Medical Policy:

Colony Stimulating Factors: Neulasta® (pegfilgrastim) Subcutaneous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.94	March 17, 2025	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Length of Authorization

Coverage will be provided for six months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

Acute Radiation Exposure

- 12 billable units weekly x 2 doses

All other indications:

- 12 billable units per 14 days

Guideline

I. Initial Approval Criteria

Neulasta *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

Neulasta and Udenyca are the preferred agents for Commercial, Medicaid, and Medicare members.

1. The patient is continuing previously established therapy with **Neulasta** for their current chemotherapy regimen; **OR**
2. A member does not have access to, or benefits for, home health services; **OR**
3. A member is expected to receive G-CSF for 5 consecutive days or more; **OR**
4. Neulasta is used in combination with one of the following chemotherapy regimens*****:
    a. Bladder Cancer
        i. dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
    b. Breast Cancer:
        ii. Dose dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel)
    a. Non-Hodgkin's Lymphoma:
        iii. Dose dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone)

** pegfilgrastim is the only G-CSF product used in the published clinical trials for these regimens. The requesting provider should provide journal citations supporting this request for regimens other than those listed.*

Coverage for Neulasta® (pegfilgrastim) is provided in the following conditions:

Prophylactic use in patients with non-myeloid malignancy †

1. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖ of greater than 20% §; **OR**
2. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖of 10% to 20% § **AND** one or more patient-related risk factors ¥;
3. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖ of <10% **AND** two or more patient related risk factors ¥ **

    ***Use in this setting is based on clinical judgment.*

    Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

§ Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org

¥ Patient risk factors for febrile neutropenia
• Age >65 years receiving full dose intensity chemotherapy • Prior exposure to chemotherapy or radiation therapy • Persistent neutropenia (ANC ≤ 1000/mm3) • Bone marrow involvement by tumor • Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts) • Recent surgery and/or open wounds • Poor performance status • Renal dysfunction (creatinine clearance <50 mL/min) • Liver dysfunction (elevated bilirubin >2.0 mg/dL) • Chronic immunosuppression in the post-transplant setting, including organ transplant
❖ Febrile neutropenia is defined as:
• Temperature: a single temperature ≥38.3 °C orally or ≥38.0 °C over 1 hour; AND • Neutropenia: <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to ≤500 neutrophils/mcL over the next 48 hours

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

Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) †

† 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.

Limitations/Exclusions

Neulasta is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

II. Renewal Criteria

Same as initial prior authorization policy criteria.

Indication	Dose
Acute radiation exposure	6 mg subcutaneously weekly for 2 doses (Use weight based dosing for pediatrics weight < 45 kg)
All other indications	6 mg subcutaneously once per chemotherapy cycle and dosed no more frequently than every 14 days (Use weight based dosing for pediatric patients weighing less than 45 kg)

*Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy

Applicable Procedure Codes

Code	Description
J2506	Injection, pegfilgrastim, 6 mg; 1 billable unit = 6 mg

Applicable NDCs

Code	Description
55513-0190-xx	Neulasta 6 mg prefilled syringe
55513-0192-xx	Neulasta 6 mg prefilled syringe Onpro Kit

ICD-10 Diagnoses

Code	Description
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.9	Neutropenia, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs sequela
T66.XXXA	Radiation sickness, unspecified, initial encounter
Z41.8	Encounter for other procedures for purposes other then remedying health state
Z48.290	Encounter for aftercare following bone marrow transplant
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy

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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
Z94.84	Stem cells transplant status

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/17/2025	Updated risk factors(patient co-morbidities) for febrile neutropenia. Added to criteria: Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of <10% AND two or more patient related risk factors ¥ ** Separated from criteria co-morbidities and created chart to reference, as well as defining febrile neutropenia
EmblemHealth & ConnectiCare	3/21/2024	Annual Review: Updated dosing chart
EmblemHealth & ConnectiCare	9/13/2023	Annual Review: Updated Dosing Limits: Removed:" 1 billable unit weekly x 2 doses for Acute Radiation Exposure 1 billable unit per 14 days for all other indications" Added: "Acute Radiation Exposure • 12 billable units weekly x 2 doses All other indications: • 12 billable units per 14 days"
EmblemHealth & ConnectiCare	4/07/2022	Transferred policy to new template. Updated billing code from J2505 to J2506.
EmblemHealth & ConnectiCare	1/01/2021	Extended coverage duration from 4 to 6 months

References

1. Neulasta [package insert]. Thousand Oaks, CA; Amgen Inc; April 2019. Accessed December 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pegfilgrastim. National Comprehensive Cancer Network, 2018. 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 June 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloid Growth Factors. Version 1.2018. National Comprehensive Cancer Network, 2018. 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 July 2018.
4. Russel N, Mesters R, Schubert J, et al. A phase 2 pilot study of pegfilgrastim and filgrastim for mobilizing peripheral blood progenitor cells in patients with non-Hodgkin's lymphoma receiving chemotherapy. Haematologica March 200893:405-412;doi:10.3324/haematol.11287

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5. Isidori A, Tani M, Bonifazi F, et al. Phase II study of a single pegfilgrastim injection as an adjunct to chemotherapy to mobilize stem cells into the peripheral blood of pretreated lymphoma patients. Haematologica January 200590:225-231
6. Jagasia MH, Greer JP, Morgan DS, et al. Pegfilgrastim after high-dose chemotherapy and autologous peripheral blood stem cell transplant: phase II study. Bone Marrow Transplant. 2005 Jun;35(12):1165-9.
7. Bruns, Ingmar, et al. "A single dose of 6 or 12 mg of pegfilgrastim for peripheral blood progenitor cell mobilization results in similar yields of CD34+ progenitors in patients with multiple myeloma." Transfusion 46.2 (2006): 180-185.
8. Staber, P. B., et al. "Fixed-dose single administration of Pegfilgrastim vs daily Filgrastim in patients with haematological malignancies undergoing autologous peripheral blood stem cell transplantation." Bone marrow transplantation 35.9 (2005): 889-893.
9. Vanstraelen, Gaëtan, et al. "Pegfilgrastim compared with Filgrastim after autologous hematopoietic peripheral blood stem cell transplantation." Experimental hematology 34.3 (2006): 382-388.
10. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L34699). Centers for Medicare & Medicaid Services, Inc. Updated on 4/20/2018 with effective date 05/1/2018. Accessed July 2018.
11. First Coast Service Options, Inc. Local Coverage Determination (LCD): Pegfilgrastim (Neulasta®) (L33747). Centers for Medicare & Medicaid Services, Inc. Updated on 9/22/2017 with effective date 10/1/2017. Accessed July 2018.
12. National Government Services, Inc. Local Coverage Article: Filgrastim, Pegfilgrastim, Tbo-filgrastim, Filgrastim-sndz (e.g., Neupogen®, Neulasta™, Granix™, Zarxio™) - Related to LCD L33394 (A52408). Centers for Medicare & Medicaid Services, Inc. Updated on 7/6/2018 with effective date 7/15/2018. Accessed July 2018.
13. Palmetto GBA. Local Coverage Article: Neulasta® (PEGFILGRASTIM) Onpro® Kit (On-Body Injector) (A54682). Centers for Medicare & Medicaid Services, Inc. Updated on 5/11/2018 with effective date 5/17/2018. Accessed July 2018.
14. CGS Administrators, LLC. Local Coverage Article: Neulasta® (PEGFILGRASTIM) Delivery Kit (On-Body Injector) (A54826). Centers for Medicare & Medicaid Services, Inc. Updated on 2/6/2017 with effective date 1/1/2017. Accessed July 2018.
15. Palmetto GBA. Local Coverage Determination: White Cell Colony Stimulating Factors (L37176). Centers for Medicare & Medicaid Services, Inc. Updated on 5/4/2018 with effective date 4/1/2018. Accessed July 2018.

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