Colony Stimulating Factors (Long) Step Therapy

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

Non-preferred: 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.*

☐	**Standard Request– (72 Hours)**	☐	**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) ☐ Fylnetra (Q5130)

☐ Non-Preferred:
☐ 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 ≤ 450/µL) but chemotherapy still indicated
- ☐ Prior radiation therapy (within previous 1 year)
- ☐ Bone marrow involvement by tumor producing cytopenias
- ☐ Persistent neutropenia (ANC < 1500/mm³)
- ☐ Poor renal function (GFR < 60 mL/min)
- ☐ Liver dysfunction (AST/ALT ≥ 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

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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 x 10^9/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

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Dose-Dense Adjuvant Breast Cancer Therapy

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

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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

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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.

ATRIO HEALTH PLANS

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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