Colony Stimulating Factors
(Preferred Product: Zarxio, Nivestym)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

This policy informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

This program applies to the colony stimulating factor products specified in this policy. For this program, Nivestym and Zarxio are the preferred products. Coverage for targeted products (Neupogen, Granix, and Leukine) is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment for an indication that is FDA-approved for the preferred product.

Table. Colony Stimulating Factors

<table>
<thead>
<tr>
<th>Medication</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td><strong>Preferred Products:</strong></td>
<td></td>
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<tr>
<td>Zarxio</td>
<td>filgrastim-sndz</td>
</tr>
<tr>
<td>Nivestym</td>
<td>filgrastim-aafi</td>
</tr>
<tr>
<td><strong>Targeted Products:</strong></td>
<td></td>
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<tr>
<td>Neupogen</td>
<td>filgrastim</td>
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<tr>
<td>Granix</td>
<td>TBO-filgrastim</td>
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<tr>
<td>Leukine</td>
<td>sargramostim</td>
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</tbody>
</table>
POLICY

EXCEPTION CRITERIA

I. Coverage for the targeted products, Neupogen or Granix, is provided when the member meets one of the following criteria:
   a. Member has failed treatment with all of the preferred products due to a documented intolerable adverse event (e.g., rash, nausea, vomiting) and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)
   b. Member has a documented latex allergy and the prescriber states that the member must use latex-free vials and the member had an inadequate response or an intolerable adverse effect to Nivestym.
   c. Neupogen or Granix are requested for doses less than 180 mcg and the member had an inadequate response or an intolerable adverse effect to Nivestym.

Approval will be for 6 months

II. Coverage for the targeted product, Leukine, is provided when the member has had a documented inadequate response or intolerable adverse effect to any of the preferred products.

Approval will be for 6 months

Prior approval is required. Submit a prior approval/treatment request now.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J1442 – Inj, filgrastim (g-csf), excludes biosimilars, 1 microgram (Neupogen)
- J2820 – Inj, sargramostim (gm-csf), 50 micrograms (Leukine)
- J1447 – Granix TBO-filgrastim

REFERENCES

- Nivestym [package insert]. Lake Forest, IL: Hospira Inc, a Pfizer company; July 2018
POLICY HISTORY

Policy #: 05.02.41
Policy Creation: January 2018
Reviewed: March 2020
Revised: March 2020
Current Effective Date: April 17, 2020