This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
3899-D

POLICY Document for NEULASTA, FULPHILA, NYVEPRIA, UDENYCA, ZIEXTENZO

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA

Colony Stimulating Factors – Long Acting

PREFERRED PRODUCTS: NEULASTA (INCLUDING ONPRO KIT), UDENYCA

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the long acting colony stimulating factor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Colony Stimulating Factors – Long Acting

	Product(s)
Preferred	• **Neulasta (including Onpro kit)** (pegfilgrastim) • **Udenyca** (pegfilgrastim-cbqv)
Targeted	• **Fulphila** (pegfilgrastim-jmdb) • **Nyvepria (**pegfilgrastim-apgf) • **Ziextenzo** (pegfilgrastim-bmez)

This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

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II. EXCEPTION CRITERIA

Coverage for the targeted products is provided when the member meets one of the following criteria:

A. Member has failed treatment with both of the preferred products due to a documented intolerable adverse event (e.g., rash, nausea, vomiting) and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)

B. Member has received treatment with the targeted product in the past 365 days

Section 2: Clinical Criteria

STANDARD MEDICARE PART B MANAGEMENT

NEULASTA (pegfilgrastim)

FULPHILA (pegfilgrastim-jmdb)

NYVEPRIA (pegfilgrastim- apgf)

UDENYCA (pegfilgrastim-cbqv)

ZIEXTENZO (pegfilgrastim-bmez)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
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A. FDA-Approved Indication[1]
1. Patients with Cancer Receiving Myelosuppressive Chemotherapy
   Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
2. Hematopoietic Syndrome of Acute Radiation Syndrome
   Neulasta is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome).

B. Compendial Use[2-4]
1. Stem cell transplantation-related indications
2. Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
3. Hematopoietic Syndrome of Acute Radiation Syndrome
4. Hairy cell leukemia
5. Chronic Myeloid Leukemia (CML), treatment of persistent neutropenia due to tyrosine kinases inhibitor therapy

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
Primary Prophylaxis of Febrile Neutropenia
Member's diagnosis and chemotherapeutic regimen.

III. CRITERIA FOR INITIAL APPROVAL

A. Prevention of neutropenia in cancer patients receiving myelosuppressive chemotherapy[1]
Authorization of 6 months may be granted for prevention of febrile neutropenia for members with solid tumors or non-myeloid malignancies when the member will not be receiving concurrent chemotherapy and radiation therapy.

B. Other indications[2-4]
Authorization of 6 months may be granted for members with any of the following indications:

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
3899-D

1. Stem cell transplantation-related indications
2. Hematopoietic Syndrome of Acute Radiation Syndrome
3. Hairy cell leukemia with neutropenic fever following chemotherapy
4. **Chronic Myeloid Leukemia** for treatment of persistent neutropenia due to tyrosine kinase inhibitor therapy

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 6 months may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with Neulasta.
B. Neulasta is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy.

DOCUMENT HISTORY

Created: Specialty Clinical Development (NU) 09/2020

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External Review:

REFERENCES:

SECTION 1

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen; January 2020.
2. Fulphila [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; June 2020.
3. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; June 2020.
4. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; September 2019.
5. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; November 2019

SECTION 2

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2020.

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
3899-D

2. Fulphila [package insert]. Zurich, Switzerland: Mylan; June 2018.
3. Udenyca [package insert]. Redwood City, California: Coherus BioSciences, Inc: September 2019.
4. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; November 2019.
5. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc., June 2020.
6. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: Accessed June 10, 2020.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors. Version 2.2020. Accessed June 02, 2020.
8. IBM Micromedex® DRUGDEX ® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at (Accessed: 06/10/2020).