SmartPA Criteria Proposal

Drug/Drug Class:	Colony Stimulating Factors PDL Edit
First Implementation Date:	October 3, 2019
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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-cbqv (Udenyca™), pegfilgrastim-jmdb (Fulphila™), pegfilgrastim-bmez (Ziextenzo™) and tbo-filgrastim (Granix®). The first and only GM-CSF product available is sargramostim (Leukine®). Filgrastim, pegfilgrastim, and tbo-filgrastim are all indicated to prevent febrile neutropenia in participants with cancer receiving myelosuppressive chemotherapy that has a high incidence of febrile neutropenia and in participants with cancer who are on high intensity chemotherapy to help aid in chemotherapy administration. Sargramostim is also indicated to reduce the risk of infection and neutrophil recovery time, but only in participants with acute myeloid leukemia receiving induction or consolidation therapy. Neupogen, Neulasta, 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 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 NCNN Clinical Practice Guidelines in Oncology on myeloid 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 G-CSF based on participant risk factors in participants 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, the NCCN guideline does rate filgrastim, filgrastim-aafi, filgrastim-sndz, tbo-filgrastim or pegfilgrastim as category 1 recommendations and pegfilgrastim-cbqv and pegfilgrastim-jmdb as category 2A recommendations. Available randomized

controlled trials and observational data suggest that pegfilgrastim may be a preferred option. Guidelines for stem cell mobilization recommend use of G-CSFs. For allogenic donor cell mobilization, filgrastim is preferred; its biosimilars and tbo-filgrastim can be considered. However, it is important to note that tbo-filgrastim is not approved for this use.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Fulphila™ • Leukine® • Neulasta® Onpro® • Neulasta® Syringe • Neupogen® • Udenyca™ • **Ziextenzo™**	• Granix® • Nivestym™ • Zarxio®

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 no approval criteria are 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. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology myeloid growth factors. Vol 2.2019: National Comprehensive Cancer Network; 2019.
5. 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.
6. Evidence-Based Medicine and Fiscal Analysis: “Colony Stimulating Factors – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; April 2020
7. Evidence-Based Medicine Analysis: “Colony Stimulating Factors”, UMKC-DIC; April 2020.