**GRANULOCYTE COLONY-STIMULATING FACTORS**

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>FILGRASTIM-SNDZ</td>
<td>ZARXIO</td>
<td>41814</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FILGRASTIM</td>
<td>NEUPOGEN</td>
<td>06070</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PEGFILGRASTIM</td>
<td>NEULASTA</td>
<td></td>
<td>15666</td>
<td></td>
</tr>
<tr>
<td>TBO-FILGRASTIM</td>
<td>GRANIX</td>
<td>40426</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**GUIDELINES FOR USE**

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever for nonmyeloid malignancies?
   - If yes, continue to #7.
   - If no, continue to #2.

2. Is the patient undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML)?
   - If yes, continue to #7.
   - If no, continue to #3.

3. Is the patient experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia) after undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) for nonmyeloid malignancies?
   - If yes, continue to #7.
   - If no, continue to #4.

4. Will this drug be used to mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis?
   - If yes, continue to #7.
   - If no, continue to #5.

5. Does the patient have a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia?
   - If yes, continue to #7.
   - If no, continue to #6.

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GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE (CONTINUED)

6. Is the request for Neupogen to be used to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)?

If yes, approve Neupogen with duration of treatment up to 1 year.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the prescription written or currently being supervised by a hematologist or an oncologist?

If yes, approve the requested medication with duration of treatment up to 1 year.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for GRANULOCYTE COLONY-STIMULATING FACTORS requires that this medication is prescribed or currently being supervised by a hematologist or oncologist for one of the following indications:
- Patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- Patients with acute myeloid leukemia (AML) undergoing induction or consolidation chemotherapy treatment
- Patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) who are experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
- Mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
- Patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

For patients acutely exposed to myelosuppressive doses of radiation, only Neupogen will be approved.

RATIONALE
Ensure proper utilization and appropriate place in therapy according to FDA Approved Indications.

FDA APPROVED INDICATION
NEUPOGEN is indicated for treatment of Chronic idiopathic neutropenia, Congenital neutropenia, Cyclic neutropenia, Idiopathic neutropenia, Mobilization: Peripheral blood stem cells, Neutropenia: Bone Marrow Transplant, Neutropenia: Chemotherapy induced, severe chronic neutropenia, and to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

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GRANULOCYTE COLONY-STIMULATING FACTORS

FDA APPROVED INDICATION (CONTINUED)
NEULASTA is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

NEULASTA is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

FILGRASTIM-SNDZ is indicated to:
• Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever
• Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
• Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
• Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
• Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

TBO-FILGRASTIM is indicated for reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

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## GRANULOCYTE COLONY-STIMULATING FACTORS

### FDA APPROVED INDICATION (CONTINUED)

<table>
<thead>
<tr>
<th>Population</th>
<th>FDA labeling</th>
<th>Drug(s) Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients receiving radiation</td>
<td>Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)</td>
<td>Neupogen (filgrastim)</td>
</tr>
<tr>
<td>Non-myeloid cancer patients receiving myelosuppressive chemo</td>
<td><em>For reduction in the duration of severe neutropenia</em> in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia*</td>
<td>Granix (TBO-filgrastim) Neupogen (filgrastim) Zarxio (filgrastim-sndz) Neulasta (pegfilgrastim)</td>
</tr>
<tr>
<td>AML patients receiving induction or consolidation chemo</td>
<td>Reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)</td>
<td>Neupogen (filgrastim) Zarxio (filgrastim-sndz)</td>
</tr>
<tr>
<td>Cancer patients undergoing BMT</td>
<td>Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation</td>
<td>Neupogen (filgrastim) Zarxio (filgrastim-sndz)</td>
</tr>
<tr>
<td>Undergoing peripheral blood progenitor cell collection</td>
<td>For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis</td>
<td>Neupogen (filgrastim) Zarxio (filgrastim-sndz)</td>
</tr>
<tr>
<td>Severe chronic neutropenia</td>
<td>For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia</td>
<td>Neupogen (filgrastim) Zarxio (filgrastim-sndz)</td>
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</tbody>
</table>
GRANULOCYTE COLONY-STIMULATING FACTORS

DOSAGE

- Patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML
  o Recommended starting dose is 5 mcg/kg/day subcutaneous injection
- Patients with cancer undergoing bone marrow transplantation
  o 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours
- Patients undergoing autologous peripheral blood progenitor cell collection and therapy
  o 10 mcg/kg/day subcutaneous injection administered for at least 4 days before first leukapheresis procedure and continue until last leukapheresis
- Patients with congenital neutropenia
  o Recommended starting dose is 6 mcg/kg subcutaneous injection twice daily
- Patients with cyclic or idiopathic neutropenia
  o Recommended starting dose is 5 mcg/kg subcutaneous injection daily
- Patients acutely exposed to myelosuppressive doses of radiation
  o Recommended starting dose is 10 mcg/kg subcutaneous injection daily

REFERENCES

- Granix [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; December 2014.

Created: 01/11/18
Effective: 03/01/18