



OREGON DEPARTMENT OF CORRECTIONS (ODOC)

THERAPEUTIC SUBSTITUTION

SUMMARY:

Oregon Department of Corrections Health Services recognizes that in many cases “therapeutic substitution” is a safe, effective, and reasonable medical and pharmacy practice. Substitution of certain “ordered” medications with a different specific medication of similar therapeutic efficacy may be made by pharmacy.

BACKGROUND:

Filgrastim (Neupogen®), filgrastim-sndz (Zarxio®), tbo-filgrastim (Granix®) and filgrastim-aafi (Nivestym®) are granulocyte colony-stimulating factors (G-CSF) that stimulate bone marrow to produce neutrophils. Otherwise, neutropenia leaves patients susceptible to infection. Filgrastim-sndz and filgrastim-aafi are biosimilars to filgrastim and have no meaningful differences in terms of safety and efficacy. Biosimilars are only approved by the FDA if only minor differences in inactive ingredients exist between the biosimilar and reference product. Tbo-filgrastim (Granix®) is an alternative recombinant methionyl form of human G-CSF with the same dosing as filgrastim. According to guidelines from the American Society of Clinical Oncology (ASCO), all these forms of G-CSF, including biosimilars, may be used for the prevention of treatment-related febrile neutropenia, and the treatment choice should be based on convenience, cost, and clinical situation. NCCN (National Comprehensive Cancer Network) guidelines also state that FDA-approved biosimilars are appropriate substitutes for filgrastim and pegfilgrastim.

Pegfilgrastim (Neulasta®) is a pegylated form of G-CSF with a prolonged half-life allowing for a single dose rather than daily administration. Three biosimilars of pegfilgrastim are available in the US: pegfilgrastim-jmdb (Fulphila®), pegfilgrastim-cbqv (Udenyca®), and pegfilgrastim-bmez (Ziextenzo®). The pegylated form of G-CSF is considered at least as effective and more convenient than G-CSF; however, it may not be appropriate for use in all patients due to its long duration of action.

MEDICATION ORDERED	THERAPEUTIC SUBSTITUTION
FILGRASTIM (NEUPOGEN®) 300mcg	Filgrastim-aafi (Nivestym®) 300mcg
FILGRASTIM (NEUPOGEN®) 480mcg	Filgrastim-aafi (Nivestym®) 480mcg
PEGFILGRASTIM (NEULASTA®) 6mg	Pegfilgrastim-bmez (Ziextenzo®) 6mg

ACTION:

ODOC pharmacies will dispense filgrastim-aafi (Nivestym®), the least expensive biosimilar to filgrastim, when filgrastim is ordered by providers. Similarly, the pharmacies will dispense pegfilgrastim-bmez when pegfilgrastim is ordered. When conversion occurs, it should be done on a mcg-for-mcg or mg-for-mg (in the case of pegfilgrastim) basis. If cost or availability dictates that another G-CSF be ordered, the ordering provider will be notified.

This protocol is effective upon receipt of signatures from Medical Director and Chief Pharmacy Officer and must be reviewed annually.


APPROVED:



Clinical Medical Director

4/29/2020

Date



Chief Pharmacy officer

4/29/20.

Date

REFERENCE(S):

Cardinal Health Order Express Product Information. Available with account at:
<https://orderexpress.cardinalhealth.com/>. Accessed 4/22/20.

Larson RA. Use of Granulocyte Colony Stimulating Factors in Adult Patients with Chemotherapy-Induced Neutropenia and Conditions Other Than Acute Leukemia, Myelodysplastic Syndrome, and Hematopoietic Cell Transplantation. UpToDate online. Available at: https://www.uptodate.com/contents/use-of-granulocyte-colony-stimulating-factors-in-adult-patients-with-chemotherapy-induced-neutropenia-and-conditions-other-than-acute-leukemia-myelodysplastic-syndrome-and-hematopoietic-cell-transplantation?search=granix&source=search_result&selectedTitle=2~148&usage_type=default&display_rank=1#H938520. Accessed 2/6/20.

National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2020, Jan 2020. Hematopoietic Growth Factors. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed 4/22/20.