



Colony Stimulating Factors (Long) Step Therapy

Preferred: : Neulasta (pegfilgrastim ex bio) J2506, Ziextenzo (pegfilgrastim-bmez) Q5120 and Flyneta (pegfilgrastim-pbbk) Q5130

Non-preferred: Neulasta (pegfilgrastim) J2505, Fulphila (pegfilgrastim-jmdb) Q5108, Udenyca (pegfilgrastim-cbqv) Q5111, Nyvepria (pegfilgrastim-apgf) Q5122, Stimufend (pegfilgrastim-fpgk)

Prior Authorization Step Therapy

Medicare Part B Request Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

- 6 mg (0.6 mL) subQ once per chemotherapy cycle
- 6 mg subQ administered 1 week apart for 2 doses;

Additional Regimen _____

Self-administered Provider-administered Home Infusion

Chart notes attached. Other important information: _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Preferred:

Neulasta (J2506) Ziextenzo (Q5120) Flyneta (Q5130)

Non-Preferred:

Neulasta (J2505) Fulphila (Q5108) Udenyca (Q5111) Nyvepria (Q5122) Simufend (Q5130)

Patient has tried and failed at least TWO Preferred alternatives

Indication Specific Criteria:

Primary Prophylaxis for Febrile Neutropenia (FN)

- Patient with nonmyeloid malignancy is using for primary prophylaxis of FN; **AND**
- Patient has a risk of FN of **20% or greater** based on chemotherapy regimen.

Primary Prophylaxis (Intermediate Risk with Factor)

- Patient with nonmyeloid malignancy is using for primary prophylaxis of FN; **AND**
- Patient has a risk of developing FN is **greater than or equal to 10% and less than 20%** based on chemotherapy regimen (see Appendix, Table 1); **AND**
- Patient has **any ONE** of the following risk factors for FN:
 - Age greater than 65 years
 - Poor performance status (ECOG 3 or 4) or HIV infection (especially CD4 \leq 450/ μ L) but chemotherapy still indicated
 - Prior radiation therapy (within previous 1 year)
 - Bone marrow involvement by tumor producing cytopenias
 - Persistent neutropenia (ANC $<$ 1500/ mm^3)
 - Poor renal function (GFR $<$ 60 mL/min)
 - Liver dysfunction (AST/ALT \geq 2x ULN or bilirubin $>$ 2.0 mg/dL)
 - Recent surgery as part of cancer management within previous 30 days
 - History of active infection within previous 60 days
 - Current open wound and chemotherapy cannot be delayed

Secondary Prophylaxis

- Patient with nonmyeloid malignancy is using for secondary prophylaxis of FN; **AND**
- Patient has experienced a neutropenic complication from a prior cycle of chemotherapy (without prophylaxis), where a dose reduction may compromise survival or treatment outcome

Adjunctive Treatment for Active FN

- Patient is using as adjunctive treatment for FN; **AND**
- Patient has **NOT** received prophylactic therapy with pegfilgrastim; **AND**
- Patient has a high risk for infection-associated complications as demonstrated by **any one** of the following:
 - Expected prolonged ($>$ 10 days) and profound ($<$ 0.1 \times 10⁹/L) neutropenia
 - Age greater than 65 years;
 - Pneumonia or other clinically documented infections;
 - Hypotension and multi-organ dysfunction (sepsis syndrome);
 - Invasive fungal infection;
 - Prior episode of febrile neutropenia;
 - Hospitalized at the time of the development of fever.

Classic Hodgkin Lymphoma (Age 18-60)

- Patient has a diagnosis of Classic Hodgkin lymphoma (age 18-60 years) **AND**
 - Patient is using in combination with **brentuximab vedotin with AVD; OR**
 - Patient is using in combination with **brentuximab vedotin, etoposide, cyclophosphamide, doxorubicin, dacarbazine, and dexamethasone.**

Pediatric Aggressive Mature B-Cell Lymphomas

- Patient has a diagnosis of Pediatric Aggressive Mature B-Cell Lymphomas

Dose-Dense Adjuvant Breast Cancer Therapy

- Patient is receiving dose-dense therapy (e.g., every 2 weeks) for adjuvant treatment of breast cancer

Radiation Exposure (ARS)

- Patient is using after accidental or intentional total body radiation of myelosuppressive doses ($>$ 2 Grays) for Hematopoietic Syndrome of Acute Radiation Syndrome

Hematopoietic Stem Cell Transplant

Patient is using after a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution **OR** when engraftment is delayed/has failed.

Stem Cell Mobilization (with Plerixafor)

Patient is using for treatment of hematopoietic cell mobilization in combination with **plerixafor**

Wilms Tumor (Nephroblastoma)

- Patient is using for Wilms Tumor (Nephroblastoma); **AND**
- Using with **Regimen M** and **Regimen I** for **ONE** of the following courses:
 - Cyclophosphamide and etoposide; **OR**
 - Cyclophosphamide, doxorubicin, and vincristine.

Autologous HSC Mobilization for Gene Therapy

Patient is using for autologous hematopoietic stem cell (HSC) mobilization as part of the development of an FDA-approved ex vivo gene therapy (e.g., Zynteglo).

Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.

Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.



Prior Authorization Group – Colony Stimulating Factor PA

Drug Name(s):

NEULASTA (pegfilgrastim)

FULPHILA (pegfilgrastim-jmdb)

UDENYCA (pegfilgrastim-cbqv)

FYLNETRA (pegfilgrastim-pbbk)

NEULASTA (pegfilgrastim ex bio)

NYVEPRIA (pegfilgrastim-apgf)

ZIEXTENZO (pegfilgrastim-bmez)

STIMUFEND (pegfilgrastim-fpgk)

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE of the formulary alternatives: **Neulasta (pegfilgrastim ex bio)**, **Ziextenzo (pegfilgrastim-bmez)**, **Fylnetra (pegfilgrastim-pbbk)** OR
 - There is clinical documentation stating formulary alternatives are contraindicated.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Neulasta, Udenyca, Ziextenzo, Fylnetra, Stimufend

- Febrile neutropenia, In patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia; Prophylaxis
- Hematopoietic subsyndrome of acute radiation syndrome

Fulphila, Nyvepria,

- Febrile neutropenia, In patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs; Prophylaxis

Off-Label Uses:

All Drugs

- Harvesting of peripheral blood stem cells, Prior to autologous stem-cell transplantation

Age Restrictions:

N/A

Other Clinical Consideration:

- Contraindicated in pure red cell aplasia that begins following treatment with darbepoetin alfa or other erythropoietin protein drugs
- Contraindicated in uncontrolled hypertension



Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/47BC49/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/66F156/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=926953&contentSetId=100&title=Pegfilgrastim&servicesTitle=Pegfilgrastim&brandName=Neulasta&UserMdxSearchTerm=Neulasta&=null

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