Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Colony Stimulating Factors

CG-DRUG 16

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Fulphila (Pegfilgrastim-jmdb)	N/A
Granix (Tbo-Filgrastim)	N/A
Leukine (Sargramostim-Granulocyte Macrophage Colony Stimulating Factor; GM-CSF)	N/A
Neulasta (Pegfilgrastim)	2 syringes per 28 days
Neulasta on-body injector delivery kit (Pegfilgrastim)	2 injectors/kits per 28 days
Neupogen (Filgrastim-Granulocyte Colony Stimulating Factor; G-CSF)	N/A N/A
Nivestym (Filgrastim-aafi)	N/A
Zarxio (Filgrastim-sndz)	N/A

APPROVAL CRITERIA

I. Requests for filgrastim (Neupogen), filgrastim-aafi (Nivestym), filgrastim-sndz (Zarxio), pegfilgrastim (Neulasta, Neulasta on-body injector delivery kit), pegfilgrastim-jmdb (Fulphila), sargramostim (Leukine) and tbo-filgrastim (Granix) may be approved when used for any of the following:

A. Primary prophylaxis

1. Primary prophylaxis of febrile neutropenia (FN) in individuals with a risk of FN of 20% or greater based on chemotherapy regimen; **OR**

2. Primary prophylaxis in individuals with a risk of FN greater than or equal to 10% and less than 20% based on chemotherapy regimen and individuals have one or more of the following risk factors for FN:

a. Age greater than 65 years; or

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CRX-ALL-0292-18

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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b. Poor performance status (Eastern Cooperative Oncology Group [ECOG] 3 or 4); or
c. Previous episodes of FN; or
d. Bone marrow involvement by tumor producing cytopenias; or
e. Pre-existing neutropenia (absolute neutrophil count [ANC] less than 1500mm^3); or
f. Poor nutritional status (baseline albumin less than or equal to 3.5g/dL or body mass index [BMI] less than 20); or
g. Poor renal function (glomerular filtration rate [GFR] less than 60mL/min); or
h. Liver dysfunction (liver function tests at least 2X upper limit of normal): or
i. The presence of open wounds; or
j. Advanced cancer; or
k. Other serious comorbidities

B. <u>Secondary Prophylaxis</u>

1. Secondary prophylaxis of FN in individuals who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome.

C. <u>Adjunctive Treatment</u>

1. Adjunctive treatment of individuals with FN and high risk for infection-associated complications as demonstrated by any of the following:
a. Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10^9/L) neutropenia; **or**
b. Age greater than 65 years; **or**
c. Uncontrolled primary disease; **or**
d. Pneumonia; **or**
e. Hypotension and multi organ dysfunction (sepsis syndrome); **or**
f. Invasive fungal infection; **or**
g. Hospitalized at the time of the development of fever

II. Requests for filgrastim (Neupogen), filgrastim-aafi (Nivestym), or filgrastim-sndz (Zarxio) may be approved for individuals who meet any of the following criteria:

A. In an individual with *acute lymphocytic leukemia (ALL)* after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy; **or**

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CRX-ALL-0292-18

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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B. Use in adult individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML; **or**

C. Treatment of moderate to severe *aplastic anemia*; **or**

D. Treatment of severe neutropenia in individuals with hairy cell leukemia; **or**

E. In an individual with myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophils count (ANC) less than or equal to 500 mm^3) or experiencing recurrent infection; **or**

F. In an individual receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer; **or**

G. 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**

H. Treatment of (non-chemotherapy) drug-induced neutropenia; **or**

I. Treatment of low neutrophil counts in individuals with glycogen storage disease type 1b; **or**

J. Treatment for neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy; **or**

K. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected; **or**

L. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome); **or**

M. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for the following indications:

1. To promote myeloid reconstitution; **or**

2. When engraftment is delayed or has failed; **or**

N. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT); **or**

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

III. Requests for pegfilgrastim (Neulasta, Neulasta on-body injector delivery kit) or pegfilgrastim-jmdb (Fulphila) may be approved for individuals who meet any of the following criteria:

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CRX-ALL-0292-18

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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A. In an individual with *acute lymphocytic leukemia (ALL)* after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy; **or**

B. In an individual with myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophils count (ANC) less than or equal to 500 mm^3 or experiencing recurrent infection; **or**

C. In an individual receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer; **or**

D. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome); **or**

E. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT)for the following indications:

1. To promote myeloid reconstitution; **or**

2. When engraftment is delayed or has failed.

IV. Requests for sargramostim (Leukine) may be approved for individuals who meet any of the following criteria:

A. In an individual receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer; **or**

B. In an individual with acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy; **or**

C. For administration shortly after the completion of induction or repeat induction chemotherapy of acute myeloid leukemia (AML) for individuals over 55 years of age; **or**

D. In an individual with myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophils count (ANC) less than or equal to 500 mm^3 or experiencing recurrent infection; **or**

E. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected; or

F. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy])(such as Hematopoietic Syndrome of Acute Radiation Syndrome); **or**

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Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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G. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for the following indications:
  1. To promote myeloid reconstitution; **or**
  2. When engraftment is delayed or has failed; **or**

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

V. Requests for Tbo-Filgrastim (Granix) may be approved for individuals who meet any of the following criteria:

I. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for the following indications:
  1. To promote myeloid reconstitution; **or**
  2. When engraftment is delayed or has failed; **or**

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

May not be approved:

The use of CSFs (filgrastim, filgrastim-aafi, filgrastim-sndz, pegfilgrastim, pegfilgrastim-jmdb, sargramostim and tbo-filgrastim) may not be approved for **any** of the following:

1. As prophylaxis for FN, except when criteria above are met; **or**
2. As treatment in neutropenic individuals who are **afebrile, except** when criteria above are met; **or**
3. As adjunctive therapy in individuals 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; **o**r
4. Chemo sensitization of myeloid leukemias; **or**
5. As prophylaxis for FN during concomitant chemotherapy and radiation therapy; **or**
6. Continued use if no response is seen within 28-42 days (individuals who have failed to respond within this time frame are considered non-responders); **or**
7. For uses not meeting the criteria above.

State Specific Mandates

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CRX-ALL-0292-18

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
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CRX-ALL-0292-18