# Medical Policy:

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

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



## 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/mm3) 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/$mm^3$; **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 |

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|---|---|
| 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: Treatment of chemotherapy-induced febrile neutropenia‡<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);"**OR**<br>Myelodysplastic Syndrome‡<br>Added "Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate]); **AND**<br>Used for treatment of symptomatic anemia with no del(5q) mutation; **AND"** |
| 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.