

# Clover

## Colony Stimulating Factors: Neulasta® (pegfilgrastim)

(Subcutaneous)

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### I. Length of Authorization

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

### II. Dosing Limits

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

- Neulasta 6 mg prefilled syringe: 1 syringe per 14 days

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

- 1 billable unit weekly x 2 doses for Acute Radiation Exposure
- 1 billable unit per 14 days for all other indications

### III. Initial Approval Criteria

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

Prophylactic use in patients with non-myeloid malignancy †

- o Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater § ; **OR**
- o 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 ( $ANC \leq 1000/mm^3$ ) 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 (creatinine clearance <50)
- Liver dysfunction (elevated bilirubin >2.0)
- Chronic immunosuppression in the post-transplant setting including organ transplant

**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) †**

**Bone marrow transplantation (BMT) failure or engraftment delay ‡**

**Peripheral blood progenitor cell (PBPC) mobilization and transplant ‡**

† FDA-labeled indication(s); ‡ Compendia recommended 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                                                                                                                                                                                                                                             |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| All other indications*   | <ul style="list-style-type: none"> <li>- &lt;10 kg = 0.1 mg/kg</li> <li>- 10-20 kg = 1.5 mg</li> <li>- 21-30 kg = 2.5 mg</li> <li>- 31-44 kg = 4 mg</li> <li>- 45 kg and up = 6 mg</li> </ul> <p>Dosed no more frequently than every 14 days</p> |
| Acute Radiation Exposure | 6 mg subcutaneously weekly x 2 doses (Use weight based dosing for pediatrics weighing <45 kg)                                                                                                                                                    |

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

\*Onpro On-body Injector may be administered on the same day as chemotherapy as long as the Neulasta is administered no less than 24 hours after administration of chemotherapy. Not recommended for use in patients with acute radiation exposure

#### VI. Billing Code/Availability Information

Jcode:

- J2505 – Injection, pegfilgrastim, 6 mg; 1 billable unit = 6 mg

NDC:

- Neulasta 6 mg prefilled syringe: 55513-0190-xx

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#### NEULASTA® (pegfilgrastim) Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

- Neulasta 6 mg prefilled syringe Onpro Kit: 55513-0192-xx

## VII. References

1. Neulasta [package insert]. Thousand Oaks, CA; Amgen Inc; June 2018. Accessed October 2018.
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 October 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloid Growth Factors. Version 2.2018. 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 October 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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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.
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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 9/19/2018 with effective date 10/1/2018. Accessed October 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 October 2018.
12. National Government Services, Inc. Local Coverage Article: Filgrastim, Pegfilgrastim, Tbofilgrastim, Filgrastim-sndz (e.g., Neupogen®, Neulasta™, Granix™, Zarxio™) - Related to LCD L33394 (A52408). Centers for Medicare & Medicaid Services, Inc. Updated on 10/13/2018 with effective date 10/01/2018. Accessed October 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 October 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 October 2018.
15. Palmetto GBA. Local Coverage Determination: White Cell Colony Stimulating Factors (L37176). Centers for Medicare & Medicaid Services, Inc. Updated on 10/11/2018 with effective date 10/18/2018. Accessed October 2018.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10   | ICD-10 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 than remedying health state     |
| Z48.290  | Encounter for aftercare following bone marrow transplant                          |
| Z51.11   | Encounter for antineoplastic chemotherapy                                         |
| Z51.12   | Encounter for antineoplastic immunotherapy                                        |
| 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                                                      |

## 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.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

|                                                                                                                                                                                                                                                                         |                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| <b>Jurisdiction(s):</b> 5,8                                                                                                                                                                                                                                             | <b>NCD/LCD Document (s):</b> L34699 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34699&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34699&amp;bc=gAAAAAAAAAAAA</a>                                 |                                     |
| <b>Jurisdiction(s):</b> 6, K                                                                                                                                                                                                                                            | <b>NCD/LCD Document (s):</b> A52408 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A52408&amp;bc=gAAAAAAAAAAAA&amp;">https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A52408&amp;bc=gAAAAAAAAAAAA&amp;</a> |                                     |
| <b>Jurisdiction(s):</b> N                                                                                                                                                                                                                                               | <b>NCD/LCD Document (s):</b> L33747 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33747&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33747&amp;bc=gAAAAAAAAAAAA</a>                                 |                                     |
| <b>Jurisdiction(s):</b> J, M                                                                                                                                                                                                                                            | <b>NCD/LCD Document (s):</b> L37176 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L37176&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L37176&amp;bc=gAAAAAAAAAAAA</a>                                 |                                     |
| <b>Jurisdiction(s):</b> N                                                                                                                                                                                                                                               | <b>NCD/LCD Document (s):</b> A54826 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54826&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54826&amp;bc=gAAAAAAAAAAAA</a>                         |                                     |
| <b>Jurisdiction(s):</b> M                                                                                                                                                                                                                                               | <b>NCD/LCD Document (s):</b> A54682 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54682&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54682&amp;bc=gAAAAAAAAAAAA</a>                         |                                     |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                        |                                                   |
|---------------------------------------------------------------|----------------------------------------|---------------------------------------------------|
| Jurisdiction                                                  | Applicable State/US Territory          | Contractor                                        |
| E (1)                                                         | CA, HI, NV, AS, GU, CNMI               | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)                                                     | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC                |
| 5                                                             | KS, NE, IA, MO                         | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6                                                             | MN, WI, IL                             | National Government Services, Inc. (NGS)          |
| H (4 & 7)                                                     | LA, AR, MS, TX, OK, CO, NM             | Novitas Solutions, Inc.                           |
| 8                                                             | MI, IN                                 | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)                                                         | FL, PR, VI                             | First Coast Service Options, Inc.                 |
| J (10)                                                        | TN, GA, AL                             | Palmetto GBA, LLC                                 |

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

| <b>Jurisdiction</b> | <b>Applicable State/US Territory</b>                                                        | <b>Contractor</b>                        |
|---------------------|---------------------------------------------------------------------------------------------|------------------------------------------|
| M (11)              | NC, SC, WV, VA (excluding below)                                                            | Palmetto GBA, LLC                        |
| L (12)              | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                  |
| K (13 & 14)         | NY, CT, MA, RI, VT, ME, NH                                                                  | National Government Services, Inc. (NGS) |
| 15                  | KY, OH                                                                                      | CGS Administrators, LLC                  |