



MEDICARE FORM

Pegfilgrastim Precertification Request

(Fulphila[®], Neulasta[®], Neulasta Onpro[®], Nyvepria[®], Udenyca[®], Ziextenzo[®])

For Medicare Advantage Part B:

FAX: 1-844-268-7263

PHONE: 1-866-503-0857

For other lines of business:

Please use other form.

Note: Fulphila, Nyvepria and Ziextenzo are non-preferred. Neulasta/Neulasta Onpro and Udenyca are preferred.

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(All fields must be completed and legible for precertification review.)

Please indicate: Start of treatment: Start date ____ / ____ / ____
 Continuation of therapy: Date of last treatment ____ / ____ / ____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

| | | | | | |
|--|--|---|-------|--------------------|-------------|
| First Name: | | Last Name: | | DOB: | |
| Address: | | | City: | | State: ZIP: |
| Home Phone: | | Work Phone: | | Cell Phone: Email: | |
| Patient Current Weight: ____ lbs or ____ kgs | | Patient Height: ____ inches or ____ cms | | Allergies: | |

B. INSURANCE INFORMATION

| | | | |
|--|--|--|--|
| Aetna Member ID #: _____ | | Does patient have other coverage? <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Group #: _____ | | If yes, provide ID#: _____ Carrier Name: _____ | |
| Insured: _____ | | Insured: _____ | |
| Medicare: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide ID #: _____ | | Medicaid: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide ID #: _____ | |

C. PRESCRIBER INFORMATION

| | | | | | |
|--|--|------------|----------------------|--|-------------|
| First Name: | | Last Name: | | (Check one): <input type="checkbox"/> M.D. <input type="checkbox"/> D.O. <input type="checkbox"/> N.P. <input type="checkbox"/> P.A. | |
| Address: | | | City: | | State: ZIP: |
| Phone: | | Fax: | | St Lic #: NPI #: DEA #: UPIN: | |
| Provider Email: | | | Office Contact Name: | | Phone: |
| Specialty (Check one): <input type="checkbox"/> Oncologist <input type="checkbox"/> Hematologist <input type="checkbox"/> Other: _____ | | | | | |

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

| | | | |
|--|--|---|--|
| Place of Administration: <input type="checkbox"/> Self-administered <input type="checkbox"/> Physician's Office <input type="checkbox"/> Home Infusion Center Center Name: _____ Phone: _____ <input type="checkbox"/> Outpatient Facility: Facility Name: _____ Phone: _____ <input type="checkbox"/> Outpatient Infusion Center: Center Name: _____ <input type="checkbox"/> Administration code(s) (CPT): _____ Address: _____ City: _____ State: _____ ZIP: _____ Phone: _____ Fax: _____ TIN: _____ PIN: _____ NPI: _____ | | Dispensing Provider/Pharmacy: Patient Selected choice <input type="checkbox"/> Physician's Office <input type="checkbox"/> Retail Pharmacy <input type="checkbox"/> Specialty Pharmacy <input type="checkbox"/> Home Care <input type="checkbox"/> Other: _____ Name: _____ Address: _____ City: _____ State: _____ ZIP: _____ Phone: _____ Fax: _____ TIN: _____ PIN: _____ NPI: _____ | |
|--|--|---|--|

E. PRODUCT INFORMATION

| | | |
|--|-------------|---------------------------|
| <input type="checkbox"/> Fulphila (pegfilgrastim-jmdb) | Dose: _____ | Directions for Use: _____ |
| <input type="checkbox"/> Neulasta/Neulasta Onpro (pegfilgrastim) | Dose: _____ | Directions for Use: _____ |
| <input type="checkbox"/> Nyvepria (pegfilgrastim-apgf) | Dose: _____ | Directions for Use: _____ |
| <input type="checkbox"/> Udenyca (pegfilgrastim-cbqv) | Dose: _____ | Directions for Use: _____ |
| <input type="checkbox"/> Ziextenzo (pegfilgrastim-bmez) | Dose: _____ | Directions for Use: _____ |

F. DIAGNOSIS INFORMATION - Please indicate primary ICD code and specify any other where applicable.

Primary Indication: _____ Other: _____

G. CLINICAL INFORMATION - Required clinical information must be completed in its entirety for all precertification requests.

For All requests (clinical documentation required):
 Please indicate the patient's absolute neutrophil count: ____ mm³ Date obtained: ____ / ____ / ____

Yes No Does the patient have a nadir count that requires an immediate need for Fulphila, Neulasta/ Neulasta Onpro, Nyvepria, Udenyca, or Ziextenzo?
 Yes No Will Fulphila, Neulasta/Neulasta Onpro, Nyvepria, Udenyca, or Ziextenzo be used with another colony stimulating factor?
 Yes No Is Fulphila, Neulasta/Neulasta Onpro, Nyvepria, Udenyca, or Ziextenzo part of a stem cell mobilization protocol?
 Yes No Will Fulphila, Neulasta/Neulasta Onpro, Nyvepria, Udenyca, or Ziextenzo be given with weekly chemotherapy regimens?
 Yes No Will Fulphila, Neulasta/Neulasta Onpro, Nyvepria, Udenyca, or Ziextenzo be used in the same chemotherapy cycle as another colony stimulating factor?
 Yes No Is the patient currently receiving concomitant chemotherapy and radiation therapy?

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G. CLINICAL INFORMATION (continued) – Required clinical information must be completed in its entirety for all precertification requests.

For Initiation requests:

Note: Fulphila, Nyvepria, and Ziextenzo are non-preferred. Neulasta/Neulasta Onpro and Udenyca are preferred.

Yes No Has the patient had prior therapy with Fulphila (pegfilgrastim-jmdb), Nyvepria (pegfilgrastim-apgf) or Ziextenzo (pegfilgrastim-bmez) within the last 365 days?

Yes No Has the patient had a trial, intolerance, or contraindication to Neulasta/Neulasta Onpro (pegfilgrastim) or Udenyca (pegfilgrastim-cbqv)?

Please explain if there are any other medical reason(s) that the patient cannot use Neulasta/Neulasta Onpro (pegfilgrastim) or Udenyca (pegfilgrastim-cbqv).

Acute lymphoblastic leukemia (ALL)

Yes No Has the first days of chemotherapy been completed?

Yes No Is this the initial induction of chemotherapy?

Yes No Is this the first post-remission course of chemotherapy?

Please provide the chemotherapy regimen and date started: Regimen: _____ Date started: ____/____/____

Acute myeloid leukemia

Yes No Is the patient receiving induction chemotherapy?

→ Please indicate the regimen: _____

Yes No Is the patient receiving consolidation chemotherapy?

→ Please indicate the regimen: _____

Yes No Is the patient receiving chemotherapy for relapsed or refractory disease?

→ Relapsed disease Refractory disease

Please indicate the regimen: _____

Advanced HIV infection

Please indicate the myelosuppressive anti-retroviral medication the patient is receiving: _____

Yes No Is the patient neutropenic?

Bone Marrow Transplantation

Yes No Does the patient have a documented diagnosis of non-myeloid malignancy?

Yes No Is the medication being requested to reduce the duration of neutropenia and neutropenia-related infectious complications?

Yes No Is the patient undergoing myeloablative chemotherapy?

→ Please identify if the treatment will be followed by: Autologous bone marrow transplantation

Allogeneic bone marrow transplantation

None

Congenital, cyclic or idiopathic neutropenia

Please identify which documented type of neutropenia that patient has: congenital neutropenia cyclic neutropenia idiopathic neutropenia

Yes No Is the patient currently symptomatic?

Yes No Is Fulphila (pegfilgrastim-jmdb), Neulasta/Neulasta Onpro (pegfilgrastim), Nyvepria (pegfilgrastim-apgf), Udenyca (pegfilgrastim-cbqv), or Ziextenzo (pegfilgrastim-bmez) being requested for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers)?

Chronic Myeloid Leukemia

Yes No Does the patient have resistant neutropenia?

Yes No Is the neutropenia secondary to use of any of the following medications?

→ Bosulif (bosutinib) Gleevec (imatinib) Iclusig (ponatinib) Sprycel (dasatinib) Taspiga (nilotinib)

Drug-induced agranulocytosis

Yes No Is the agranulocytosis caused by chemotherapy?

→ Please provide the medication(s) that caused the agranulocytosis: _____

Glycogen storage disease (GSD) type 1

Yes No Does the patient have a low neutrophil count?

Hairy Cell Leukemia

Yes No Does the patient have clinical evidence of neutropenic fever following chemotherapy?

Increase dose intensity chemotherapy regimens

Yes No Is the patient being treated in a setting in which clinical research demonstrates that dose-intensive therapy produces improvement in disease control?

→ Please indicate the type of cancer the patient is being treated for: _____

Please enter the exact chemotherapy regimen patient is currently being treated with: _____

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What is the expected percentage of febrile neutropenia incidence from the chemotherapy regimen?
 0-9% (Low risk) 10-19% (Intermediate risk) 20% or greater (high risk)

Yes No Is the patient considered to be at high risk for chemotherapy-induced febrile neutropenia infectious complications?
 → Please indicate which of the following reasons that categorizes the patient to be at high risk:
 Active infections Age greater than or equal to 65 years Bone marrow compromise
 Bone marrow involvement by tumor producing cytopenias Open wounds Persistent neutropenia Poor nutritional status
 Poor performance status Previous chemotherapy Previous radiation therapy Previous episodes of FN
 Recent surgery
 Other serious co-morbidities: Cardiovascular disease HIV infection Liver dysfunction Renal dysfunction
 Other- Please explain: _____

Intermittent use in patients with myelodysplastic syndromes
 Yes No Does the patient have symptomatic anemia?
 Yes No Has the patient been tested for 5q gene deletion?
 → Please indicate the result of the test and date obtained: _____ Date obtained: ____/____/____
 Yes No Does the patient present with other cytogenetic abnormalities?
 Yes No Has a serum erythropoietin test been completed?
 → Please indicate the result of the test and date obtained: _____ Date obtained: ____/____/____

Lymphoma
 Yes No Is there clinical evidence that the patient is being treated with curative chemotherapy (e.g. (R- CHOP) rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) or more aggressive regimens?
 → Please indicate the patient's chemotherapy regimen: _____

Primary prophylaxis of neutropenia
 Yes No Does the patient have a documented diagnosis of non-myeloid malignancy?
 Yes No Is the patient receiving myelosuppressive chemotherapy?
 → Please indicate the type of cancer the patient is being treated for: _____
 Please enter the exact chemotherapy regimen patient is currently being treated with: _____

What is the expected percentage of febrile neutropenia incidence from the chemotherapy regimen?
 0-9% (Low risk) 10-19% (Intermediate risk) 20% or greater (high risk)

Yes No Is the patient considered to be at high risk for chemotherapy-induced febrile neutropenia infectious complications?
 → Please indicate which of the following reasons that categorizes the patient to be at high risk:
 Active infections Age greater than or equal to 65 years Bone marrow compromise
 Bone marrow involvement by tumor producing cytopenias Open wounds Persistent neutropenia Poor nutritional status
 Poor performance status Previous chemotherapy Previous radiation therapy Previous episodes of FN
 Recent surgery
 Other serious co-morbidities: Cardiovascular disease HIV infection Liver dysfunction Renal dysfunction
 Other- Please explain: _____

Radiation therapy alone
 Yes No Are prolonged delays in radiation therapy expected due to neutropenia?

Secondary prophylaxis of neutropenia
 Yes No Does the patient have a documented diagnosis of non-myeloid malignancy?
 Yes No Did the patient experience a febrile neutropenic complication from a prior cycle of chemotherapy?
 → Please indicate the neutropenic complication the patient experienced from the prior cycle of chemotherapy:
 Neutropenic complication: _____
 Please indicate the prior cycle of chemotherapy that the patient received with the neutropenic complication: _____
 Yes No Did the patient experience a dose-limiting neutropenic event (a nadir or day of treatment count impacting the planned dose of chemotherapy) from a prior cycle of similar chemotherapy?
 Yes No Was the patient treated with the same dose and schedule planned for current cycle?
 Yes No Did the patient receive primary prophylaxis against febrile neutropenia?

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G. CLINICAL INFORMATION (continued) – Required clinical information must be completed in its entirety for all precertification requests.

Therapeutic use in a high-risk, febrile neutropenic patient

Please indicate which of the following prognostic factors pertains to the patient:

- Age greater than 65 years
- Being hospitalized at the time of the development of fever
 → Please provide date of hospitalization: ____ / ____ / ____
- Invasive fungal infection
 → Provide type of fungal infection and date infection occurred: _____ Date: ____ / ____ / ____
- Pneumonia
 → Please provide date of pneumonia infection: ____ / ____ / ____
- Prior episodes of febrile neutropenia
- Prolonged neutropenia
 → Yes No Is the prolonged neutropenia expected to last greater than 10 days?
- Profound neutropenia
- Sepsis syndrome
- Other
 → Please explain: _____

Treatment for radiation injury

Please indicate the radiation dose that caused the injury: ____ grays (Gy)

For Continuation requests:

- Yes No Is this continuation request a result of the patient receiving samples of Fulphila (pegfilgrastim-jmdb), Neulasta/Neulasta Onpro (pegfilgrastim), Nyvepria (pegfilgrastim-apgf), Udenyca (pegfilgrastim-cbqv), or Ziextenzo (pegfilgrastim-bmez)?
 (Sampling of Fulphila, Neulasta/Neulasta Onpro, Nyvepria, Udenyca, or Ziextenzo) does not guarantee coverage under the provisions of the pharmacy benefit)
- Yes No Is the patient continuing to respond to Fulphila (pegfilgrastim-jmdb), Neulasta/Neulasta Onpro (pegfilgrastim), Nyvepria (pegfilgrastim-apgf), Udenyca (pegfilgrastim-cbqv), or Ziextenzo (pegfilgrastim-bmez) therapy?

H. ACKNOWLEDGEMENT

Request Completed 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.

The plan may request additional information or clarification, if needed, to evaluate requests.