



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

21 September 2021

**DEPARTMENT CIRCULAR**

No. 2021 - 0423

**FOR: ALL DIRECTORS OF CENTRAL OFFICE BUREAUS AND CENTERS FOR HEALTH DEVELOPMENT, BARMM MINISTER OF HEALTH; CHIEFS OF MEDICAL CENTERS, HOSPITALS AND SANITARIA, AND OTHERS CONCERNED**

**SUBJECT: Inclusion of Dolutegravir (DTG) 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 and the Philippine Health Insurance Corporation.

Following the release of the preliminary recommendation of the Health Technology Assessment Council (HTAC) on *Dolutegravir (DTG)-based regimens for treatment-naïve and treatment-experienced adolescents and adults living with HIV* with no appeals received from 27 August to 10 September 2021, we are respectfully submitting the recommendation and Evidence Summary attached herewith for the approval and signature of the Secretary of Health.

The HTAC recommends the inclusion of **Dolutegravir 50 mg tablet** in the Philippine National Formulary (PNF) for the preferred first-line treatment for **treatment-naïve adolescents and adults living with HIV, with TB co-infection** [in combination with TLD fixed-dose combination (*Tenofovir (TDF) 300mg + Lamivudine (3TC) 300mg + Dolutegravir (DTG) 50mg*)]. Please be informed that the Secretary of Health approved the final recommendation of the Health Technology Assessment Council (HTAC), to wit based on the following evidence:

- The use of DTG compared to standard dose EFV shows statistical significance in terms of efficacy for achieving viral suppression at 48 and 96 weeks based on high quality of evidence.
- The use of DTG compared to standard dose EFV shows lower odds for treatment-related adverse events, based on moderate quality of evidence. No statistical differences were found for odds for mortality and treatment-related serious adverse events, based on very low to low quality of evidence.
- In terms of cost, the 5-year comparative drug costing calculation shows incremental cost for the government in using DTG-based regimen versus EFV-based regimen ranging from PHP 3,974,015.39 to PHP 20,747,206.56, but is cost-effective per data. However, additional costs for adverse drug reactions and hospitalization due to opportunistic infections were not considered. Despite the additional cost, DTG-based regimen (i.e., TLD+DTG) is still recommended in this population due to the safety and efficacy data.

In addition, the HTAC recommends **Dolutegravir 50 mg tablet** [as part of the preferred treatment regimen: *Zidovudine (AZT) 300mg + Lamivudine (3TC) + Dolutegravir (DTG) (fixed-dose combination)*] for the second-line treatment for **treatment-experienced** adolescents and adults





living with HIV, specifically for those **failing from TDF-based regimen**, based on the following evidence:

- The use of DTG compared to standard dose EFV shows statistical significance in terms of efficacy for achieving viral suppression at 24 and 48 weeks based on moderate to high quality of evidence.
- The use of DTG compared to standard dose EFV shows lower odds for treatment-related adverse events, based on low quality of evidence. No statistical differences were found for odds for mortality and treatment-related serious adverse events, based on very low quality of evidence.
- In terms of cost, the 5-year comparative drug costing calculation shows cost-savings for the government in using DTG-based regimen versus LPV/r-based regimen ranging from PHP 32,791,686.48 to PHP 70,062,325.20.
- In addition, shifting to once-daily dosing of the fixed-dose combination TLD + DTG may improve patient adherence compared with the current regimen *LPV/r + AZT/3TC* consisting of separate drugs required to be taken multiple times a day (*i.e., LPV/r - 2 tablets twice a day and AZT/3TC - 1 tablet twice a day*).

The HTAC recommends the following steps be taken to improve surveillance, and to fill the identified research gaps:

1. Program evaluation should be in place to measure the real world effectiveness with the use of DTG, especially for treatment-experienced PLHIV failing TDF-based regimens, in the local implementation.
2. DOH should ensure high-quality surveillance following the WHO guidelines and this should begin within the year to enable the conduct of impact monitoring and assessment.

Lastly, including DTG in the PNF shall enable nationwide access to fully subsidized, safe, and effective therapies for treatment-naïve and treatment-experienced PLHIV in the Philippines.

To optimize access to this therapy, the DPCB, through the NASPCP, must ensure consistent supply and equitable distribution through all its treatment hubs across the country.

The Evidence Summary and HTAC recommendation approved by the Secretary of Health may be accessed via the HTA website through this link:

<https://hta.doh.gov.ph/2021/09/21/signed-by-secretary-of-health-letter-of-endorsement-for-dolutegravir-for-the-second-line-treatment-for-treatment-experienced-adolescents-and-adults-living-with-hiv/>

Kindly disseminate to all concerned officials in your areas of responsibility, so 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.

By Authority of the Secretary of Health:

*Charade B. Mercado-Grande*

Digitally signed by Mercado-Grande Charade Ballucanag  
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**ATTY. CHARADE B. MERCADO-GRANDE**

Undersecretary of Health  
Health Regulation Team

