

## Long-Acting Granulocyte Colony Stimulating Factors (LA-G-CSF):

**Armlupeg®; Fulphila®; Fylnetra®; Neulasta®; Nyvepria™; Pegfilgrastim-fpgk; Rolvedon®; Ryzneuta®; Stimufend®; Udenyca®; Ziextenzo®**  
(Subcutaneous)

Document Number: IC-0234

**Last Review Date: 05/05/2026**

**Date of Origin: 10/17/2008**

**Dates Reviewed: 06/2009, 12/2009, 06/2010, 07/2010, 09/2010, 12/2010, 03/2011, 06/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 06/2018, 09/2018, 12/2018, 03/2019, 06/2019, 09/2019, 12/2019, 02/2020, 06/2020, 07/2020, 09/2020, 01/2021, 04/2021, 10/2021, 04/2022, 06/2022, 10/2022, 04/2023, 02/2024, 04/2024, 05/2025, 11/2025, 05/2026**

### **I. Length of Authorization** <sup>1-9,16-21,39</sup>

#### **Armlupeg, Fulphila, Fylnetra, Neulasta, Nyvepria, Stimufend/Pegfilgrastim-fpgk, Udenyca, and Ziextenzo**

- Initial: Prior authorization validity will be provided initially for 4 months (120 days), unless otherwise specified.
  - Bone marrow transplantation (BMT) failure or engraftment delay: Prior authorization validity will be provided for 1 dose only.
  - Peripheral blood progenitor cell (PBPC) mobilization and transplant: Prior authorization validity will be provided for 1 dose only.
  - Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]): Prior authorization validity will be provided for 2 doses only.
- Renewal: Prior authorization validity may be renewed every 4 months (120 days) thereafter, unless otherwise specified:
  - Prior authorization validity may NOT be renewed for the following indications:
    - ❖ Bone marrow transplantation (BMT) failure or engraftment delay
    - ❖ Peripheral blood progenitor cell (PBPC) mobilization and transplant
    - ❖ Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS])

#### **Rolvedon, Ryzneuta**

- Initial: Prior authorization validity will be provided initially for 4 months (120 days), unless otherwise specified.
  - Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]): Prior authorization validity will be provided for 2 doses only.

- Renewal: Prior authorization validity may be renewed every 4 months (120 days) thereafter, unless otherwise specified:
  - Acute exposure to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]): Prior authorization validity may not be renewed.

## II. Dosing Limits

### Max Units (per dose and over time) [HCPCS Unit]:

| Drug Name  | Indication  | Billable Units                      |
|--|---|-------------------------------------|
| Armlupeg, Fulphila, Fylnetra, Neulasta, Nyvepria, Stimufend/Pegfilgrastim-fpgk, Udenyca, and Ziextenzo | Acute Radiation Exposure  | 12 billable units weekly x 2 doses  |
|  | BMT failure or engraftment delay/PBPC mobilization and transplant | 12 billable units x 1 dose          |
|  | All other indications   | 12 billable units per 14 days       |
| Rolvedon   | Acute Radiation Exposure  | 132 billable units weekly x 2 doses |
|  | All other indications   | 132 billable units per 14 days      |
| Ryzneuta   | Acute Radiation Exposure  | 40 billable units weekly x 2 doses  |
|  | All other indications   | 40 billable units per 14 days       |

## III. Initial Approval Criteria <sup>1-9,39</sup>

Prior authorization validity is provided in the following conditions:

- Patient must have a contraindication, intolerance, or failure to **Fulphila® AND Udenyca®** prior to consideration of Fylnetra®, Neulasta®, Nyvepria™, Stimufend®/Pegfilgrastim-fpgk, OR Ziextenzo®; **OR**
- Patient must have a contraindication, intolerance, or failure to **Rolvedon®** prior to consideration of Ryzneuta; **AND**

- Member is at least 18 years of age (*Rolvedon and Ryzneuta ONLY*); **AND**

### Prophylactic use in members with solid tumors or non-myeloid malignancy † ‡ <sup>1-12,22,24-32,39</sup>

- Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia❖ of > 20% §; **OR**
- Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia❖ of 10% to 20% § **AND one** or more member-related risk factors ¥; **OR**
- Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia❖ of <10% § **AND two** or more member-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.

**Members who experience a neutropenic complication from a prior cycle of the same chemotherapy †<sup>11,12</sup>**

**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.

**Members acutely exposed to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]) † ‡ Φ<sup>1,3,4,6,7,11,12,31,32,39</sup>**

**Bone marrow transplantation (BMT) failure or engraftment delay ‡<sup>16-21</sup> (Note: NOT applicable to Rolvedon or Ryzneuta)**

**Peripheral blood progenitor cell (PBPC) mobilization and transplant ‡<sup>11</sup> (Note: NOT applicable to Rolvedon or Ryzneuta)**

**Wilms Tumor (Nephroblastoma) ‡<sup>11</sup> (Note: NOT applicable to Rolvedon or Ryzneuta)**

- Member has favorable histology disease; **AND**
- Used in combination with a cyclophosphamide-based chemotherapy regimen (i.e., Regimen M or Regimen I only)

**Pediatric Aggressive Mature B-Cell Lymphomas ‡<sup>11,38</sup> (Note: NOT applicable to Rolvedon or Ryzneuta)**

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

**¥ Member risk factors for febrile neutropenia<sup>12</sup>**

- Age >65 years receiving full dose intensity chemotherapy
- Prior exposure to chemotherapy or radiation therapy
- Persistent neutropenia
- Bone marrow involvement by tumor
- Human immunodeficiency virus (HIV) infection
- 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:<sup>12</sup>**

- **Temperature:** a single temperature  $\geq 38.3$  °C orally or  $\geq 38.0$  °C over 1 hour; **AND**
- **Neutropenia:** <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to  $\leq 500$  neutrophils/mcL over the next 48 hours

**§** Examples of incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the National Comprehensive Cancer Network (NCCN) Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org<sup>12</sup>

#### IV. Renewal Criteria <sup>1-9,39</sup>

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: splenic rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, myelodysplastic syndrome and acute myeloid leukemia in members with breast and lung cancer, etc.

#### V. Dosage/Administration <sup>1-9,12,16-21,39</sup>

##### Armlupeg, Fulphila, Fylnetra, Neulasta, Nyvepria, Stimufend/Pegfilgrastim-fpgk, Udenyca, and Ziextenzo

| Indication  | Dose   |
|---|--|
| Acute Radiation Exposure (Hematopoietic Acute Radiation Syndrome)   | <ul style="list-style-type: none"><li>• Administer 6 mg* subcutaneously weekly x 2 doses</li><li>• *For pediatric members weighing &lt;45 kg:<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></ul></li></ul>   |
| BMT failure or engraftment delay<br>PBPC mobilization and transplant  | Administer 6 mg subcutaneously for 1 dose only   |
| All other indications   | <ul style="list-style-type: none"><li>• Administer 6 mg* subcutaneously once per chemotherapy cycle and dosed no more frequently than every 14 days</li><li>• * For pediatric members weighing &lt;45 kg:<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></ul></li></ul> |
| <b>NOTE:</b> <ul style="list-style-type: none"><li>• Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy.</li><li>• Use of the pre-filled syringe products may be self-administered or administered by a caregiver or healthcare professional.</li><li>• A healthcare provider must fill the on-body injector with Neulasta or Udenyca using the prefilled syringe and then apply the on-body injector to the member's skin (abdomen or back of arm).</li></ul> |  |

- On-body Injectors may be applied on the same day as chemotherapy as long as the Neulasta or Udenyca is administered no less than 24 hours after administration of chemotherapy. Not recommended for use in members with acute radiation exposure or in pediatric members.

### **Rolvedon**

| <b>Indication</b>  | <b>Dose</b>   |
|--|---|
| Prophylactic use in members with solid tumors or non-myeloid malignancy<br><br>Member who experienced a neutropenic complication from a prior cycle of the same chemotherapy   | <ul style="list-style-type: none"> <li>• Administer 13.2 mg subcutaneously once per chemotherapy cycle approximately 24 hours after cytotoxic chemotherapy</li> </ul> |
| Acute Radiation Exposure (Hematopoietic Acute Radiation Syndrome)  | <ul style="list-style-type: none"> <li>• Administer 13.2 mg subcutaneously weekly x 2 doses</li> </ul>  |
| <b><u>NOTE:</u></b>  |   |
| <ul style="list-style-type: none"> <li>• Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy.</li> <li>• Rolvedon may be self-administered or administered by a caregiver or healthcare professional.</li> </ul> |   |

### **Ryzneuta**

| <b>Indication</b>   | <b>Dose</b>   |
|---|---|
| Prophylactic use in members with solid tumors or non-myeloid malignancy<br><br>Member who experienced a neutropenic complication from a prior cycle of the same chemotherapy  | <ul style="list-style-type: none"> <li>• Administer 20 mg subcutaneously once per chemotherapy cycle at least 24 hours after cytotoxic chemotherapy.</li> </ul> |
| Acute Radiation Exposure (Hematopoietic Acute Radiation Syndrome)   | <ul style="list-style-type: none"> <li>• Administer 20 mg subcutaneously weekly x 2 doses</li> </ul>  |
| <b><u>NOTE:</u></b>   |   |
| <ul style="list-style-type: none"> <li>• Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy.</li> <li>• Ryzneuta is administered subcutaneously via a single-dose prefilled syringe by a healthcare professional.</li> </ul> |   |

## **VI. Billing Code/Availability Information**

### **HCPCS Code(s):**

- J2506 – Injection, pegfilgrastim, excludes biosimilar, 0.5 mg; 1 billable unit = 0.5 mg (*Neulasta only*)
- Q5108 – Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg; 1 billable unit = 0.5 mg
- Q5111 – Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg; 1 billable unit = 0.5 mg

- Q5120 – Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg; 1 billable unit = 0.5 mg
- Q5122 – Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg; 1 billable unit = 0.5 mg
- Q5127 – Injection, pegfilgrastim-fpgk, biosimilar, (Stimufend), 0.5 mg; 1 billable unit = 0.5 mg  
(Includes unbranded biologic<sup>§</sup>)
- Q5130 – Injection, pegfilgrastim-pbbk, biosimilar, (Fylnetra), 0.5 mg; 1 billable unit = 0.5 mg
- Q5169 – Injection, pegfilgrastim-unne (Armlupeg), biosimilar, 0.5 mg; 1 billable unit = 0.5 mg  
(Effective 07/01/2026)
- J3590 – Unclassified biologics (Armlupeg ONLY) (Discontinue use on 07/01/2026)
- J1449 – Injection, eflapegrastim-xnst, 0.1 mg; 1 billable unit = 0.1 mg (Rolvedon only)
- J9361 – Injection, efbemalenograstim alfa-vuxw, 0.5 mg; 1 billable unit = 0.5 mg (Ryzneuta only)

#### NDC(s):

- Neulasta 6 mg single-dose prefilled syringe: 55513-0190-xx
- Neulasta 6 mg single-dose prefilled syringe Onpro Kit: 55513-0192-xx
- Neulasta 4 mg/0.4 mL single-dose vial: 55513-0099-xx
- Fulphila 6 mg single-dose prefilled syringe: 83257-0005-xx
- Fulphila 6 mg single-dose prefilled syringe: 67457-0833-xx
- Udenyca 6 mg single-dose prefilled syringe: 70114-0101-xx
- Udenyca 6mg single-dose prefilled syringe: 69448-0025-xx
- Udenyca 6 mg single-dose prefilled autoinjector: 70114-0120-xx
- Udenyca 6 mg single-dose prefilled autoinjector: 69448-0026-xx
- Udenyca 6 mg single-dose prefilled syringe ONBODY kit: 70114-0130-xx
- Udenyca 6 mg single-dose prefilled syringe ONBODY kit: 69448-0027-xx
- Ziextenzo 6 mg single-dose prefilled syringe: 61314-0866-xx
- Nyvepria 6 mg single-dose prefilled syringe: 00069-0324-xx
- Fylnetra 6 mg single-dose prefilled syringe: 70121-1627-xx
- Stimufend 6 mg single-dose prefilled syringe: 65219-0371-xx
- Pegfilgrastim-fpgk 6 mg single-dose prefilled syringe: xxxxx-xxxx-xx (Unbranded biologic of Stimufend<sup>§</sup>)
- Armlupeg 6 mg single-dose prefilled syringe: 70748-0273-xx
- Rolvedon 13.2 mg single-dose prefilled syringe: 76961-0101-xx
- Ryzneuta 20 mg/mL prefilled syringe: 72893-0016-xx

<sup>§</sup>An unbranded biologic is the same as the brand biologic and uses the same cell-line as the brand-name reference biologic.

## VII. References

1. Neulasta [package insert]. Thousand Oaks, CA; Amgen Inc.; August 2025. Accessed April 2026.

2. Fulphila [package insert]. Cambridge, MA; Biocon Biologics Inc.; June 2023. Accessed October 2025.
3. Udenyca [package insert]. Raleigh, NC; Accord BioPharma, Inc.; July 2025. Accessed October 2025.
4. Ziextenzo [package insert]. Princeton, NJ; Sandoz, Inc.; February 2024. Accessed October 2025.
5. Nyvepria [package insert]. Lake Forest, IL; Hospira, Inc.; March 2023. Accessed October 2025.
6. Fylnetra [package insert]. Piscataway, NJ; Kashiv BioSciences, LLC; April 2025. Accessed October 2025.
7. Stimufend/Pegfilgrastim-fpgk [package insert]. Lake Zurich, IL; Fresenius Kabi USA, LLC; March 2025. October 2025.
8. Rolvedon [package insert]. Lake Forest, IL; Spectrum Pharmaceuticals, Inc; July 2025. Accessed October 2025.
9. Ryzneuta [package insert]. Singapore; Evive Biotechnology, LTD; December 2024. Accessed October 2025.
10. Vogel CL, Wojtukiewicz MZ, Carroll RR, et al. First and subsequent cycle use of pegfilgrastim prevents febrile neutropenia in patients with breast cancer: a multicenter, double-blind, placebo-controlled phase III study. *J Clin Oncol*. 2005 Feb 20;23(6):1178-84.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pegfilgrastim. National Comprehensive Cancer Network, 2025. 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](https://www.nccn.org). Accessed October 2025.
12. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hematopoietic Growth Factors. Version 1.2025. National Comprehensive Cancer Network, 2025. 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](https://www.nccn.org). Accessed October 2025.
13. Holmes FA, O'Shaughnessy JA, Vukelja S, et al. Blinded, randomized, multicenter study to evaluate single administration pegfilgrastim once per cycle versus daily filgrastim as an adjunct to chemotherapy in patients with high-risk stage II or stage III/IV breast cancer. *J Clin Oncol*. 2002;20:727–31.
14. Green MD, Koelbl H, Baselga J, et al.; International Pegfilgrastim 749 Study Group. A randomized double-blind multicenter phase III study of fixed-dose single-administration pegfilgrastim versus daily filgrastim in patients receiving myelosuppressive chemotherapy. *Ann Oncol*. 2003;14(1):29-35.
15. Burris HA, Belani CP, Kaufman PA, et al. Pegfilgrastim on the same day versus next day of chemotherapy in patients with breast cancer, non-small-cell lung cancer, ovarian cancer, and non-

- Hodgkin's lymphoma: Results of four multicenter, double-blind, randomized phase II studies. *J Oncol Pract.* 2010;6(3):133-140.
16. 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 2008;93:405-412;doi:10.3324/haematol.11287.
  17. 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 2005;90:225-231.
  18. 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.
  19. Bruns I, Steidl U, Kronenwett R, 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.* 2006 Feb;46(2):180-5.
  20. Staber PB, Holub R, Linkesch W, 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 Transplant.* 2005 May;35(9):889-93.
  21. Vanstraelen G, Frere P, Ngirabacu MC, et al. Pegfilgrastim compared with Filgrastim after autologous hematopoietic peripheral blood stem cell transplantation. *Exp Hematol.* 2006 Mar;34(3):382-8.
  22. Spunt S, Irving H, Frost J, et al. Phase II, Randomized, Open-Label Study of Pegfilgrastim-Supported VDC/IE Chemotherapy in Pediatric Sarcoma Patients. *J Clin Oncol.* 2010 Mar 10; 28(8): 1329–1336.
  23. Hankey KG, Farese AM, Blaauw EC, et al. Pegfilgrastim Improves Survival of Lethally Irradiated Nonhuman Primates. *Radiat Res.* 2015 Jun;183(6):643-55. Epub 2015 Jun 2.
  24. Waller CF, Ranganna GM, Pennella EJ, et al. Randomized phase 3 efficacy and safety trial of proposed pegfilgrastim biosimilar MYL-1401H in the prophylactic treatment of chemotherapy-induced neutropenia. *Ann Hematol.* 2019 May;98(5):1217-1224. doi: 10.1007/s00277-019-03639-5. Epub 2019 Mar 1.
  25. Hoy SM. Pegfilgrastim-jmdb/MYL-1401H: A Pegfilgrastim Biosimilar. *BioDrugs.* 2019 Feb;33(1):117-120. doi: 10.1007/s40259-019-00334-9.
  26. Blackwell K, Donskih R, Jones CM, et al. A Comparison of Proposed Biosimilar LA-EP2006 and Reference Pegfilgrastim for the Prevention of Neutropenia in Patients With Early-Stage Breast Cancer Receiving Myelosuppressive Adjuvant or Neoadjuvant Chemotherapy: Pegfilgrastim Randomized Oncology (Supportive Care) Trial to Evaluate Comparative Treatment (PROTECT-2), a Phase III, Randomized, Double-Blind Trial. *Oncologist.* 2016 Jul; 21(7): 789–794. Published online 2016 Apr 18. doi: 10.1634/theoncologist.2016-0011
  27. Nakov R, Gattu S, Wang J, et al. Abstract P3-14-10: Proposed biosimilar pegfilgrastim LA-EP2006 shows similarity in pharmacokinetics and pharmacodynamics to reference pegfilgrastim in healthy

- subjects. Abstracts: 2017 San Antonio Breast Cancer Symposium; December 5-9, 2017; San Antonio, Texas. DOI: 10.1158/1538-7445.SABCS17-P3-14-10 Published February 2018
28. Glaspy JA, O'Connor PG, Tang H, et al. Randomized, single-blind, crossover study to assess the pharmacokinetic and pharmacodynamic bioequivalence of CHS-1701 to pegfilgrastim in healthy subjects *Journal of Clinical Oncology* 35, no. 15\_suppl. DOI: 10.1200/JCO.2017.35.15\_suppl.e21693. Published online May 30, 2017.
29. Lickliter J, Kanceva R, Vincent E, et al. Pharmacokinetics and Pharmacodynamics of a Proposed Pegfilgrastim Biosimilar MSB11455 Versus the Reference Pegfilgrastim Neulasta in Healthy Subjects: A Randomized, Double-blind Trial. *Clin Ther.* 2020 Aug;42(8):1508-1518.e1. doi: 10.1016/j.clinthera.2020.05.020. Epub 2020 Jul 11.
30. Wynne C, Schwabe C, Vincent E, et al. Immunogenicity and safety of a proposed pegfilgrastim biosimilar MSB11455 versus the reference pegfilgrastim Neulasta® in healthy subjects: A randomized, double-blind trial. *PRP*, Volume 8, Issue 2, April 2020, e00578. <https://doi.org/10.1002/prp2.578>.
31. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) eflapegrastim. National Comprehensive Cancer Network, 2025. 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 2025.
32. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) efbemalenograstim. National Comprehensive Cancer Network, 2025. 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 2025.
33. Schwartzberg LS, Bhat G, Bharadwaj JS, et al. Eflapegrastim, a novel and potent long-acting G-CSF for reducing chemotherapy-induced neutropenia: Integrated results from two phase III trials in breast cancer patients. DOI: 10.1200/JCO.2019.37.15\_suppl.539 *Journal of Clinical Oncology* 37, no. 15\_suppl (May 20, 2019) 539-539.
34. Schwartzberg LS, Bhat G, Peguero J, et al. Eflapegrastim, a Long-Acting Granulocyte-Colony Stimulating Factor for the Management of Chemotherapy-Induced Neutropenia: Results of a Phase III Trial, *The Oncologist*, Volume 25, Issue 8, August 2020, Pages e1233–e1241, <https://doi.org/10.1634/theoncologist.2020-0105>
35. Cobb PW, Moon YW, Mezei K, et al. A comparison of eflapegrastim to pegfilgrastim in the management of chemotherapy-induced neutropenia in patients with early-stage breast cancer undergoing cytotoxic chemotherapy (RECOVER): A Phase 3 study. *Cancer Medicine*. Volume 9, Issue 17. September 2020. Pages 6234-6243. <https://doi.org/10.1002/cam4.3227>.
36. Glaspy J, Bondarenko I, Burdaeva O, et al. Efbemalenograstim alfa, an Fc fusion protein, long-acting granulocyte-colony stimulating factor for reducing the risk of febrile neutropenia following

chemotherapy: results of a phase III trial. Support Care Cancer. 2023 Dec 16;32(1):34. doi: 10.1007/s00520-023-08176-6. PMID: 38103088; PMCID: PMC10725375.

37. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015 Oct 1;33(28):3199-212. doi: 10.1200/JCO.2015.62.3488.
38. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Pediatric Aggressive Mature B-Cell Lymphomas. Version 2.2025. National Comprehensive Cancer Network, 2025. 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 2025.
39. Armlupeg [package insert]. Maharashtra, India; Lupin Limited (Biotech Division); December 2025. Accessed April 2026.
40. Palmetto GBA. Local Coverage Article: Billing and Coding: Neulasta® (pegfilgrastim) Onpro® Kit / Udenyca® ONBODY™ (On-body Injector) (A54682). Centers for Medicare & Medicaid Services, Inc. Updated on 01/25/2024 with effective date 01/01/2024. Accessed April 2026.
41. Palmetto GBA. Local Coverage Article: Billing and Coding: White Cell Colony Stimulating Factors (A56748). Centers for Medicare & Medicaid Services, Inc. Updated on 08/20/2025 with effective date 10/01/2025. Accessed April 2026.

## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

| Factor                     | Conclusion            |
|----------------------------|-----------------------|
| Indication                 | Yes: Consider for PA  |
| Safety and efficacy        | No: PA not a priority |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug               | Yes: Consider for PA  |

## Appendix 1 – Covered Diagnosis Codes

### Armlupeg, Fulphila, Fynetra, Neulasta, Nyvepria, Stimufend/Pegfilgrastim-fpgk, Udenyca, and Ziextenzo

| ICD-10 | ICD-10 Description                                      |
|--------|---|
| C64.1  | Malignant neoplasm of right kidney, except renal pelvis |

| ICD-10 | ICD-10 Description  |
|--------|---|
| C64.2  | Malignant neoplasm of left kidney, except renal pelvis                                    |
| C64.9  | Malignant neoplasm of unspecified kidney, except renal pelvis                             |
| C65.1  | Malignant neoplasm of right renal pelvis  |
| C65.2  | Malignant neoplasm of left renal pelvis   |
| C65.9  | Malignant neoplasm of unspecified renal pelvis  |
| C83.30 | Diffuse large B-cell lymphoma unspecified site  |
| C83.31 | Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck                        |
| C83.32 | Diffuse large B-cell lymphoma intrathoracic lymph nodes                                   |
| C83.33 | Diffuse large B-cell lymphoma intra-abdominal lymph nodes                                 |
| C83.34 | Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb                        |
| C83.35 | Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb              |
| C83.36 | Diffuse large B-cell lymphoma intrapelvic lymph nodes                                     |
| C83.37 | Diffuse large B-cell lymphoma, spleen   |
| C83.38 | Diffuse large B-cell lymphoma lymph nodes of multiple sites                               |
| C83.39 | Diffuse large B-cell lymphoma extranodal and solid organ sites                            |
| C83.70 | Burkitt lymphoma, unspecified site  |
| C83.71 | Burkitt lymphoma, lymph nodes of head, face, and neck                                     |
| C83.72 | Burkitt lymphoma, intrathoracic lymph nodes   |
| C83.73 | Burkitt lymphoma, intra-abdominal lymph nodes   |
| C83.74 | Burkitt lymphoma, lymph nodes of axilla and upper limb                                    |
| C83.75 | Burkitt lymphoma, lymph nodes of inguinal region and lower limb                           |
| C83.76 | Burkitt lymphoma, intrapelvic lymph nodes   |
| C83.77 | Burkitt lymphoma, spleen  |
| C83.78 | Burkitt lymphoma, lymph nodes of multiple sites   |
| C83.79 | Burkitt lymphoma, extranodal and solid organ sites  |
| C85.20 | Mediastinal (thymic) large B-cell lymphoma, unspecified site                              |
| C85.21 | Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck            |
| C85.22 | Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes                     |
| C85.23 | Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes                   |
| C85.24 | Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb          |
| C85.25 | Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb |
| C85.26 | Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes                       |
| C85.27 | Mediastinal (thymic) large B-cell lymphoma, spleen  |
| C85.28 | Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites                 |
| C85.29 | Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites              |
| D47.Z1 | Post-transplant lymphoproliferative disorder (PTLD)                                       |

| ICD-10   | ICD-10 Description  |
|----------|---|
| D61.810  | Antineoplastic chemotherapy induced pancytopenia                                  |
| 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                                |
| T66.XXXD | Radiation sickness, unspecified, subsequent encounter                             |
| T66.XXXS | Radiation sickness, unspecified, sequela  |
| W88.1    | Exposure to radioactive isotopes  |
| W88.8    | Exposure to other ionizing radiation  |
| 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   |
| Z52.011  | Autologous donor, stem cells  |
| Z52.091  | Other blood donor, stem cells   |
| Z76.89   | Persons encountering health services in other specified circumstances             |
| Z94.81   | Bone marrow transplant status   |
| Z94.84   | Stem cells transplant status  |

### **Rolvedon & Ryzneuta**

| ICD-10   | ICD-10 Description  |
|----------|---|
| D61.810  | Antineoplastic chemotherapy induced pancytopenia                                  |
| D61.811  | Other drug-induced pancytopenia   |
| D61.818  | Other pancytopenia  |
| 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                                |
| T66.XXXD | Radiation sickness, unspecified, subsequent encounter                             |
| T66.XXXS | Radiation sickness, unspecified, sequela  |
| W88.1    | Exposure to radioactive isotopes  |
| W88.8    | Exposure to other ionizing radiation  |

| ICD-10 | ICD-10 Description  |
|--------|---|
| Z41.8  | Encounter for other procedures for purposes other than remedying health state |
| Z51.11 | Encounter for antineoplastic chemotherapy                                     |
| Z51.12 | Encounter for antineoplastic immunotherapy                                    |
| Z51.89 | Encounter for other specified aftercare                                       |
| Z76.89 | Persons encountering health services in other specified circumstances         |

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

| Medicare Part B Covered Diagnosis Codes |                          |              |
|---|--------------------------|--------------|
| Jurisdiction                            | NCD/LCA/LCD Document (s) | Contractor   |
| J, M                                    | A56748                   | Palmetto GBA |
| J, M                                    | A54682                   | Palmetto GBA |

| 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                                      |
| M (11)  | NC, SC, WV, VA (excluding below)  | Palmetto GBA                                      |
| 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                           |