Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

11 September 2021

HON. FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

Dear Secretary Duque:

Greetings!

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).

Following the release of the preliminary recommendation of the Health Technology Assessment Council (HTAC) on ***Dolutegravir (DTG)-based regimens for treatment-naive 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** in the Philippine National Formulary (PNF) for the preferred first-line treatment for **treatment-naive adolescents and adults living with HIV, with TB co-infection** 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.

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 local 1108, 1111, 1112, 1113
Direct Line: 711-9502; 711-9503 Fax: 743-1829 • URL: http://www.doh.gov.ph; e-mail: ftduque@doh.gov.ph

Table 1. Proposed specific indications for DTG use as **preferred first-line treatment for treatment-naive adolescents and adults living with HIV, with TB co-infection** (following the 2018 WHO recommendations)

Indication/ Population	Treatment regimens where DTG is proposed to be used
Preferred first-line treatment for **treatment-naive adolescents and adults living with HIV, with TB co-infection**	**Dolutegravir** (DTG) 50mg in combination with TLD fixed-dose combination *(Tenofovir (TDF) 300mg + Lamivudine (3TC) 300mg + Dolutegravir (DTG) 50mg)* Treatment duration: Treatment with solo DTG + TLD combination until Tuberculosis (TB) infection is completely treated

In addition, the HTAC recommends **Dolutegravir** 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).*

Table 2. Proposed specific indications for DTG as **second-line treatment for treatment-experienced adolescents and adults living with HIV, specifically for those failing from TDF-based regimen** (following the 2018 WHO recommendations)

Indication/ Population	Treatment regimens where DTG is proposed to be used
Second-line treatment for **treatment-experienced** adolescents and adults living with HIV, specifically for those **failing from TDF-based regimen***** ****Treatment failure, in this context, refers to one blood draw with greater than or equal to*	**Dolutegravir (DTG)** 50mg as part of the preferred treatment regimen: *Zidovudine (AZT) 300mg + Lamivudine (3TC) + Dolutegravir (DTG)* Treatment duration: Lifetime treatment

1000 HIV RNA copies/mL only	

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-naive 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.

We thank you for the opportunity to be of assistance to the Department of Health.

Respectfully yours,

For the Health Technology Assessment Council (HTAC):

Marita V. T- Reyes

MARITA V. TOLENTINO-REYES, MD
Chair, HTAC

Approval of the HTAC Recommendation:

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

CC: **UNDERSECRETARY GERARDO V. BAYUGO, MD, MPH, CESO I**
Health Regulation Team

ASSISTANT SECRETARY ATTY. CHARADE B. MERCADO-GRANDE
Health Regulation Team

UNDERSECRETARY MARIA ROSARIO S. VERGEIRE, MPH, CESO IV
Public Health Services Team

DIRECTOR BEVERLY LORRAINE C. HO, MD, MPH
Disease Prevention and Control Bureau (DPCB)

RAFFY DERAY, MD, MPH
National AIDS and STI Prevention and Control Program, DPCB