Policy Title: Short Acting Granulocyte Colony Stimulating Factors: Nivestym (filgrastim-aafi), Neupogen (filgrastim), Granix (tbo-filgrastim)

NON-ONCOLOGY POLICY

<table>
<thead>
<tr>
<th>Department:</th>
<th>PHA</th>
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Effective Date: 01/01/2020

Review Date: 04/19/2019, 09/18/2019, 12/13/2019, 01/29/2020, 08/3/2020, 07/22/2021

Revision Date: 04/19/2019, 09/18/2019, 12/13/2019, 01/29/2020, 08/3/2020, 07/22/2021

**Purpose:** To support safe, effective and appropriate use of short-acting Granulocyte Colony Stimulating Factors.

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**
Colony Stimulating Factors are covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process. Zarxio (filgrastim-sndz) is the preferred short-acting Colony Stimulating Factor. **For oncology indications, please refer to Myeloid Growth Factors Policy.**

**Procedure:**
Coverage of short-acting Colony Stimulating Factors will be reviewed prospectively via the prior authorization process based on criteria below.

**Initial Criteria:**
- Patient has one of the following conditions:
  - Bone marrow transplant (BMT); OR
  - Peripheral Blood Progenitor Cell (PBPC) mobilization and transplant (Nivestym/Neupogen-ONLY); OR
  - Peripheral Blood Stem Cell (PBSC) mobilization and transplant (Granix- ONLY); OR
  - Severe chronic neutropenia (Nivestym/Neupogen- ONLY);
    - Patient must have an absolute neutrophil count (ANC) < 500/mm³; AND
    - Patient must have a diagnosis of one of the following:
      - Congenital neutropenia; OR
      - Cyclic neutropenia; OR
      - Idiopathic neutropenia; OR
  - Bone Marrow Transplantation (BMT) failure or Engraftment Delay; AND
- Patients must have a documented failure, contraindication, or intolerance to Zarxio (filgrastim-sndz) OR for patients that are currently on treatment with Nivestym (filgrastim-aafi), Neupogen
(filgrastim), or Granix (tbo-filgrastim) can remain on treatment OR MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

**Coverage Duration:** 4 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

**Dosage/Administration:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Maximum dose (1 billable unit = 1 mcg)</th>
</tr>
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<tbody>
<tr>
<td>BMT/PBPC</td>
<td>• 10mcg/kg daily for up to 14 days</td>
<td>• 1200 billable units per day</td>
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<tr>
<td>Severe Chronic Neutropenia</td>
<td>• 5 mcg/kg daily for up to 14 days for idiopathic or cyclic neutropenia  • 6mcg/kg twice daily for severe congenital neutropenia</td>
<td>• 1380 billable units per day</td>
</tr>
<tr>
<td>All other indications</td>
<td>• 5mcg/kg daily for up to 14 days</td>
<td>• 600 billable units per day</td>
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**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.
The following HCPCS/CPT codes are:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>Q5101</td>
<td>Injection, filgrastim-sndz, biosimilar, (Zarxio)</td>
</tr>
<tr>
<td>J1442</td>
<td>Injection, filgrastim (g-csf), excludes biosimilar, 1 microgram</td>
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<tr>
<td>J1447</td>
<td>Injection, tho-filgrastim, 1 microgram</td>
</tr>
<tr>
<td>Q5110</td>
<td>Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram</td>
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References: