

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Colony Stimulating Factors PDL Edit
<b>First Implementation Date:</b>	October 3, 2019
<b>Revised Date:</b>	October 14, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Hematopoietic growth factors include both granulocyte colony stimulating factor (G-CSF) and granulocyte macrophage colony stimulating factor (GM-CSF). Recombinant forms of G-CSFs are available as filgrastim (Neupogen®), filgrastim-aafi (Nivestym®), filgrastim-sndz (Zarxio®), pegfilgrastim (Neulasta®, Neulasta® Onpro®), pegfilgrastim-apgf (Nyvepria™), pegfilgrastim-bmez (Ziextenzo®), pegfilgrastim-cbqv (Udenyca®), pegfilgrastim-jmdb (Fulphila®), and tbo-filgrastim (Granix®). The first and only GM-CSF product available is sargramostim (Leukine®). Filgrastim, pegfilgrastim, and tbo-filgrastim are all indicated to decrease the incidence or duration of febrile neutropenia in participants with cancer receiving myelosuppressive chemotherapy associated with a significant incidence of febrile neutropenia. Filgrastim, pegfilgrastim, and sargramostim are also indicated to increase survival in participants acutely exposed to myelosuppressive doses of radiation; corresponding biosimilars do not have this indication. Both filgrastim and sargramostim also carry additional indications, including mobilization of autologous hematopoietic progenitor cells and use in bone marrow transplantation.

All the agents are well-tolerated and not associated with significant safety concerns. In general, no major differences in pharmacokinetics, efficacy or safety have been found between reference and biosimilar G-CSF agents. Current NCCN Clinical Practice Guidelines in Oncology for hematopoietic growth factors recommend primary prophylaxis with a G-CSF in participants with a planned chemotherapy regimen associated with a high risk (>20%) of febrile neutropenia. The guidelines also recommend considering prophylactic G-CSF based on participant-specific risk factors for individuals with a planned chemotherapy regimen associated with an intermediate risk (10%-20%) of febrile neutropenia and does not recommend sargramostim for participants with solid tumors receiving myelosuppressive chemotherapy. There are no specific recommendations as to which G-CSF agent should be used however, filgrastim, tbo-filgrastim, pegfilgrastim, and biosimilars of both filgrastim and pegfilgrastim are a category 1 recommendation for febrile neutropenia prophylaxis. For allogeneic donor cell mobilization, filgrastim, tbo-filgrastim and filgrastim biosimilars are a category 2B recommendation.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>• Leukine®</li> <li>• Neulasta® Onpro®</li> <li>• Neupogen®</li> <li>• Nyvepria™</li> <li>• Ziextenzo®</li> </ul>	<ul style="list-style-type: none"> <li>• Fulphila®</li> <li>• Granix®</li> <li>• Neulasta® Syringe</li> <li>• Nivestym®</li> <li>• Udenyca®</li> <li>• Zarxio®</li> </ul>

Type of Criteria:  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

Data Sources:  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Colony Stimulating Factors
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:  Progress Notes:   
 MedWatch Form:  Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
 Rule Type: PDL

## Default Approval Period

1 year

## References

1. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology growth factors. Version 4.2021 – May 2021. National Comprehensive Cancer Network; 2021.

4. Kuan JW, Su AT, Leong CF. Pegylated granulocyte-colony stimulating factor versus non-pegylated granulocyte-colony stimulating factor for peripheral blood stem cell mobilization: a systematic review and meta-analysis. *J Clin Apher.* 2017;32(6):517-542.
5. Evidence-Based Medicine and Fiscal Analysis: “Colony Stimulating Factors – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
6. Evidence-Based Medicine Analysis: “Colony Stimulating Factors”, UMKC-DIC; May 2021.