Clinical Policy Title:	pegfilgrastim
Policy Number:	RxA.131
Drug(s) Applied:	Neulasta®, Neulasta Onpro®, Nyvepria™, Fulphila®, Fylnetra®, Rolvedon™, Stimufend®, Ziextenzo®
Original Policy Date:	03/06/2020
Last Review Date:	5/15/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Febrile Neutropenia (must meet all)**:** Neulasta®, Neulasta Onpro®, Nyvepria™, Fulphila®, Fylnetra®, Rolvedon™, Stimufend®, Ziextenzo®

1. Febrile neutropenia prophylaxis with non-myeloid malignancies (i.e., solid tumor and lymphoid malignancies);
2. Patient is receiving myelosuppressive anti-cancer drugs with significant incidence of severe neutropenia with fever;
3. Trial and failure of all three (3) agents: Fulphila®, Neulasta® and Ziextenzo®, unless contraindicated and clinically significant adverse effects are experienced.

Initial Approval Duration:

All Lines of Business (except Medicare): 6 months

B. Acute Radiation Syndrome (must meet all)**:** Neulasta®, Neulasta Onpro®**,** Ziextenzo®

1. Diagnosis of suspected or confirmed acute exposure to myelosuppressive doses of radiation.

Approval Duration:

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration:

All Lines of Business (except Medicare): 6 months

References

1. National Comprehensive Cancer Network. Chronic Myeloid Leukemia Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed May 10, 2024.

2. Smith TJ, Khatcheressian J, Lyman GH, et al. 2006 Update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline. JCO 2006 July. 24(19): 3187-3205. Available at: https://pubmed.ncbi.nlm.nih.gov/16682719/. Accessed May 10, 2024.
3. 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. 2015 October. JCO 33(28): 3199-3212. Available at: https://pubmed.ncbi.nlm.nih.gov/26169616/. Accessed May 10, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2020	03/06/2020
Policy reviewed and updated. 1. Added Ziextenzo™ to the policy. 2. Continued Therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…” 3. References were updated.	05/2020	05/21/2020
Policy was reviewed and updated. 1. Nyvepria™ was added to the policy. 2. Clinical policy title and lines of business were updated. 3. Compendial uses updated. 4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.	01/27/2021	03/09/2021
Policy was reviewed and updated. 1. Initial Approval Criteria, I.C.2: Updated trial and failure criteria from Member has tried and failed sargramostim*, unless contraindicated or clinically significant adverse effects are experienced to Failure of sargramostim* at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	11/25/2021	01/17/2022
Policy was reviewed: 1. Clinical Policy Title: Updated to include pegfilgrastim-fpgk and eflapegrastim-xnst. 2. Clinical Policy Title, Drug(s) Applied: Updated to include new brand Stimufend® and Rolvedon™.	12/09/2022	01/17/2023

3. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of nonmyeloid malignancy to Diagnosis of non-myeloid malignancy (i.e., solid tumor and lymphoid malignancies). Initial Approval Criteria, I.A.5: Updated to add Confirmation that there is at least 12 days between pegfilgrastim/eflapegrastim-xnst dose and the next cycle of chemotherapy. 5. Initial Approval Criteria, I.A.7: Updated dosing criteria from Dose does not exceed 6 mg (1 syringe) per chemotherapy cycle to Dose does not exceed one of the following (a or b): a. For pegfilgrastim: 6 mg (1 syringe) per chemotherapy cycle; b. For eflapegrastim: 13.2 mg (1 syringe) per chemotherapy cycle 6. Initial Approval Criteria, I.B and I.C: Updated to include new request criteria Request is not for Rolvedon™. 7. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Wilms Tumor (off-label). 8. Initial Approval Criteria, I.C: Updated to remove approval criteria for Compendial Indications (off-label). 9. Continued Therapy Approval, II.A.3.a: Updated dosing criteria from Chemotherapy-induced neutropenia: 6 mg administered once per chemotherapy cycle to Chemotherapy-induced neutropenia (i or ii): i. For pegfilgrastim: 6 mg administered once per chemotherapy cycle; ii. For eflapegrastim: 13.2 mg (1 syringe) per chemotherapy cycle; 10. Continued Therapy Approval, II.A.3.c: Updated dosing criteria to remove Bone marrow transplantation: 6 mg per dose, or dose is supported by practice guidelines or peerreviewed literature for the relevant off-label use (provider must submit supporting evidence). 11. Continued Therapy Approval, II.A.3.d: Updated to include new dosing criteria Wilms tumor: 6 mg (1 syringe) administered once per chemotherapy cycle for Wilms tumor. 12. References were reviewed and updated.		

Policy was reviewed: 1. Clinical Policy Title: Updated to include new generic pegfilgrastim-pbbk. 2. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Fylnetra®. 3. Initial Approval Criteria, I.A.4 and I.B.3: Updated to remove prior trial and failure criteria "For members age ≥ 18 years, member has tried and failed preferred filgrastim product(s), unless one of the following are present (a, b, or c): a. Member has intolerance or contraindication to filgrastim; b. Documentation of member's inability to self-administer filgrastim due to both of the following (i and ii): i. Lack of caregiver or support system to assist with administration; ii. Inadequate access to healthcare facility or home care interventions; c. Member requires 10 or more doses of filgrastim". 4. Initial Approval Criteria, I.A.5: Updated to remove prior criteria pertaining to indication Chemotherapy- Induced Neutropenia, "Confirmation that there is at least 12 days between pegfilgrastim/eflapegrastim-xnst dose and the next cycle of chemotherapy". 5. Initial Approval Criteria, I.A.5: Updated to include new trial and failure criteria, For Rolvedon™, Nyvepria™, Udenyca®, Fylnetra®, Stimufend®, Rolvedon™: Trial and failure of all three (3) agents: Fulphila®, Neulasta® and Ziextenzo®, unless contraindicated and clinically significant adverse effects are experienced. 6. Initial Approval Criteria, I.A.6: Updated to remove prior criteria pertaining to indication Chemotherapy- Induced Neutropenia, " For members receiving palliative chemotherapy, provider attests that chemotherapy dose reduction has been considered". 7. Initial Approval Criteria, I.B.2: Updated request criteria from Request is not for Rolvedon™ to Request is not for Rolvedon™, Neulasta Onpro®. 8. Initial Approval Criteria, I.B.3: Updated to include new trial and failure criteria For Nyvepria™, Udenyca®, Fylnetra®, Stimufend®: Trial and failure of all three (3) agents: Fulphila®, Neulasta® and Ziextenzo®, unless	06/05/2023	07/13/2023

contraindicated and clinically significant adverse effects are experienced. 9. Initial Approval Criteria, I.C: Updated to remove approval criteria for Wilms Tumor (off-label). 10. Continued Therapy Approval Criteria, II.A.3.c: Updated to remove prior dosing criteria "Wilms tumor: 6 mg (1 syringe) administered once per chemotherapy cycle." 11. References were reviewed and updated.		

Policy was reviewed.	10/19/2023	10/19/2023
Policy Reviewed: Updated policy from Q1 P&T	2/28/2024	2/28/2024
Policy Reviewed: 1. Ziextenzo® is added to indication acute radiation syndrome.	05/15/2024	