Policy Title:	Short Acting Granulocyte Colony Stimulating Factors: Nivestym (filgrastim-aafi), Neupogen (filgrastim), Granix (tbo-filgrastim), Releuko (filgrastim-ayow), (Zarxio (filgrastim-sndz) **NON-ONCOLOGY POLICY**		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	04/19/2019, 09/18/2019, 12/13/2019, 1/29/2020, 8/3/2020, 7/22/2021, 6/16/2022, 10/6/2022, 2/9/2023		
Revision Date:	04/19/2019, 09/18/2019, 12/13/2019, 1/29/2020, 8/3/2020, 7/22/2021		

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/mm^3; 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), Releuko (filgrastim-ayow), 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:

Indication	Dose	Maximum dose (1 billable unit = 1 mcg)
BMT/PBPC	• 10mcg/kg daily for up to 14 days	• 1200 billable units per day
Severe Chronic Neutropenia	• 5 mcg/kg daily for up to 14 days for idiopathic or cyclic neutropenia • 6mcg/kg twice daily for severe congenital neutropenia	• 1380 billable units per day
All other indications	• 5mcg/kg daily for up to 14 days	• 600 billable units per day

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:

HCPCS/CPT Code	Description
Q5101	Injection, filgrastim-sndz, biosimilar, (Zarxio)
J1442	Injection, filgrastim (g-csf), excludes biosimilar, 1microgram
J1447	Injection, tbo-filgrastim, 1 microgram
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram
Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram

References:

1. Zarxio [package insert]. Princeton, NJ; Sandoz Inc; March 2021. Accessed June 2022.
2. Granix [package insert]. North Wales, PA; Teva Pharmaceuticals USA, Inc.; April 2020. Accessed June 2022.
3. Neupogen [package insert]. Thousand Oaks, CA; Amgen Inc; April 2021. Accessed June 2022.
4. Nivestym [package insert]. Lake Forest, IL; Hospira Inc; November 2021. Accessed June 2022.
5. Releuko [package insert]. Bridgewater, NJ; Amneal Pharmaceuticals; April 2022. Accessed February 2023.
6. Kelaidi C Beyne-Rauzy O, Braun T, et al. High Response rate and improved exercise capacity and quality of life with a new regimen of darbepoetin alfa with or without filgrastim in lower-risk myelodysplastic syndromes: a phase II study by the GFM. Ann Hematol 2013; 92:621-631.
7. First Coast Service Options, Inc. Local Coverage Determination (LCD): G-CSF (Neupogen®, Granix™, Zarxio™) (L34002). Centers for Medicare & Medicaid Services, Inc. Updated on 4/25/2018 with effective date 4/1/2018. Accessed July 2018.
8. National Government Services, Inc. Local Coverage Article: Filgrastim, Pegfilgrastim, Tbo-filgrastim, Filgrastim-sndz (e.g., Neupogen®, Neulasta™, Granix™, Zarxio™) - Related to LCD L33394 (A52408). Centers for Medicare & Medicaid Services, Inc. Updated on 7/06/2018 with effective date 7/15/2018. Accessed July 2018.
9. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L34699). Centers for Medicare & Medicaid Services, Inc. Updated on 4/20/2018 with effective date 05/1/2018. Accessed July 2018.
10. Palmetto GBA. Local Coverage Determination (LCD): White Cell Colony Stimulating Factors (L37176). Centers for Medicare & Medicaid Services, Inc. Updated on 5/4/2018 with effective date 4/1/2018. Accessed July 2018.