CareSource

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Neulasta (Pegfilgrastim), Neulasta Onpro (Pegfilgrastim on-body injector)
BILLING CODE	For medical - J2505 (1 unit = 6 mg) For Rx - must use valid NDC
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 2 units per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Neulasta (Pegfilgrastim), Neulasta Onpro (Pegfilgrastim on-body injector) are **preferred** products and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME

For **initial** authorization:

1. Medication is prescribed by physician with expertise in treating acute radiation syndrome; AND
2. Documentation of member's suspected or confirmed exposure to radiation levels greater than 2 gray (Gy).
3. **Dosage allowed:** Two doses, 6 mg each, administered one week apart.

If member meets all the requirements listed above, the medication will be approved for 14 days.

For **reauthorization**:

1. Neulasta will not be reauthorized for the same radiation phase after 2 allowed doses. If another round of radiation therapy is needed in the future, the initial authorization criteria will be applied.

PREVENTION OF FEBRILE NEUTROPENIA

For **initial** authorization:

1. Member has a non-myeloid malignancy; AND
2. Medication will not be administered less than 14 days before OR less than 24 hours after chemotherapy; AND
3. Member has a documented history of febrile neutropenia (defined as an ANC < 1000/mm^3 and temperature > 38.2°C) following a previous course of chemotherapy and is receiving myelosuppressive chemotherapy; OR
4. Member is receiving myelosuppressive anti-cancer drugs associated with a high risk (> 20%, see Appendix for description) for incidence of febrile neutropenia; OR
5. Member is receiving myelosuppressive anti-cancer drugs associated with an intermediate risk (10-20%, see Appendix for description) for incidence of febrile neutropenia including **one** of the following:
   a) Previous chemotherapy or radiation therapy;
   b) Persistent neutropenia;

c) Bone marrow involvement with tumor;
d) Recent surgery and/or open wounds;
e) Liver dysfunction (bilirubin > 2.0);
f) Renal dysfunction (creatinine clearance < 50);
g) Age >65 years receiving full chemotherapy dose intensity.

6. **Dosage allowed:** Up to 6 mg per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Neulasta (Pegfilgrastim) and Neulasta Onpro (Pegfilgrastim on-body injector) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplant

DATE	ACTION/DESCRIPTION
10/19/2017	New Neulasta policy created. Age limits and degree of hematotoxicity were removed; radiation exposure level requirement was decreased. Criteria coverage for Prevention of Febrile Neutropenia was expanded. Chemotherapy regimens with high and intermediate risk of febrile neutropenia were added to the policy's appendix. Not covered diagnosis was added.
2/19/2020	Policy updated to include coverage under pharmacy benefit and requirement for chart notes detailing chemotherapy regimen cycle removed.
3/11/2021	Annual review, no changes

References:

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen Inc; 2016. Accessed March 15, 2017.
2. Neulasta. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed March 15, 2017.
3. Neulasta. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed March 15, 2017.
4. National Comprehensive Cancer Network. (2016). NCCN Drugs & Biologics Compendium™. Pegfilgrastim. Retrieved November 22, 2016 from the National Comprehensive Cancer Network.

Effective date: 01/01/2022
Revised date: 03/11/2021

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Appendix

Chemotherapy Regimens with a High Risk for Febrile Neutropenia (> 20%)

Cancer Type	Regimen
Acute Lymphoblastic Leukemia (ALL)	ALL induction regimens (see NCCN guidelines)
Bladder Cancer	MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) (neoadjuvant, adjuvant, metastatic)
Breast Cancer	Docetaxel + trastuzumab (metastatic or relapsed)
	Dose-dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel) (adjuvant)
	TAC (docetaxel, doxorubicin, cyclophosphamide) (adjuvant)
Esophageal and Gastric Cancers	Docetaxel/cisplatin/fluorouracil
Hodgkin Lymphoma	BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	Doxorubicin/gemcitabine
Non-Hodgkin's Lymphoma	ICE (ifosfamide, carboplatin, etoposide) (diffuse large B-cell lymphoma [DLBCL], peripheral T-cell lymphomas [PTCL], 2nd line)
	RICE (rituximab, ifosfamide, carboplatin, etoposide)
	CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab
	MINE (mesna, ifosfamide, novantrone, etoposide) (DLBCL, 2nd line, refractory)
	DHAP (dexamethasone, cisplatin, cytarabine)
	ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine (Ara-C)) (DLBCL, PTCL, 2nd line, recurrent)
	HyperCVAD + rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone + rituximab)
Melanoma	Dacarbazine-based combination (dacarbazine, cisplatin, vinblastine) (advanced, metastatic, or recurrent)
	Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alpha) (advanced, metastatic, or recurrent)
Ovarian Cancer	Topotecan
	Paclitaxel
	Docetaxel
Soft Tissue Sarcoma	MAID (mesna, doxorubicin, ifosfammide, dacarbazine)
	Doxorubicin
	Ifosfamide/doxorubicin
Small Cell Lung Cancer	Topotecan
Testicular Cancer	VelP (vinblastine, ifosfamide, cisplatin)
	VIP (etoposide, ifosfamide, cisplatin)
	BEP (bleomycin, etoposide, cisplatin)

	TIP (paclitaxel, ifosfamide, cisplatin)

National Comprehensive Cancer Network (NCCN): Myeloid Growth Factors, 2016.

Chemotherapy Regimens with an Intermediate Risk of Febrile Neutropenia (10% to 19%)

Cancer Type	Regimen
Occult Primary Adenocarcinoma	Gemcitabine/docetaxel
Breast Cancer	Docetaxel every 21 days
	CMF classic (cyclophosphamide, methotrexate, fluorouracil) (adjuvant)
	AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only)
	AC + sequential docetaxel + trastuzumab (adjuvant)
	FEC (fluorouracil, epirubicin, cyclophosphamide) + sequential docetaxel
	TC (docetaxel, cyclophosphamide)
Cervical Cancer	Cisplatin/topotecan (recurrent or metastatic)
	Paclitaxel/cisplatin
	Topotecan (recurrent or metastatic)
	Irinotecan (recurrent or metastatic)
Colorectal Cancer	FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Esophageal and Gastric Cancers	Irinotecan/cisplatin
	Epirubicin/cisplatin/5-fluorouracil
	Epirubicin/cisplatin/capecitabine
Multiple Myeloma	DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)
	DT-PACE + bortezomib (VTD-PACE)
Non-Hodgkin's Lymphoma	EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) (AIDS-related NHL, Burkitt lymphoma, recurrent, other NHL subtypes)
	EPOCH-IT chemotherapy (AIDS-related NHL, DLBCL, recurrent)
	GDP (gemcitabine, dexamethasone, cisplatin) (DLBCL, PTCL, 2nd line)
	GDP (gemcitabine, dexamethasone, cisplatin) + rituximab (DLBCL, 2nd line, Burkitt lymphoma, other NHL subtypes)
	FMR (fludarabine, mitoxantrone, rituximab)
	CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin or mitoxantrone substituted for doxorubicin
Non-Small Cell Lung Cancer	Cisplatin/paclitaxel (advanced/metastatic)
	Cisplatin/vinorelbine (adjuvant, advanced/metastatic)
	Cisplatin/docetaxel (adjuvant, advanced/metastatic)
	Cisplatin/etoposide (adjuvant, advanced/metastatic)

	Carboplatin/paclitaxel (adjuvant, advanced/metastatic)
	Docetaxel (advanced/metastatic)
Ovarian Cancer	Carboplatin/docetaxel
Pancreatic Cancer	FOLFIRINOX
Prostate Cancer	Cabazitaxel
Small Cell Lung Cancer	Etoposide/carboplatin
Testicular Cancer	Etoposide/cisplatin
Uterine Sarcoma	Docetaxel (advanced or metastatic)

National Comprehensive Cancer Network (NCCN): Myeloid Growth Factors, 2016.