SmartHealth Ascension

Filgrastim

(Neupogen®) J1442

Filgrastim (Neupogen®) may be authorized when the following criteria are met:

- Diagnosis of non myeloid malignancy; **AND**
- Using filgrastim for primary prophylaxis of Febrile Neutropenia (FN); **AND**
- Individual has a risk of FN of 20% or greater based on chemotherapy regimen.

OR

- Diagnosis of non myeloid malignancy; **AND**
- Using for primary prophylaxis of FN; **AND**
- Individual's risk of developing FN is between 10% and 20% based on chemotherapy regimen; **AND**
- Individual has any of the following risk factors:
    - Age greater than 65 years; **OR**
    - Poor performance status or HIV infection but chemotherapy still indicated; **OR**
    - Prior radiation therapy (within previous 1 year); **OR**
    - Bone marrow involvement by tumor producing cytopenias; **OR**
    - Persistent neutropenia (absolute neutrophil count [ANC] less than 1500 mm^3); **OR**
    - Poor renal function (glomerular filtration rate [GFR] less than 60mL/min); **OR**
    - Liver dysfunction (liver function tests at least 2X upper limit of normal or bilirubin > 2.0 mg/dL); **OR**
    - Recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc.); **OR**
    - History of active infection within previous 60 days; **OR**
    - Current open wound and chemotherapy cannot be delayed.

OR

- Diagnosis of non myeloid malignancy; **AND**
- Using for secondary prophylaxis of FN; **AND**
- Individual has experienced a neutropenic complication from a prior cycle of chemotherapy in which a reduced dose may compromise disease-free or overall survival or treatment outcome.

OR

- Individual is 18 years of age or older; **AND**
- A diagnosis of acute myeloid leukemia (AML); **AND**
- Individual is using after the completion of
    - induction or repeat induction chemotherapy; **OR**
    - consolidation chemotherapy for AML.

OR

- Diagnosis of hairy cell leukemia; **AND**
- Severe neutropenia.

OR

- Individual is receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer.

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

OR

- Individual is using for chronic administration to reduce the incidence and duration of sequelae of neutropenia (for example, fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

OR

- Individual is using to mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT).

OR

- Individual is using to reduce the duration of neutropenia and neutropenia related clinical sequelae in those with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplant (BMT).

OR

- Individual is using as adjunctive treatment for FN; **AND**
  - Individual has been on prophylactic therapy with filgrastim; **OR**
  - Individual has not received prophylactic therapy with granulocyte colony stimulating factor; **AND**
- Individual has a high risk for infection-associated complications as demonstrated by any of the following:
  - Expected prolonged (greater than 10 days) and profound (less than 0.1 x 109/L) neutropenia; **OR**
  - Age greater than 65 years; **OR**
  - Pneumonia or other clinically documented infections; **OR**
  - Hypotension and multi organ dysfunction (sepsis syndrome); **OR**
  - Invasive fungal infection; **OR**
  - Prior episode of febrile neutropenia; **OR**
  - Hospitalized at the time of the development of fever.

OR

- Individual has a diagnosis of myelodysplastic syndromes (MDS); **AND**
- Individual has severe neutropenia (ANC less than or equal to 500 mm^3) or experiencing recurrent infection or resistant infections.

OR

- Individual is using for the treatment of (non-chemotherapy) drug-induced neutropenia.

OR

- Individual is less than 21 years of age and has a diagnosis of glycogen storage disease type 1b; **AND**
- Individual is using for the treatment of low neutrophil counts.

OR

- Individual is using for the treatment for neutropenia associated with human immunodeficiency virus infection and antiretroviral therapy.

OR

- Individual is using after accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome).

OR

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

OR

- Individual is using as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant.

AND

- Dose is 5 mcg/kg/day subcutaneous injection, short intravenous infusion, or continuous intravenous infusion (for patients with cancer receiving **myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML**); **OR**
- Dose is 6 mcg/kg subcutaneous injection twice daily for patients with **congenital neutropenia**; **OR**
- 5 mcg/kg subcutaneous injection daily for patients with **cyclic or idiopathic neutropenia**; **OR**
- Dose is 10 mcg/kg/day subcutaneous injection administered for at least 4 days before first leukapheresis procedure and continuing until last leukapheresis for patients undergoing **autologous peripheral blood progenitor cell collection and therapy**; **OR**
- Dose is 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours for patients with cancer undergoing **bone marrow transplantation.**

AND

- Individual has had a trial and inadequate response or intolerance to biosimilar product (Nivestym (filgrastim-aafi); Zarxio (filgrastim-sndz)); **OR**
- Neupogen® is FDA-approved for the prescribed indication while the biosimilar product is not.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Treatment in neutropenia in those who are afebrile, except when criteria above are met;
- Adjunctive therapy in those with uncomplicated febrile neutropenia, defined as: fever less than 10 days duration, no evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection; and no uncontrolled malignancies;
- Chemosensitization of myeloid leukemias;
- Prophylaxis for FN during concomitant chemotherapy and radiation therapy;
- Continuing use if no response is seen within 28-42 days (individuals who have failed to respond within this time frame are considered non-responders);
- Using to increase the numbers of circulating hematopoietic stem cells as treatment of damaged myocardium.

Step/Alternative Therapies:

Preferred Product(s) [No PA Required]	**Non-Preferred Product(s) [PA Required]**
filgrastim-aafi (Nivestym)[Q5110]	filgrastim (Neupogen®)
filgrastim-sndz (Zarxio)[Q5101]	

Initial authorization for approved indications is up to 6 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Neupogen® is a leukocyte growth factor indicated to

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever;
- Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML);
- Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT);
- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis;
- Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia;
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome).

References:

National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines: Treatment by Cancer Type*. NCCN Clinical Practice Guidelines in Oncology. Retrieved April 22, 2022, from https://www.nccn.org/guidelines/category_1
Neupogen® (filgrastim) Label. (2021, February). Accessdata.fda.gov. Retrieved April 25, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/103353s5197lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or

email your questions to smarthealthspecialty@ascension.org.