Colony Stimulating Factors: Nivestym™ (filgrastim-aafi)

Last Review Date: September 14th, 2018	Number: MG.MM.PH.62

I. Length of Authorization

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

II. Dosing Limits

a. 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

III. Initial Approval Criteria

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

Nivestym *may be considered medically necessary if:*

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

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†

- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater § ; **OR**
- 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:
  - Elderly patients (age 65 or older)
  - History of recurrent febrile neutropenia from chemotherapy
  - Extensive prior exposure to chemotherapy
  - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
  - Pre-existing neutropenia (ANC ≤ 1000/mm3) or bone marrow involvement with tumor
  - Patient has a condition that can potentially increase the risk of serious infection (i.e. HIV/AIDS)
  - Infection/open wounds
  - Recent surgery
  - Poor performance status
  - Poor renal function (creatinine clearance <50)
  - Liver dysfunction (elevated bilirubin >2.0)

Treatment of chemotherapy-induced febrile neutropenia‡

- Patient has been on prophylactic therapy with filgrastim; **OR**
- Patient has not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
  - Patient has one or more of the following risk factors for developing infection related complications
    - Sepsis syndrome
    - Age > 65
    - Absolute neutrophil count [ANC] < 100/mcL
    - Duration of neutropenia expected to be greater than 10 days
    - Pneumonia or other clinically documented infections
    - Invasive fungal infection
    - Hospitalization at the time of fever
    - 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†

- Patient must have an absolute neutrophil count (ANC) < 500/mm^3; **AND**
- Patient must have a diagnosis of one of the following:
  - Congenital neutropenia; **OR**
  - Cyclic neutropenia; **OR**
  - Idiopathic neutropenia

Myelodysplastic Syndrome‡

- Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
- 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

IV. Renewal Criteria

Same as initial prior authorization policy criteria

V. Dosage/Administration

Dose
– 5 mcg/kg daily for up to 14 days for non-BMT/PBPC indications – 10 mcg/kg daily for up to 14 days for BMT/PBPC/Radiation indications – 5-6 mcg/kg twice daily for severe congenital neutropenia

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

Applicable Procedure Codes

Q5510	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 mcg

Applicable Diagnosis Codes

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 then 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

References

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