



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.)

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: 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, and Allergies.

B. INSURANCE INFORMATION

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

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, and Office Contact Name.

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Form section D: Dispensing Provider/Administration Information. Fields include Place of Administration (Self-administered, Physician's Office, Home, etc.) and Dispensing Provider/Pharmacy (Physician's Office, Retail Pharmacy, etc.).

E. PRODUCT INFORMATION

Form section E: Product Information. Fields include checkboxes for Granix, Leukine, Nivestym, Neupogen, Releuko, and Zarxio, along 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 for Primary Indication and Other.

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

Form section G: Clinical Information. Fields include absolute neutrophil count, and various clinical questions regarding patient history and treatment protocols.

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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.

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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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.

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, Invasive fungal infection, Pneumonia, Prior episodes of febrile neutropenia, Prolonged neutropenia, 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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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:

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?

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.