OncoHealth

Long-Acting GCSFs:

Fulphila (pegfilgrastim-jmdb), Neulasta (pegfilgrastim), Nyvepria (pegfilgrastim-apgf), Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez), Fylnetra (pegfilgrastim-pbbk), Stimufend (pegfilgrastim-fpgk), Rolvedon (eflapegrastim-xnstm), Ryzneuta (efbemalenograstim alfa)

Effective Date: 3/1/2024
Revision Date(s): 6/2021, 9/2021, 06/2022, 7/2023, 12/2023, 4/2024, 7/2024
Review Date: 7/1/2024
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Preference	Requires Prior Auth	Drug Name	HCPCS Code	Description
Preferred	Yes	**Neulasta**	**J2506**	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
Preferred	Yes	**Fulphila**	**Q5108**	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg
Non-Preferred	Yes	**Rolvedon**	**J1449**	Injection, eflapegrastim-xnst, 0.1 mg
Non-Preferred	Yes	**Ryzneuta**	**J9361**	Injection, efbemalenograstim alfa, vuxw, 0.5 mg
Non-Preferred	Yes	**Udenyca**	**Q5111**	Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg
Non-Preferred	Yes	**Ziextenzo**	**Q5120**	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg
Non-Preferred	Yes	**Nyvepria**	**Q5122**	Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg
Non-Preferred	Yes	**Stimufend**	**Q5127**	Injection, pegfilgrastim-apgf, biosimilar, (Stimufend), 0.5 mg
Non-Preferred	Yes	**Flynetra**	**Q5130**	Injection, pegfilgrastim-apgf, biosimilar, (Fylnetra), 0.5 mg
Members must have documentation of a contraindication, failure, or intolerance to any of the preferred agents prior to approval of a non-preferred product.				

Universal Criteria:

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.; **AND**
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event, the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

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Indication Specific Criteria:

Febrile neutropenia prophylaxis following myelosuppressive chemotherapy

- The patient has a solid tumor or a non-myeloid malignancy, **and**
- GCSF is administered 24-72 hours following myelosuppressive chemotherapy; **and**
    - The patient experienced a febrile neutropenic event with prior administration of the same or similar chemotherapy regimen, **or**
    - The patient is receiving dose-dense myelosuppressive chemotherapy, **or**
    - The patient is receiving myelosuppressive chemotherapy with a risk of febrile neutropenia of at least 20%, **or**
    - The patient is receiving myelosuppressive chemotherapy with an intermediate risk of febrile neutropenia of 10-20%, **and** one of the following risk factors:
        - Persistent neutropenia (Absolute Neutrophil Count < 500/mm^3 or < 1000/mm^3 and expected to decline to less than 500/mm^3 within the next 48 hours)
        - Bone marrow involvement by tumor
        - Liver dysfunction with a total bilirubin > 2 mg/dL
        - Renal dysfunction with a creatinine clearance < 50 mL/min
        - Age > 65 years and receiving full chemotherapy dose intensity
        - History of extensive chemotherapy/radiation therapy
    - The patient is receiving myelosuppressive chemotherapy that has a low risk of febrile neutropenia of <10% **and**
        - Dose reduction is not clinically appropriate; **and**
        - at least two of the following risk factors are present:
            - Persistent neutropenia (Absolute Neutrophil Count < 500/mm^3 or < 1000/mm^3 and expected to decline to less than 500/mm^3 within the next 48 hours)
            - Bone marrow involvement by tumor
            - Liver dysfunction with a total bilirubin > 2 mg/dL
            - Renal dysfunction with a creatinine clearance < 50 mL/min
            - Age > 65 years and receiving full chemotherapy dose intensity
            - History of extensive chemotherapy/radiation therapy

Wilms Tumor

- Patient is scheduled to receive cyclophosphamide with etoposide; **or**
- Patient is scheduled to receive combination therapy with cyclophosphamide, doxorubicin, and vincristine

Universal Approval Criteria:

Unless otherwise noted above the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

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- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
- Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
    - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
    - Clinical Pharmacology (Strong For)
    - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
    - Thompson Micromedex DrugDex® (Class I and IIa)
    - Wolters Kluwer Lexi-Drugs® (Level A)
- Other use of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals
    - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology
    - **Meeting abstracts and case reports are excluded from consideration.**
- Non-standard protocols may be approved based on unique clinical circumstances.

Billing Codes

Drug Name	HCPCS Code	Description
Rolvedon	J1449	Injection, eflapegrastim-xnst, 0.1 mg
Neulasta	J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
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Nivepria	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg
Stimufend	Q5127	Injection, pegfilgrastim-apgf, biosimilar, (Stimufend), 0.5 mg
Fylnetra	Q5130	Injection, pegfilgrastim-apgf, biosimilar, (Fylnetra), 0.5 mg

References

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2. Neulasta. NCCN Cancer Guidelines and Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/

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19. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed Dec 5th, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org.

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five

recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

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Revision History

Date	Updates
5/2/2022	Added preferred products and recommended step-therapy options. Added Wilms tumor per NCCN, added H-ARS per PI/NCCN
06/13/2022	Added Fylnetra(pegfilgrastim-pbbk)
07/28/2022	Removed H-ARS as per scope
10/26/2022	Added Stimufend (pegfilgrastim-fpgk), Rolvedon (eflapegrastim-xnstm)
10/27/2022	Policy approved by P&T
12/5/23	Updated Step Therapy to Table; Added Universal Criteria; Addition of efbemalenograstim alfa; Reviewed References
4/17/2024	Updated Universal Criteria
7/1/2024	Ryzneuta HCPCS Updated