pegfilgrastim (Neulasta®; Neulasta Onpro®; Fulphila®; Udenyca®; Ziextenzo®, Nyvepria™)
EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO052

Description
Granulocyte- colony stimulating factors (G-CSF) act on the hematopoietic cells by binding to specific cell surface receptors thereby stimulating the production, maturation, and activation of neutrophils.

Length of Authorization
- Initial: Four months
- Renewal: Four months

Quantity limits

pegfilgrastim	Indication	Quantity Limit
pegfilgrastim (Neulasta)	Prophylactic use in patients with non-myeloid malignancy; Neutropenic complications from prior cycle; Exposure to myelosuppressive doses of radiation; Bone marrow transplantation failure or engraftment delay; Peripheral progenitor cell (PBPC) mobilization and transplant	Two prefilled syringes per 28-day supply
pegfilgrastim (Neulasta Onpro)		Two kits per 28-day supply
pegfilgrastim-jmdb (Fulphila)		Two prefilled syringes per 28-day supply
pegfilgrastim-cbqv (Udenyca)		
pegfilgrastim-bmez (Ziextenzo)		
pegfilgrastim-apgf (Nyvepria)		

Initial Evaluation

I. **Pegfilgrastim-cbqv (Udenyca) and pegfilgrastim-bmez (Ziextenzo)** may be considered medically necessary when the following criteria below are met:
   A. A diagnosis of the following:
      1. **Peripheral Blood Progenitor Cell (PBPC) mobilization and transplant; OR**
      2. **A neutropenic complication from a prior cycle of the same chemotherapy; OR**
      3. **Bone Marrow Transplantation (BMT) failure or Engraftment Delay; OR**

4. **Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome); OR**
5. **Prophylactic use in patients with non-myeloid malignancy; AND**
    i. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater; **OR**
    ii. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or greater **AND** meeting **one** or more of the following:
        a. Age 65 or older AND receiving full dose intensity chemotherapy; **OR**
        b. History of recurrent febrile neutropenia from chemotherapy; **OR**
        c. Extensive prior exposure to chemotherapy; **OR**
        d. Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation; **OR**
        e. Pre-existing neutropenia (ANC ≤ 1000/mm3) or bone marrow involvement with tumor; **OR**
        f. Patient has a condition that can potentially increase the risk of serious infection (e.g. HIV/AIDS) ; **OR**
        g. Infection/open wounds; **OR**
        h. Recent surgery; **OR**
        i. Poor performance status; **OR**
        j. Poor renal function (creatinine clearance <50mL/min) ; **OR**
        k. Liver dysfunction (elevated bilirubin >2.0mg/dL) ; **OR**
        l. Chronic immunosuppression in the post-transplant setting including organ transplant

II. **Pegfilgrastim (Neulasta, Neulasta Onpro), pegfilgrastim- jmdb (Fulphila), and pegfilgrastim-apgf (Nyvepria)** may be considered medically necessary when the following criteria below are met:
A. Criteria I(A) above is met; **AND**
B. Treatment with pegfilgrastim-cbqv (Udenyca) AND pegfilgrastim-bmez (Ziextenzo) have been ineffective, contraindicated, or not tolerated.

Renewal Evaluation

I. Same as initial prior authorization policy criteria

Supporting Evidence

II. Indication listed under section I supported by FDA-labeled indication(s) or recommended per Compendia

References

1. Neupogen [package insert]. Thousand Oaks, CA; Amgen Inc; June 2016. Accessed March 2018.
2. Zarxio [package insert]. Princeton, NJ; Sandoz Inc; December 2017. Accessed July 2018.
3. Nivestym [package insert]. Lake Forest, IL; Hospira Inc; July 2018. Accessed July 2018
4. Neulasta [package insert]. Thousand Oaks, CA; Amgen Inc; June 2018. Accessed July 2018
5. Fulphila [package insert]. Zurich, Switzerland; Mylan GmbH; September 2018. Accessed October 2018.
6. Udenyca [package insert]. Redwood City, California; Coherus Biosciences; November 2018. Accessed November 2018.
7. Leukine [package insert]. Bridgewater, NJ; sanofi-aventis US LLC; February 2017. Accessed March 2018.
8. Granix [package insert]. North Wales, PA; Teva Pharmaceuticals USA, Inc.; June 2017. Accessed March 2018.
9. Ziextenzo [Prescribing Information]. Sandoz Inc.: Princeton, NJ. August 2019.
10. Nyvepria [Prescribing Information]. Hospira, Inc., a Pfizer Company. Lake Forest, IL. October 2020.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) filgrastim. 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 March 2018. Moda Health Plan, Inc. Medical Necessity Criteria Page 4/6
12. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloid Growth Factors. Version 1.2018. National Comprehensive Cancer Network, 2017. 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 March 2018.
13. Smith TJ, Bohlke K, Lyman GH, Carson KR, Crawford J, Cross SJ, Goldberg JM, Khatcheressian JL, Leighl NB, Perkins CL, Somlo G, Wade JL, Wozniak AJ, Armitage JO. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015 Jul 13. pii: JCO.2015.62.3488. [Epub ahead of print]
14. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L34699). Centers for Medicare & Medicaid Services, Inc. Updated on 1/23/2018 with effective date 02/1/2018. Accessed March 2018.
15. First Coast Service Options, Inc. Local Coverage Determination (LCD): G-CSF (Neupogen®, Granix™, Zarxio™) (L34002). Centers for Medicare & Medicaid Services, Inc. Updated on 6/10/2016 with effective date 7/5/2016. Accessed March 2018.
16. 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 9/23/2016 with effective date 10/1/2016. Accessed March 2018.
17. Palmetto GBA. Local Coverage Determination: White Cell Colony Stimulating Factors (L37176). Centers for Medicare & Medicaid Services, Inc. Updated on 12/7/2017 with effective date 2/26/2018. Accessed March 2018.

Policy Implementation/Update:

Action and Summary of Changes	Date
Updated preferred products to add Ziextenzo (effective on 1/1/2021) and move Neulasta/Neulasta Onpro to non-preferred (effective 1/1/2021).	11/2020
Updated policy to allow for 28 days supply	02/2020
Added Ziextenzo, biosimilar to Neulasta; update quantity limits to allow for 30 days supply	12/2019
Added Udenyca, biosimilar to Neulasta	01/2019
Neulasta, Neulasta Onpro preferred GCSF	12/2018

Added Fulphila, biosimilar to Neulasta	07/2018
Policy created	02/2018