

## Medical Policy:

### Colony Stimulating Factors: Nivestym™ (filgrastim-aafi)

| POLICY NUMBER | LAST REVIEW    | ORIGIN DATE |
|---------------|----------------|-------------|
| MG.MM.PH.62a  | March 21, 2024 | 2018        |

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## Length of Authorization

Coverage will be provided for six months and may be renewed.

## Dosing Limits [Medical Benefit]

### Max Units (per dose and over time)

- Severe Chronic Neutropenia:
  - 1380 billable units per day
- BMT, PBPC, or Radiation:
  - 1200 billable units per day
- All other indications
  - 600 billable units per day

## Guideline

### I. Initial Approval Criteria

Nivestym is a non-preferred G-CSF product. Preferred agents are Granix and Zarxio.

Granix and Zarxio are the preferred agents for Commercial, Medicaid, and Medicare members.

***Nivestym*** may be considered medically necessary if:

- The patient has a contraindication or severe intolerance to Granix and Zarxio†

† Commercial, Medicaid, AND Medicare members are subject to this step therapy

**Coverage for Nivestym™ (filgrastim-aafi) is provided in the following conditions:**

**Bone marrow transplant†**

**Peripheral Blood Progenitor Cell (PBPC) mobilization and transplant†**

**Patient with non-myeloid malignancy†**

1. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater § ; **OR**
2. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or greater § **AND** one or more of the following co-morbidities:
  - a. Elderly patients (age 65 or older)
  - b. History of recurrent febrile neutropenia from chemotherapy
  - c. Extensive prior exposure to chemotherapy
  - d. Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
  - e. Pre-existing neutropenia (ANC ≤ 1000/mm<sup>3</sup>) or bone marrow involvement with tumor
  - f. Patient has a condition that can potentially increase the risk of serious infection (i.e. HIV/AIDS)
  - g. Infection/open wounds
  - h. Recent surgery
  - i. Poor performance status
  - j. Poor renal function (creatinine clearance <50)
  - k. Liver dysfunction (elevated bilirubin >2.0)
  - l. Chronic immunosuppression in the post-transplant setting including organ transplant

**Treatment of chemotherapy-induced febrile neutropenia†**

1. Patient has been on prophylactic therapy with filgrastim; or tbo-filgrastim (*Note: therapy should not be used concomitantly with pegfilgrastim*); **OR**
2. Patient has not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
  - a. Patient has one or more of the following risk factors for developing infection related complications
    - i. Sepsis syndrome
    - ii. Age > 65
    - iii. Absolute neutrophil count [ANC] < 100/mcL
    - iv. Duration of neutropenia expected to be greater than 10 days

- v. Pneumonia or other clinically documented infections
- vi. Invasive fungal infection
- vii. Hospitalization at the time of fever
- viii. Prior episode of febrile neutropenia

**Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy ‡**

**Acute Myeloid Leukemia (AML) patient following induction or consolidation chemotherapy†**

**Bone Marrow Transplantation (BMT) failure or Engraftment Delay‡**

**Severe chronic neutropenia†**

1. Patient must have an absolute neutrophil count (ANC) < 500/mm<sup>3</sup>; **AND**
2. Patient must have a diagnosis of one of the following:
  - A. Congenital neutropenia; **OR**
  - B. Cyclic neutropenia; **OR**
  - C. Idiopathic neutropenia

**Myelodysplastic Syndrome‡**

1. Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
2. Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate]); **AND**
3. Used for treatment of symptomatic anemia with no del(5q) mutation; **AND**
4. Patient is receiving concurrent therapy with Erythropoiesis Stimulating Agents (ESAs)

**Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) ‡**

†FDA-labeled indication, ‡ Compendia recommended indication

§ expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Myeloid Growth Factors Clinical Practice Guideline at NCCN.org

## I. Renewal Criteria

Same as initial prior authorization policy criteria

## II. Dosage/Administration

| Indication             | Dose                              |
|------------------------|-----------------------------------|
| BMT/PBPC/H-ARS         | 10 mcg/kg daily for up to 14 days |
| Congenital Neutropenia | 6 mcg/kg twice daily              |
| All other indications  | 5 mcg/kg daily for up to 14 days  |

\*Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy

## Applicable Procedure Codes

| Code  | Description   |
|-------|---|
| Q5110 | Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg |

## Applicable NDCs

| Code          | Description   |
|---------------|---|
| 00069-0291-xx | Nivestym single dose prefilled syringe; 300 mcg/0.5 ml solution |
| 00069-0292-xx | Nivestym single dose prefilled syringe; 480 mcg/0.8 ml solution |
| 00069-0293-xx | Nivestym single use vial; 300 mcg/1 ml solution                 |
| 00069-0294-xx | Nivestym single use vial; 480 mcg/1.6 ml solution               |

## ICD-10 Diagnoses

| Code   | Description  |
|--------|--|
| C92.00 | Myeloid leukemia not having achieved remission                                   |
| C92.02 | Myeloid leukemia in relapse  |
| C92.50 | Acute myelomonocytic leukemia not having achieved remission                      |
| C92.52 | Acute myelomonocytic leukemia in relapse   |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission      |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse                         |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia not having achieved remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia in relapse                    |
| C93.00 | Acute monoblastic/monocytic leukemia not having achieved remission               |
| C93.02 | Acute monoblastic/monocytic leukemia in relapse                                  |
| C93.10 | Chronic myelomonocytic leukemia, not having achieved remission                   |
| C94.00 | Acute erythroid leukemia not having achieved remission                           |
| C94.02 | Acute erythroid leukemia in relapse  |
| C94.20 | Acute megakaryoblastic leukemia not having achieved remission                    |
| C94.22 | Acute megakaryoblastic leukemia in relapse                                       |
| D46.0  | Refractory anemia without ring sideroblasts, so stated                           |
| D46.1  | Refractory anemia with ring sideroblasts   |
| D46.20 | Refractory anemia with excess of blasts, unspecified                             |
| D46.21 | Refractory anemia with excess of blasts 1  |
| D46.22 | Refractory anemia with excess of blasts 2  |
| D46.4  | Refractory anemia, unspecified   |
| D46.9  | Myelodysplastic syndrome, unspecified  |
| D46.A  | Refractory cytopenia with multilineage dysplasia                                 |
| D46.B  | Refractory cytopenia with multilineage dysplasia and ring sideroblasts           |
| D46.C  | Myelodysplastic syndrome with isolated del(5q), chromosomal abnormality          |
| D46.Z  | Other myelodysplastic syndrome   |
| D70.0  | Congenital agranulocytosis   |
| D70.1  | Agranulocytosis secondary to cancer chemotherapy                                 |
| D70.2  | Other drug-induced agranulocytosis   |
| D70.4  | Cyclic neutropenia   |
| D70.9  | Neutropenia, unspecified   |
| T86.00 | Unspecified complication of bone marrow transplant                               |

|         |   |
|---------|---|
| T86.01  | Bone marrow transplant rejection  |
| T86.02  | Bone marrow transplant failure  |
| T86.03  | Bone marrow transplant infection  |
| T86.09  | Other complications of bone marrow transplant                                 |
| Z41.8   | Encounter for other procedures for purposes other than remedying health state |
| Z51.11  | Encounter for antineoplastic chemotherapy                                     |
| Z51.89  | Encounter for other specified aftercare                                       |
| Z52.001 | Unspecified donor, stem cells   |
| Z52.011 | Autologous donor, stem cells  |
| Z52.091 | Other blood donor, stem cells   |
| Z94.81  | Bone marrow transplant status   |
| Z94.84  | Stem cells transplant status  |

## Revision History

| Company(ies)                | DATE       | REVISION  |
|-----------------------------|------------|---|
| EmblemHealth & ConnectiCare | 3/21/2024  | Annual Review: Updated dosing chart, Initial Criteria: Patient with Non-myeloid malignancy: added: a. Chronic immunosuppression in the post-transplant setting including organ transplant as a co-morbidity   |
| EmblemHealth & ConnectiCare | 9/15/2023  | Annual Review:<br>Initial Criteria: <u>Treatment of chemotherapy-induced febrile neutropenia</u> ‡<br>After the Statement: Patient has been on prophylactic therapy with filgrastim; Added “ or tbo-filgrastim (Note: therapy should not be used concomitantly with pegfilgrastim);” <b>OR</b><br><u>Myelodysplastic Syndrome</u> ‡<br>Added “Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate]); <b>AND</b><br>Used for treatment of symptomatic anemia with no del(5q) mutation; <b>AND</b> ” |
| EmblemHealth & ConnectiCare | 4/08/2022  | Transferred policy to new template  |
| EmblemHealth & ConnectiCare | 1/1/2021   | Extended coverage duration from 4 to 6 months.  |
| EmblemHealth & ConnectiCare | 11/2/2020  | Effective 01/01/2021, Member must fail trial of Granix AND Zarxio, prior to using Nivestym (Medicare members are subject to this step therapy).   |
| EmblemHealth & ConnectiCare | 11/20/2019 | Granix and Zarxio are the preferred agents for Medicare members (Step protocol not mandated for Medicare members).  |
| EmblemHealth & ConnectiCare | 12/18/2018 | Added New NDC Codes 0069-0291-xx, 0069-0292-xx, 0069-0293-xx, 0069-0294-xx  |

## References

1. Nivestym [package insert]. Hospira, Inc., Lake Forest, IL. July, 2018.