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 |

*FHK- Florida Healthy Kids

Colony Stimulating Factors
CG-DRUG 16

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

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

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

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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. Secondary Prophylaxis

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. Adjunctive Treatment

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 | 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.

### Third Party Requests for pegfilgrastim (Neulasta, Neulasta on-body injector delivery kit) or pegfilgrastim-jmdb (Fulphila)

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
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*
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; or
   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.
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CRX-ALL-0292-18