup>7</sup>	
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.

<sup>†</sup>Q5120, published April 6, effective July 1, 2020. Commercial Payers may accept Q5120 prior to July 1.

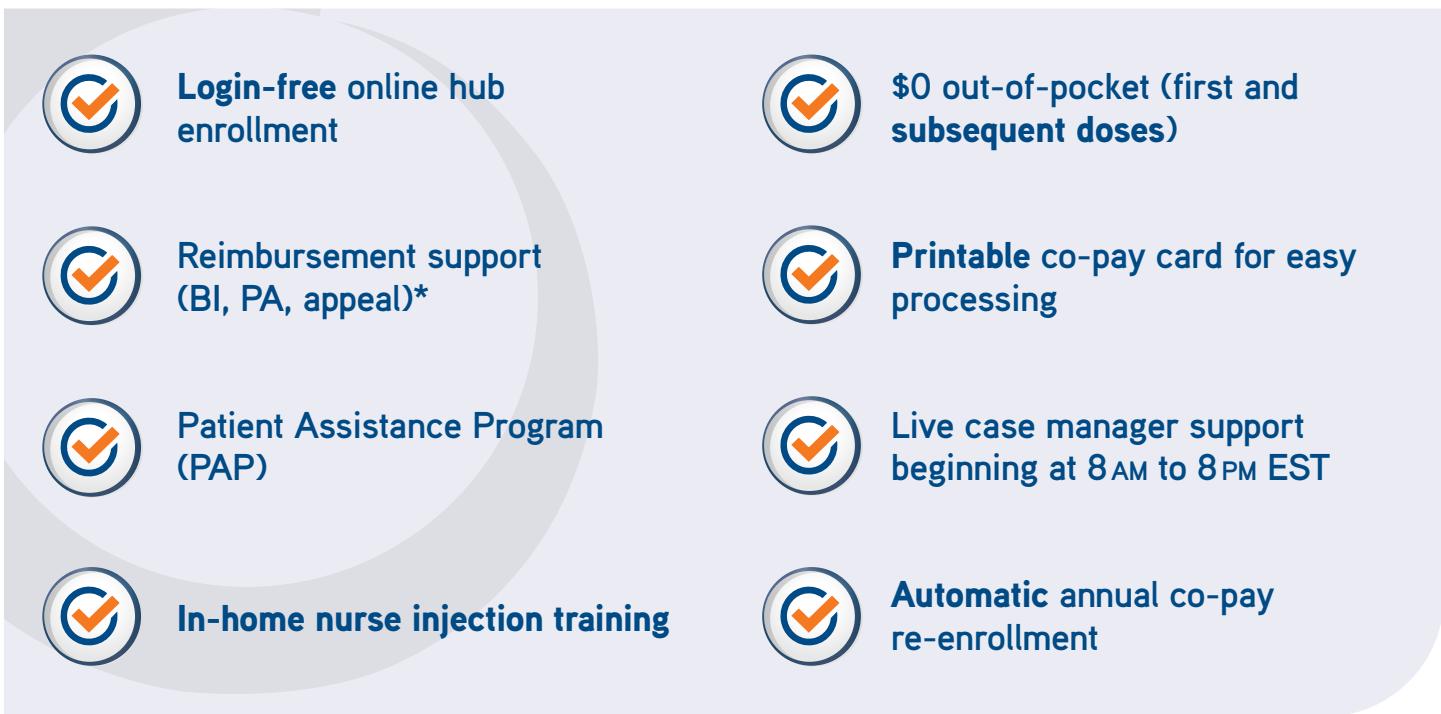
<sup>‡</sup>CPT codes describe the therapeutic injection.

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



# Additional Sandoz One Source Patient Support Services

Sandoz One Source offers the same comprehensive suite of services for both ZARXIO and ZIEXTENZO



## Contact Sandoz One Source

### Phone

 1-844-SANDOZ1  
(1-844-726-3691)  
M-F 8 AM TO 8 PM ET

### Fax

 Enrollments: 1-844-726-3695  
Claims: 833-664-7127

### Website

 [Zarxio.com](http://Zarxio.com)  
[Ziextenzo.com](http://Ziextenzo.com)

\*BI, Benefit Investigation; PA, Prior Authorization.

**References** 1. ZARXIO [prescribing information]. Princeton, NJ: Sandoz Inc; August 2019. 2. ZIEXTENZO [prescribing information]. Princeton, NJ: Sandoz Inc; November, 2019. 3. NOC Codes - HCPCS 2020. Baltimore, MD: Centers for Medicare & Medicaid Services; 2020. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-HCPCSNOC-Codes>. Accessed February 27, 2020. 4. NOC Codes - HCPCS Quarterly Update April 2020. Baltimore, MD: Centers for Medicare & Medicaid Services; 2020. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>. Accessed March 5, 2020. 5. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions: First Quarter, 2020 Coding Cycle for Drug and Biological Products. Baltimore, MD: Centers for Medicare & Medicaid Services; 2020. 6. American Medical Association. CPT® 2019 Professional Edition. 7. 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.

ZARXIO, ZIEXTENZO and the Sandoz One Source logo are registered trademarks of NOVARTIS AG.

**Please see page 10-13 for additional Important Safety Information and accompanying full Prescribing Information for Zarxio and Ziextenzo.**

**SANDOZ** A Novartis Division

© 2020 Sandoz Inc., 100 College Road West, Princeton, NJ 08540  
All Rights Reserved. S-ZIE-1389066 04/2020

 **ZARXIO®**  
(filgrastim-sndz)

 **ZIEXTENZO®**  
(pegfilgrastim-bmez)