

Colony Stimulating Factors: Zarxio™ (filgrastim-sndz)

Document Number: IC-0245

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I. Length of Authorization

Coverage is provided for four months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Zarxio 300 mcg prefilled syringe: 90 syringes per 30 days
- Zarxio 480 mcg prefilled syringe: 90 syringes per 30 days

B. Max Units (per dose and over time) [Medical Benefit]:

Zarxio (J3590)

Severe Chronic Neutropenia:

Male 1380 billable units per day

Female 1200 billable units per day

BMT or PBPC:

Male 1200 billable units per day

Female 960 billable units per day

All other indications:

Male 600 billable units per day

Female 480 billable units per day

III. Initial Approval Criteria

Coverage for Zarxio™ (filgrastim-sndz) is provided in the following conditions:

Bone marrow transplant (BMT) †

Peripheral Blood Progenitor Cell (PBPC) mobilization and transplant†

Patient with non-myeloid malignancy†

- Patient is undergoing myelosuppressive chemotherapy and/or radiotherapy with an expected incidence of febrile neutropenia of 20% or greater‡; **OR**
- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or greater‡ AND one or more of the following co-morbidities:
 - Elderly patients (age 65 or older)
 - History of recurrent febrile neutropenia from chemotherapy
 - Extensive prior exposure to chemotherapy
 - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
 - Pre-existing neutropenia (ANC \leq 1000/mm³) or bone marrow involvement with tumor
 - Patient has a condition that can potentially increase the risk of serious infection (i.e. HIV/AIDS) Infection/open wounds
 - Recent surgery
 - Poor performance status
 - Poor renal function
 - Liver dysfunction (elevated bilirubin)

Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy

Acute Myeloid Leukemia (AML) patient following induction or consolidation chemotherapy†

Bone Marrow Transplantation (BMT) failure or Engraftment Delay

Severe chronic neutropenia (ANC<500)†

Acute treatment of chemotherapy-induced febrile neutropenia

†FDA-labeled indication(s)

‡ expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Myeloid Growth Factors Clinical Practice Guideline at NCCN.org.

IV. Renewal Criteria

Same as initial prior authorization policy criteria.

V. Dosage/Administration

Indication	Dose
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Zarxio	10mcg/kg daily for up to 14 days for BMT and PBPC 6mcg/kg twice daily for up to 14 days for congenital neutropenia 5mcg/kg daily for up to 14 days for all other indications
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VI. Billing Code/Availability Information

JCode:

- Q5101 – Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram

NDC:

- Zarxio 300 mcg prefilled syringe – 61314-304-xx (Sandoz)
- Zarxio 480 mcg prefilled syringe – 61314-312-xx (Sandoz)

VII. References

1. Zarxio [package insert]. Princeton, NJ; Sandoz Inc; March 2016. Accessed April 2016.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) filgrastim-sndz. National Comprehensive Cancer Network, 2016. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2016.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloid Growth Factors. Version 1.2016. National Comprehensive Cancer Network, 2016. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2016.
4. First Coast Service Options, Inc. Local Coverage Determination (LCD): G-CSF (Neupogen®, Granix™) (L34002). Centers for Medicare & Medicaid Services, Inc. Updated on 1/19/2016 with effective date 1/1/2016. Accessed April 2016.
5. National Government Services, Inc. Local Coverage Article: Filgrastim, Pegfilgrastim, Tbofilgrastim (e.g., Neupogen®, Neulasta™, Granix™) - Related to LCD L33394 (A52408). Centers for Medicare & Medicaid Services, Inc. Updated on 12/24/2015 with effective date 1/1/2016. Accessed April 2016.
6. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L34699). Centers for Medicare & Medicaid Services, Inc. Updated on 2/16/2016 with effective date 3/1/2016. Accessed April 2016.

Appendix 1 – Covered Diagnosis Codes

ICD-9 Codes	Diagnosis
288.00	Neutropenia, unspecified
288.01	Congenital neutropenia
288.02	Cyclic neutropenia
288.03	Drug induced neutropenia
996.85	Complications of transplanted bone marrow
V07.8	Other specified prophylactic or treatment measure
V42.81	Bone marrow replaced by transplant
V42.82	Peripheral stem cells replaced by transplant
V58.11	Encounter for antineoplastic chemotherapy
V59.02	Blood donors, stem cells
V66.2	Convalescence following chemotherapy

ICD-10	ICD-10 Description
D70.0	Congenital agranulocytosis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
D70.4	Cyclic neutropenia
D70.9	Neutropenia, unspecified
T86.00	Unspecified complication of bone marrow transplant
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.03	Bone marrow transplant infection
T86.09	Other complications of bone marrow transplant
Z41.8	Encounter for other procedures for purposes other than remedying health state
Z48.290	Encounter for aftercare following bone marrow transplant
Z51.11	Encounter for antineoplastic chemotherapy
Z51.89	Encounter for other specified aftercare
Z52.001	Unspecified donor, stem cells
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
Z94.81	Bone marrow transplant status

ICD-10	ICD-10 Description
Z94.84	Stem cells transplant status

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Jurisdiction(s): 9 (N)	NCD/LCD Document (s): L34002
ICD-10 Codes	Diagnosis
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34002&ver=7&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=Ed&PolicyType=Final&s=All&KeyWord=filgrastim&KeyWordLookUp=Doc&	

Jurisdiction(s): 6, K	NCD/LCD Document (s): A52408
ICD-10 Codes	Diagnosis
https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52408&ver=13&SearchType=Advanced&CoverageSelection=Both&NCSelection=NC A%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=Ed&PolicyType=Final&s=All&KeyWord=filgrastim&KeyWordLo	

Jurisdiction(s): 5,8	NCD/LCD Document (s): L34699
ICD-10 Codes	Diagnosis
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34699&ver=15&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=Ed&PolicyType=Final&s=All&KeyWord=filgrastim&KeyWordLookUp=Doc	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor

E	CA, HI, NV, AS, GU, CNMI	Noridian Administrative Services (NAS)
F	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Administrative Services (NAS)
5	KS, NE, IA, MO	Wisconsin Physicians Service (WPS)
6	MN, WI, IL	National Government Services (NGS)
H	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions
8	MI, IN	Wisconsin Physicians Service (WPS)
9 (N)	FL, PR, VI	First Coast Service Options
10 (J)	TN, GA, AL	Cahaba Government Benefit Administrators
11 (M)	NC, SC, VA, WV	Palmetto GBA
12 (L)	DE, MD, PA, NJ, DC	Novitas Solutions
K	NY, CT, MA, RI, VT, ME, NH	National Government Services (NGS)
15	KY, OH	CGS Administrators, LLC