

Recommendation

The **Health Technology Assessment Council (HTAC)** recommends the inclusion of **Oral PrEP (Emtricitabine 200 mg FDC + Tenofovir Disoproxil Fumarate 300 mg)** in the Philippine National Formulary (PNF) to **reduce the risk of acquiring sexually-transmitted HIV infection** based on the following evidence:

- **Clinical Efficacy and Safety:**

- The use of Oral PrEP (in combination with other HIV preventive strategies) compared to placebo or no Oral PrEP shows statistical significance in terms of efficacy for reducing the risk of acquiring HIV infection.
- The use of Oral PrEP (in combination with other HIV preventive strategies) compared to placebo or no Oral PrEP shows no significant difference in risk in terms of serious adverse events, withdrawal due to adverse events, fracture, any bacterial transmitted infection, syphilis, gonorrhea, herpes simplex virus infection and hepatitis C virus infection. In terms of renal adverse events, results show that oral PrEP was associated with increased risk of renal adverse events compared with placebo or no PrEP. There was an increased risk of gastrointestinal adverse events among users of oral PrEP compared with placebo or no oral PrEP.
- The use of oral PrEP is safe and efficacious in preventing the transmission of the HIV infection following the WHO Recommendation (2016) with strong recommendation and high certainty of evidence.

- **ELSHI:**

- There is high acceptability of Oral PrEP among potential users, and its role is being valued as part of national strategy to address HIV/AIDS.
- Both potential users and implementers agreed that, upon inclusion of oral PrEP to the PNF, social stigma on oral PrEP use (*e.g., censoring of terms related to HIV; perceiving that the use of oral PrEP would supposedly lead to promiscuity; HIV services-related discrimination; poor health-seeking behavior*) may still ensue. Health system and program implementation changes for oral PrEP must be streamlined or scaled up so these societal implications can be addressed. These changes included community mobilization activities (*e.g., participation of members of the community in policy-making and the program cycle for oral PrEP*), multi-population level capacity building for oral PrEP, and oral PrEP streamlining / institutional scaling up, among others.
- Non-inclusion of oral PrEP for HIV can bind at-risk individuals to the limited number of HIV preventive strategies currently being implemented in the Philippines. Since there are individuals who opt not to use condoms or other existing preventive strategies, the non-inclusion of PrEP can restrict both the general and at-risk individuals from achieving better health outcomes.

- Although there are policy barriers, such as obtaining child ascent and access among key populations, there are existing policy enablers for the service delivery of PrEP as well as laws with indirect impact on oral PrEP.
- Potential users and implementers support the need to strengthen health system processes in order to improve access to oral PrEP, not only among key populations, but also among other individuals depending on risks.
- **Cost-effectiveness:**

While there are studies showing potential value for money on implementing oral PrEP, the results found cannot be directly adopted in the Philippine context and inferred for the Philippine setting on the cost-effectiveness due to differences in the assumed efficacy, cost of oral PrEP, and incidence rate applied in those model settings versus the Philippine setting.
- **Budget Impact:**
 - In terms of cost, including oral PrEP in the Philippine National Formulary for the year 2022 procurement will not incur immediate budget impact to the government, as supplies will have still been donated by the Global Fund prior to this period.
 - It was found to have an anticipated incremental cost of Php 9,264.67 per user in a year (which covers the cost of treatment regimen and monitoring of adverse drug reactions) considering that this will be an add-on to existing HIV preventive strategies (i.e., NPIs).
 - Based on the 5-year costing analysis, while there are observed savings from the treatment of averted HIV infections, the total cost of the intervention arm remains to be more costly considering the cost of oral PrEP:
 - Scenario 1: Target number of users based on enrollment (2,500 to 10,000) - shows that there will be an additional cost of approximately Php 23,161,675.00 to Php 290,642,947.69
 - Scenario 2: Projected number of seronegative individuals at substantial risk (578,300 to 607,500) - shows incremental cost of Php 5,357,758,661.00 to Php 21,133,946,954.22.
 - If all the seronegative at-risk population are eligible for oral PrEP and the projected budget will be covered by the government, the projected budget for oral PrEP and HIV Program will not be sufficient. Nevertheless, implementing oral PrEP is potentially affordable if the target number of users is based on the enrollment rate of the Program, and if additional available funds are secured by the Program.

Finally, the HTAC recommends that:

1. Program evaluation be put in place to measure the real world effectiveness with the use of Oral PrEP in the local implementation to reduce the risk of sexually acquired HIV-infection;
2. DOH ensures high-quality surveillance following the WHO guidelines to enable the conduct of impact monitoring and assessment;
3. The Program conducts information dissemination on the limitations of PrEP and active campaigns for other STI-preventive strategies;
4. Oral PrEP initiatives be integrated as a part of existing health system processes to reach communities more efficiently; and,
5. The DPCB, through the NASPCP, strengthens the health system domains (e.g., service delivery, interprofessional collaboration, increasing rural/GIDA access to oral PrEP, among others) to ensure a safe and consistent supply, and equitable distribution through all its treatment hubs across the country.