



MEDICARE FORM

Filgrastim Precertification Request (Granix, Leukine, Neupogen, Nivestym, Releuko, Zarxio)

Page 1 of 5

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

Virginia (HMO D-SNP) FAX: 1-833-280-5224 PHONE: 1-855-463-0933

For other lines of business: Please use other form.

Note: Granix, Leukine, Neupogen, Nivestym, and Releuko are non-preferred. Zarxio is preferred.

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

Precertification Requested By: Phone: Fax:

A. PATIENT INFORMATION

Form section A: Patient Information. Fields include First Name, Last Name, DOB, Address, City, State, ZIP, Home Phone, Work Phone, Cell Phone, Email, Patient Current Weight, Patient Height, Allergies.

B. INSURANCE INFORMATION

Form section B: Insurance Information. Fields include Aetna Member ID #, Group #, Insured, Does patient have other coverage?, Carrier Name, Insured.

C. PRESCRIBER INFORMATION

Form section C: Prescriber Information. Fields include First Name, Last Name, Address, City, State, ZIP, Phone, Fax, St Lic #, NPI #, DEA #, UPIN, Provider Email, Office Contact Name, Phone.

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Form section D: Dispensing Provider/Administration Information. Fields include Place of Administration (Self-administered, Physician's Office, Home, Outpatient Infusion Center, Home Infusion Center), Administration code(s) (CPT), Address, Dispensing Provider/Pharmacy (Physician's Office, Retail Pharmacy, Specialty Pharmacy, Mail Order, Other), Name, Address, Phone, Fax, TIN, NPI.

E. PRODUCT INFORMATION

Form section E: Product Information. Fields include checkboxes for Granix, Leukine, Nivestym, Neupogen, Releuko, Zarxio, each with Dose and Directions for Use.

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

Form section F: Diagnosis Information. Field: Primary Indication: Other:

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

Form section G: Clinical Information. Fields include For All requests (clinical documentation required for all requests): Please indicate the patient's absolute neutrophil count: mm^3 Date obtained: / / / Does the patient have a nadir count that requires an immediate need for Granix... Is the requested dose less than 180 mcg (0.3 mL)? Has the patient tried Zarxio... Does the patient have a contraindication to Zarxio... Is the patient completing an existing chemotherapy regimen... Will Granix... be used with another colony stimulating factor? Is Granix... part of a stem cell mobilization protocol? Will Granix... be used in the same chemotherapy cycle as another colony stimulating factor? Is the patient currently receiving concomitant chemotherapy and radiation therapy? Will Granix... be used within 7 days of Neulasta (pegfilgrastim)?

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Patient First Name Patient Last Name Patient Phone Patient DOB

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

For Initiation requests:

Note: Granix, Leukine, Neupogen, Nivestym, and Releuko are non-preferred. Zarxio is preferred.

Yes No Has the patient had prior therapy with Granix (tbo-filgrastim), Leukine (sargramostim), Neupogen (filgrastim), Nivestym (filgrastim-aafi), or Releuko (filgrastim-ayow) within the last 365 days?

Yes No Has the patient had a trial and failure, intolerance, or contraindication to Zarxio (filgrastim-sndz)?

Please explain if there are any other medical reason(s) that the patient cannot use Zarxio (filgrastim-sndz).

Granix (tbo-filgrastim):

Yes No Does the patient have a solid tumor or non-myeloid malignancy and will receive myelosuppressive chemotherapy associated with a clinically significant incidence of febrile neutropenia for primary or secondary prophylaxis?

Leukine (sargramostim):

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:

Adjunct to progenitor cell-transplantation [to mobilize peripheral-blood progenitor-cells (PBPC)]

Please indicate which type of transplant and date received: Autologous Allogeneic Date of transplant: / /

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?

Drug-induced agranulocytosis

Yes No Is the agranulocytosis caused by chemotherapy?

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

Hematopoietic Subsyndrome of Acute Radiation Syndrome (H-ARS)

Yes No Is the medication being requested for the treatment of radiation-induced myelosuppression following a radiological/nuclear incident?

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: / /

Neuroblastoma

Yes No Is the patient's disease considered high-risk?

Yes No Will the requested medication be used in combination with ALL of the following medications: dinutuximab (Unituxin), interleukin-2 (Aldesleukin), (Proleukin), isotretinoin (13-cis-retinoic acid)?

Yes No Will the requested medication be used in combination with Naxitamab-gqgk (Danyelza)?

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Note: Granix, Leukine, Neupogen, Nivestym, and Releuko are non-preferred. Zarxio is preferred.

Patient First Name Patient Last Name Patient Phone Patient DOB

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

Primary prophylaxis of neutropenia

- Does the patient have a documented diagnosis of non-myeloid malignancy?
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)
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:

Secondary prophylaxis of neutropenia

- Does the patient have a documented diagnosis of non-myeloid malignancy?
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:
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?
Was the patient treated with the same dose and schedule planned for current cycle?
Did the patient receive primary prophylaxis against febrile neutropenia?

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
Is the prolonged neutropenia expected to last greater than 10 days?
Profound neutropenia
Sepsis syndrome
Other
Please explain:

Neupogen (filgrastim), Nivestym (filgrastim-aafi), Releuko (filgrastim-ayow), Zarxio (filgrastim-sndz):

Acute lymphoblastic leukemia (ALL)

- Has the first days of chemotherapy been completed?
Is this the initial induction of chemotherapy?
Is this the first post-remission course of chemotherapy?
Please provide the chemotherapy regimen and date started: Regimen: Date started:

Acute myeloid leukemia

- Is the patient receiving induction chemotherapy?
Please indicate the regimen:
Is the patient receiving consolidation chemotherapy?
Please indicate the regimen:
Is the patient receiving chemotherapy for relapsed or refractory disease?
Relapsed disease Refractory disease
Please indicate the regimen:

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Table with 4 columns: Patient First Name, Patient Last Name, Patient Phone, Patient DOB

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

Adjunct to progenitor cell-transplantation [to mobilize peripheral-blood progenitor-cells (PBPC)]

Please indicate which type of transplant and date received: Autologous Allogeneic Date of transplant: / /

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 Granix (tbo-filgrastim), Leukine (sargramostim), Neupogen (filgrastim), Nivestym (filgrastim-aafi), Releuko (filgrastim-ayow), or Zarxio (filgrastim-sndz) 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) Tassigna (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:

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:

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB
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G. CLINICAL INFORMATION (continued) – Required clinical information must be completed in its entirety for all precertification requests.

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:

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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?

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 of high-risk neuroblastoma

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 Granix (tbo-filgrastim), Leukine (sargramostim), Neupogen (filgrastim), Nivestym (filgrastim-aafi), Releuko (filgrastim-ayow), or Zarxio (filgrastim-sndz)?

Yes No Is the patient continuing to respond to Granix (tbo-filgrastim), Leukine (sargramostim), Neupogen (filgrastim), Nivestym (filgrastim-aafi), Releuko (filgrastim-ayow), or Zarxio (filgrastim-sndz) 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.