



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

1 February 2023

DEPARTMENT CIRCULAR

No. 2023 - 0061

FOR: ALL CENTERS FOR HEALTH DEVELOPMENT, NATIONAL DRUG POLICY COMPLIANCE OFFICES, LEAGUES OF CITIES, PROVINCES AND MUNICIPALITIES, PROFESSIONAL HEALTH SOCIETIES, DIRECTORS OF BUREAUS AND REGIONAL OFFICES, BARMM MINISTER OF HEALTH, CHIEFS OF MEDICAL CENTERS AND SANITARIA, AND OTHER CONCERNED

SUBJECT: Health Technology Assessment Council (HTAC) Recommendation for the Inclusion of Filgrastim 300 mcg/0.9 mL solution (IV, SC), 0.9 mL pre-filled syringe for the treatment of neutropenia in patients undergoing bone marrow transplantation and patients receiving myelosuppressive cancer chemotherapy in the Philippine National Formulary (PNF)

By virtue of Republic Act 11223, otherwise known as the Universal Health Care (UHC) Act, health technology assessment (HTA) shall be institutionalized as a fair and transparent priority-setting mechanism to provide financing and coverage recommendations on health technologies to be funded by the Department of Health (DOH) and the Philippine Health Insurance Corporation (PhilHealth).

Please be apprised that as of 24 January 2023, the Office of the Secretary approves the HTA Council recommendation to include **Filgrastim 300 mcg/0.9 mL solution (IV, SC), 0.9 mL pre-filled syringe for the treatment of neutropenia in patients undergoing bone marrow transplantation and patients receiving myelosuppressive cancer chemotherapy in the PNF** on the basis of the following:

- Only the net volume of the pre-filled syringe that contains 300 mcg of filgrastim was changed from 0.5mL to 0.9 mL. Both dosage formulations contain 300 mcg of filgrastim; hence, the number of pre-filled syringes that will be consumed per dose will not differ.
- The unit price of Filgrastim 300mcg/0.9mL Solution for Injection (IV/SC), 0.9mL Pre-filled syringe (P650.00, based on the government price offer of the manufacturer) is lower than the unit price of Filgrastim 300 mcg/0.5mL Solution for Injection (IV/SC), 0.5mL Pre-filled syringe (P2,120.00, based on the 2022 DOH Drug Price Reference Index).
- Since the unit cost of the proposed dosage formulation is lower than the unit cost of the comparator (i.e., the currently listed form in the PNF) and there are no differences in the number of pre-filled syringes that will be consumed per patient per regimen, cost savings are expected with the use of the proposed *filgrastim, 300 mcg/0.9 mL solution for injection (IV, SC), 0.9mL pre-filled syringe*.

- For an average pediatric patient (30 kg patient*) with neutropenia due to concurrent myelosuppressive chemotherapy which is the widest indication for this drug, the cost savings (per patient) associated with the use of the new formulation with new net content are the following:
 - 5 mcg/kg/day for 10 days dosing regimen: ₱88,200.00 for the whole 6 cycles of chemotherapy
 - 5 mcg/kg/day for 14 days dosing regimen: ₱123,480.00 for the whole 6 cycles of chemotherapy
- For an average adult patient (60 kg patient*) with neutropenia due to concurrent myelosuppressive chemotherapy which is the widest indication for this drug, the cost savings (per patient) associated with the use of the new formulation with new net content are the following:
 - 5 mcg/kg/day for 14 days dosing regimen: ₱123,480.00 for the whole 6 cycles of chemotherapy

**average weight of patients were based on consultation with medical societies (Philippine Society of Medical Oncology [PSMO] and Philippine Society for Hematology and Blood Transfusion [PSHBT]). Each pre-filled syringe is assumed for single-use only and should not be reused for the next dose. The remaining content of the PFS that will not be consumed will be discarded after use.*


For more details, you may refer to *Annex A* on the summary of evidence reviewed and *Annex B* on the costing analysis.

Kindly disseminate this to all concerned officials in your areas of responsibility so that they may be appropriately guided in their procurement activities. All are enjoined to ensure rational procurement, distribution, and use of health technologies in all government and private facilities.

Your full cooperation in this endeavor is expected and highly appreciated.

For your information and guidance.

By Authority of the OIC-Secretary of Health:


ATTY. CHARADE MERCADO-GRANDE
 Assistant Secretary of Health
 Health Regulation Team

Annex A. Summary of Evidence Reviewed

The new dosage and net content of the medicine:	Yes	No	Remarks/Evidence
1. Has good quality	✓		Filgrastim 300 mcg/0.9 mL solution for injection (IV/SC) 0.9 mL pre-filled syringe has a valid Certificate of Product Registration with the Philippine Food and Drug Administration (FDA) assuring the public of its quality .
2. Has proven safety based on sound evidence	✓		<ol style="list-style-type: none"> 1. The active FDA CPR of Filgrastim 300 mcg/0.9 mL solution for injection (IV/SC) 0.9 mL pre-filled syringe certifies for the safety of the product. 2. Filgrastim and its different dosage formulations are currently included in the Philippine National Drug Formulary (8th edition) which establishes the recognition of the product's safety by the Department of Health.
3. Has proven efficacy for the stated indication based on sound evidence	✓		<ol style="list-style-type: none"> 1. The active FDA CPR of Filgrastim 300 mcg/0.9 mL solution for injection (IV/SC) 0.9 mL pre-filled syringe certifies the efficacy of the product. 2. Filgrastim 300 mcg/0.9 mL solution for injection (IV/SC) 0.9 mL pre-filled syringe and its different dosage formulations are currently included in the Philippine National Drug Formulary (8th edition) which establishes the recognition of the product's efficacy by the Department of Health
4. Has favorable cost-effectiveness analysis	✓		The addition of the listing of Filgrastim 300 mcg/0.9 mL solution for injection (IV/SC) 0.9 mL pre-filled syringe in the PNF will result in cost-savings of Php 88,200.00 to Php 123,480.00 for pediatric patients with neutropenia due to concurrent myelosuppressive chemotherapy; and Php 123,480.00 for adult patients with neutropenia due to concurrent myelosuppressive chemotherapy.
5. Other considerations			N/A

Annex B. Comparative costing analysis on the use of Filgrastim 300 mcg/0.9 mL solution for injection (IV, SC), 0.9mL pre-filled syringe vs 300 mcg/0.5 mL solution for injection (IV, SC), 0.5 mL pre-filled syringe

Notes on the costing analysis:

- There was no difference in other medical costs associated with the use of the intervention and the comparator since only the net volume was proposed to be changed and not the dosing regimen.
- The intervention is more affordable than the comparator due to significant differences in the total treatment regimen costs.
- The indication for neutropenia in patients receiving myelosuppressive cancer chemotherapy was included in the costing analysis with the assumption that this is its widest indication targeting more patients as compared to its other indications such as neutropenia due to bone marrow transplantation and severe chronic neutropenia were excluded from the costing analysis.
- Each pre-filled syringe (PFS) is for single-use only and should not be reused for the next dose. The remaining content of the PFS that will not be consumed will be discarded after use.
- The total of expected number of users were not computed in the costing sheets due to the lack of data available specific for neutropenia due to concurrent myelosuppressive chemotherapy. Meanwhile, the intervention is notably more affordable as seen on the unit cost differences of the intervention and comparator but there was no justification given as to why the unit price of filgrastim 300 mcg/0.9mL is much cheaper than filgrastim 300 mcg/0.5mL.

1. Pediatric Indication: For the treatment or prevention of neutropenia in patients receiving myelosuppressive cancer chemotherapy.

Parameter	Intervention <i>Filgrastim 300mcg/0.9mL Solution for Injection (IV/SC), 0.9mL Pre-filled syringe</i>		Reference, Year Remarks	Comparator <i>Filgrastim 300 mcg/0.5 mL Solution for Injection (IV/SC), 0.5 mL Pre-filled syringe</i>		Reference, Year Remarks
Unit Cost of Medicine (A)	₱650.00	PHP	<u>Global Pharma Trade, 2022</u> Price per PFS	₱2,120.00	PHP	<u>Drug Price Index, 2022</u>
Dosing regimen (B)	5	mcg/kg/day	<u>Martindale 36th Edition, Standard Therapeutic Guideline [from Jose B. Lingad Memorial Regional Hospital]</u> <u>Product Insert</u> <u>Pediatric Dosage Handbook, PSPH, 2022</u> <u>PNF 8th edition</u>	5	mcg/kg/day	<u>Martindale 36th Edition, Standard Therapeutic Guideline [from Jose B. Lingad Memorial Regional Hospital]</u> <u>Pediatric Dosage Handbook, PSPH, 2022</u> <u>PNF 8th edition</u>
Average weight of a pediatric patient (C)	30	kg	<u>Pediatric Dosage Handbook, PSPH, 2022</u>	30	kg	<u>Pediatric Dosage Handbook, PSPH, 2022</u>
Daily dosage (D=B*C)	150	mcg/day		150	mcg/day	<u>mcg/day</u>
PFS per day (E)	1	Pre-filled syringe	Filgrastim 300mcg/0.9mL Solution for Injection (IV/SC), 0.9 mL Pre-filled syringe MIMS, 2022 Filgrastim prefilled syringes are for single use	1	Pre-filled syringe	Filgrastim 300 mcg/0.5 mL Solution for Injection (IV/SC), 0.5 mL Pre-filled syringe MIMS, 2022 Filgrastim prefilled syringes are for single use
Duration of Treatment per episode (F)	10	days	<u>PSPH, 2022</u>	10	days	<u>PSPH, 2022</u>
	14			14		

Number of episodes per year	6	episodes	<u>PSPH, 2022</u> <u>One per cycle</u>	6	episodes	<u>PSPH, 2022</u> <u>One per cycle</u>
Total direct cost per patient per treatment course (G) =A*E*F	₱39,000.00		for the 10-day duration of treatment per episode	₱127,200.00		for the 10-day duration of treatment per episode
	₱54,600.00		for the 14-day duration of treatment per episode	₱178,080.00		for the 14-day duration of treatment per episode
Incremental cost	-₱88,200.00 for the 10-day duration of treatment per episode					
	-₱123,480.00 for the 14-day duration of treatment per episode					

2. Adult Indication: For the treatment or prevention of neutropenia in patients receiving myelosuppressive cancer chemotherapy.

Parameter	Intervention <i>Filgrastim 300mcg/0.9mL Solution for Injection (IV/SC), 0.9mL Pre-filled syringe</i>		Reference, Year Remarks	Comparator <i>Filgrastim 300 mcg/0.5 mL Solution for Injection (IV/SC), 0.5 mL Pre-filled syringe</i>		Reference, Year Remarks
Unit Cost of Medicine (A)	₱650.00	PHP	<u>Global Pharma Trade, 2022</u> Price per PFS	₱2,120.00	PHP	<u>Drug Price Index, 2022</u>
Dosing regimen (B)	5	mcg/kg/day	<u>Martindale 36th Edition, Standard Therapeutic Guideline [from Jose B. Lingad Memorial Regional Hospital]</u> <u>PNF 8th edition</u>	5	mcg/kg/day	<u>Martindale 36th Edition, Standard Therapeutic Guideline [from Jose B. Lingad Memorial Regional Hospital]</u> <u>PNF 8th edition</u>
Average weight of an adult patient (C)	60	kg	PSMO, 2022	60	kg	PSMO, 2022

Daily dosage (D=B*C)	300	mcg/day		300	mcg/day	
PFS per day (E)	1	Pre-filled syringe	Filgrastim 300mcg/0.9mL Solution for Injection (IV/SC), 0.9 mL Pre-filled syringe MIMS, 2022 Filgrastim prefilled syringes are for single use	1	Pre-filled syringe	Filgrastim 300 mcg/0.5 mL Solution for Injection (IV/SC), 0.5 mL Pre-filled syringe MIMS, 2022 Filgrastim prefilled syringes are for single use
Duration of Treatment per episode (F)	14		<u>PNF 8th edition</u>	14		<u>PNF 8th edition</u>
Number of episodes per year	6	episodes	<u>PSPH, 2022</u> <u>One per cycle</u>	6	episodes	<u>PSPH, 2022</u> <u>One per cycle</u>
Total direct cost per patient per treatment course (G) =A*E*F	₱54,600.00		for the 14-day duration of treatment per episode	₱178,080.00		for the 14-day duration of treatment per episode
Incremental cost	-₱123,480.00 for the 14-day duration of treatment per episode					