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-0407-19
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-0407-19
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-0407-19
Y. Individual is using after a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed (NCCN 2A);

OR

Z. Individual is using to mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT);

OR

AA. Individual is using s an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant (DrugPoints B IIa);

OR

BB. Individual is using to reduce the duration of neutropenia and neutropenia related clinical sequelae in those with nonmyeloid malignancies undergoing myeloblastic chemotherapy followed by bone marrow transplant (BMT).

II. Requests for pegfilgrastim (Neulasta), pegfilgrastim-jmdb (Fulphila) or pegfilgrastim-cbqv (Udenyca) may be approved if the following criteria are met:

A. Individual with nonmyeloid malignancy is using for primary prophylaxis of FN; AND

B. Individual has a risk of FN of 20% or greater based on chemotherapy regimen (NCCN 2A);

OR

C. Individual with nonmyeloid malignancy is using for primary prophylaxis of FN; AND

D. Individual’s risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy regimen and individual has any risk factors for FN (NCCN 2A):

Patient risk factors for the development of febrile neutropenia include but are not limited to (NCCN Guidelines Version 1.2018):

1. Age greater than 65 years; OR
2. Poor performance status (Eastern Cooperative Oncology Group 3 or 4) or HIV infection (in particular, those with low CD4 counts); OR
3. Prior chemotherapy or radiation therapy; OR
4. Bone marrow involvement by tumor producing cytopenias; OR
5. Persistent neutropenia (absolute neutrophil count [ANC] less than 1500 mm$^3$); OR
6. Poor renal function (glomerular filtration rate [GFR] less than 60 mL/min); OR
7. Liver dysfunction (liver function tests at least 2X upper limit of normal); 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-0407-19
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-0407-19
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-0407-19
<table>
<thead>
<tr>
<th>Market</th>
<th>DC</th>
<th>GA</th>
<th>KY</th>
<th>MD</th>
<th>NJ</th>
<th>NY</th>
<th>WA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>NA</td>
</tr>
</tbody>
</table>

3. Prior chemotherapy or radiation therapy; OR
4. Bone marrow involvement by tumor producing cytopenias; OR
5. Persistent neutropenia (absolute neutrophil count [ANC] less than 1500mm$^3$); OR
6. Poor renal function (glomerular filtration rate [GFR] less than 60mL/min); OR
7. Liver dysfunction (liver function tests at least 2X upper limit of normal); OR
8. Recent surgery and/or the presence of open wounds;

OR
E. Individual with nonmyeloid malignancy is using for secondary prophylaxis of FN; AND
F. Individual has experienced a neutropenic complication from a prior cycle of chemotherapy (for which prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome (NCCN 2A);

OR
G. Individual is using as an adjunctive treatment for FN;
AND
H. Individual was previously using Granix (tbo-filgrastim) prophylactically (NCCN 2A); OR
I. Individual has not received prophylactic therapy with a granulocyte colony stimulating factor (NCCN Guidelines Myeloid Growth Factors);
AND
J. Individual has a high risk for infection-associated complications as demonstrated by any of the following:
   1. Expected prolonged (greater than 10 days) and profound (less than 0.1 x 10$^9$/L) neutropenia (NCCN 2A); OR
   2. Age greater than 65 years; OR
   3. Pneumonia or other clinically documented infections; OR
   4. Hypotension and multi organ dysfunction (sepsis syndrome); OR
   5. Invasive fungal infection; OR
   6. Prior episode of febrile neutropenia; OR
   7. Hospitalized at the time of the development of fever;

OR
K. Individual is using after a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed (NCCN 2A);

OR
L. Individual has a diagnosis of myelodysplastic syndrome (MDS); AND
M. Individual has severe neutropenia (ANC less than or equal to 500mm$^3$) or experiencing recurrent or resistant infections (NCCN 2A);

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-0407-19
N. Individual is using to mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT) (AHFS).

Colony Stimulating Factors (filgrastim, pegfilgrastim, sargramostim, and tbo-filgrastim) may not be approved for any of the following:

I. Individual is using as prophylaxis for FN, except when criteria above are met; OR
II. Individual is using as treatment in neutropenia in those who are afebrile, except when criteria above are met; OR
III. Individual is using as adjunctive therapy in those 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
IV. Individual is using for chemosensitization of myeloid leukemias; OR
V. Individual is using for prophylaxis for FN during concomitant chemotherapy and radiation therapy; OR
VI. Individual is continuing use if no response is seen within 28-42 days (individuals who have failed to respond within this time frame are considered non-responders).

Key References:
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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-0407-19