



Republic of the Philippines

DEPARTMENT OF SCIENCE AND TECHNOLOGY



CALL FOR STAKEHOLDER COMMENTS ON THE PRELIMINARY RECOMMENDATION OF THE HEALTH TECHNOLOGY ASSESSMENT (HTA) COUNCIL ON PRIORITY TOPICS: DAPIVIRINE VAGINAL RING, DONEPEZIL HYDROCHLORIDE, TENOFOVIR/ LAMIVUDINE/ DOLUTEGRAVIR, AND TENOFOVIR + LAMIVUDINE in combination with DOLUTEGRAVIR

Published as of 21 October 2024

As of 21 October 2024, the Health Technology Assessment (HTA) Council hereby makes public its preliminary recommendations on the possible inclusion in the Philippine National Formulary (PNF) and thus the government financing of the following health technologies, for stakeholder feedback/comments.

These health technologies were reviewed against national clinical practice guidelines (CPGs) [local and approved by the Department of Health (DOH); and/or international, but locally adopted guidelines], existing recommendations by the World Health Organization (WHO), and DOH Omnibus Health Guidelines (OHG). Further, costing analyses of these health technologies were performed. The supporting evidence reviewed and discussed by the HTA Council are shown in **Annex A**.

	Health Technology	Preliminary HTAC Recommendation <i>(further details in Annex A)</i>
1	Dapivirine vaginal ring <i>25 mg vaginal delivery system</i>	<p>Positive recommendation for human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) in adult women specifically as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches (e.g., oral PrEP)</p> <p>Dapivirine vaginal ring is recommended in the WHO Consolidated HIV guidelines for prevention, treatment, service delivery & monitoring (2021) specifically for women at substantial risk of HIV infection (<i>Note: there are concerns about use among pregnant and breastfeeding women because of a lack of sufficient evidence</i>). It is included in the DOH OHG for Adults (2023) for chemoprophylaxis which cited the same WHO Consolidated HIV guidelines (2021).</p> <p>The cost of the health technology is PHP 9,514.80 per patient per year.</p>
2	Donepezil hydrochloride <i>23 mg film-coated tablet</i>	<p>Positive recommendation for moderate to severe Alzheimer’s disease</p> <p>This health technology is recommended as first-line therapy for moderate to severe Alzheimer’s disease as supported by the Dementia Council of the Philippine Neurological Association Practice Recommendations for the Diagnosis, Management and Prevention of Dementia (2019).</p> <p>The cost of this health technology ranges from PHP 10,555.20 to PHP 34,906.80 per patient per year, depending on the monitoring frequency.</p>
3	Tenofovir/ Lamivudine/ Dolutegravir <i>300mg/300mg/50 mg tablet</i>	<p>Positive recommendation for HIV treatment for treatment-experienced people living with HIV (PLHIV) (<i>including those that are stable in their current regimen</i>)</p> <p>This health technology is included in the WHO EML as fixed-dose combination formulation of dolutegravir + lamivudine + tenofovir disoproxil fumarate. It is also strongly recommended by the DOH OHG for Adults (2023), citing the WHO consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring (2021).</p> <p>The following costs of the health technology are noted:</p> <ul style="list-style-type: none"> • PHP 12,502.35 per patient if virologically suppressed* in the first year of administration • PHP 17,502.35 per patient if with poor adherence to treatment** in the first year of administration • PHP 7,502.35 per patient in the succeeding years

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		<i>*viral load testing conducted twice in the first year</i> <i>**viral load testing conducted thrice (minimum) in the first year</i>
4	Tenofovir + Lamivudine <i>300mg / 300mg tablet</i> In combination with Dolutegravir <i>50 mg tablet</i>	Positive recommendation for HIV treatment for treatment-experienced people living with HIV (PLHIV) (<i>including those that are stable in their current regimen</i>) This health technology is included in the WHO EML as fixed-dose combination formulation of dolutegravir + lamivudine + tenofovir disoproxil fumarate and is also strongly recommended by the DOH OHG for Adults (2023) , citing the WHO consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring (2021) . The following costs of the health technology is noted: <ul style="list-style-type: none"> • PHP 15,582.95 per patient if virologically suppressed* in the first year of administration • PHP 20,582.95 per patient if with poor adherence to treatment** in the first year of administration • PHP 10,582.95 per patient in the succeeding years <i>*viral load testing conducted twice in the first year</i> <i>**viral load testing conducted thrice (minimum) in the first year</i>

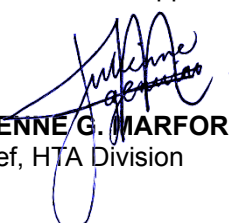
All comments, inputs, and/or appeals on the above preliminary recommendation may be submitted until **05 November 2024 (Tuesday)**, for the consideration of the HTA Council, through email at hta@dost.gov.ph.

Please use the prescribed form for appeals indicated in the official HTA Philippines website [<https://hta.dost.gov.ph/appeals-2/>]. **Appeals not following the prescribed format, and those submitted beyond the deadline shall not be entertained.**

Should you have any questions or concerns regarding the preliminary recommendation, please do not hesitate to contact us through the same email address or *via telephone call via (02) 8651-7800 local 2410*.





Thank you very much and best regards.

On behalf of the HTA Philippines:


ANNE JULIENNE G. MARFORI, RPh, MSc
Division Chief, HTA Division


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Chairperson, HTA Council

Annex A. Summary of Evidence for the Preliminary Recommendation of Priority Topics

Health technology	Clinical Practice Guidelines	WHO recommendation	Costing
<p>Dapivirine vaginal ring 25 mg vaginal delivery system for human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) in adult women</p>	<p>Included in the DOH Omnibus Guidelines for Adults (2023) which cited the WHO Consolidated HIV guidelines for prevention, treatment, service delivery & monitoring (2021):</p> <p><i>“Chemoprophylaxis: Offer the dapivirine vaginal ring for adult women at substantial risk of HIV infection, to be worn for 28 days (Conditional recommendation)”</i></p> <p>Reference:  Omnibus Health Guidelines for Adults Version 2023.pdf</p>	<p>Recommended in the WHO Consolidated HIV guidelines for prevention, treatment, service delivery & monitoring (2021):</p> <p><i>“The dapivirine vaginal ring may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches (conditional recommendation, moderate-certainty evidence).</i></p> <p><i>*For the recommendation on the dapivirine vaginal ring, the term women applies to cisgender women, meaning women assigned female at birth. There is no research at this time to support the dapivirine vaginal ring for other populations.”</i></p> <p><i>For the conditional recommendation - “there are concerns about use among pregnant and breastfeeding women because of a lack of sufficient evidence”</i></p> <p>Reference:  The WHO Consolidated Guidelines on HIV Prevention,...</p>	<p>PHP 9,514.80 per patient per year <i>(PHP475,740.00 per patient assuming lifetime use*)</i></p> <p><i>*Lifetime use is at around 50 years assuming a patient will use dapivirine ring as early as 18 years old.</i></p> <p>Reference:  Dapivirine Vaginal Ring Costing (as of Oct 2...</p>
<p>Donepezil hydrochloride 23 mg film-coated tablet for moderate to severe Alzheimer’s disease</p>	<p>1. Recommended as first-line therapy for moderate to severe Alzheimer’s disease based on the Dementia Council of the Philippine Neurological Association Practice Recommendations for the Diagnosis, Management and Prevention of Dementia (2019)</p> <p><i>“For Moderate to Severe Alzheimer’s disease dementia, either cholinesterase inhibitors (donepezil and rivastigmine) or the N-Methyl D-Aspartate receptor antagonist memantine are recommended first line therapy. Later combination therapy with both cholinesterase inhibitors and memantine may also be considered.”</i></p> <p><i>“A subset of patients with severe Alzheimer’s disease dementia may benefit from donepezil</i></p>	<p>Not included in the WHO EML</p> <p>Reference: WHO List of Essential Medicines</p>	<p>Php 10,555.20 per patient per year (with 2x monitoring)</p> <p>Php 22,731.00 per patient per year (with 3x monitoring)</p> <p>Php 34,906.80 per patient per year (with 4x monitoring)</p> <p>Reference:  [Donepezil HCl] Costing .pdf</p>

	<p>23 mg per day or rivastigmine 13.3mg/24 patch 15.”</p> <p>Reference: PNA Dementia Guidelines 2019.pdf</p>		
<p>Tenofovir/ Lamivudine/ Dolutegravir 300mg/300mg/50 mg tablet as HIV treatment for treatment-experienced people living with HIV (PLHIV) (including those that are stable in their current regimen)</p>	<p>Strong recommendation by DOH Omnibus Health Guidelines for Adults (2023) to wit:</p> <p><i>“Pharmacologic Therapy. Offer antiretroviral treatment (ART) to all patients diagnosed to have HIV infection after thorough clinical and laboratory evaluation.</i></p> <ul style="list-style-type: none"> ● <i>First-line. Offer the following first-line regimens to eligible patients (strong recommendation).</i> <ul style="list-style-type: none"> - <i>Tenofovir Disoproxil Fumarate (TDF) + lamivudine (3TC) + Dolutegravir (DTG) 300 mg once daily, 150 mg twice daily or 300 mg once daily, 50 mg once daily”</i> <p>Reference: Omnibus Health Guidelines for Adults Version 2023.pdf WHO consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring (2021).</p>	<p>Included in the WHO EML as fixed-dose combination formulation of dolutegravir + lamivudine + tenofovir disoproxil fumarate.</p> <p>Indication: - Human immunodeficiency virus disease without mention of associated disease or condition, clinical stage unspecified - Adolescents and adults</p> <p>Formulation: 50 mg + 300 mg + 300 mg (tenofovir disoproxil fumarate equivalent to 245 mg tenofovir disoproxil)</p> <p>References:</p> <ul style="list-style-type: none"> ● WHO List of Essential Medicines ● WHO, 2016 ● WHO CDS HIV 	<p>PHP 12,502.35 per patient if virologically suppressed* in the first year of administration</p> <p>PHP 17,502.35 per patient if with poor adherence to treatment** in the first year of administration</p> <p>PHP 7,502.35 per patient in the succeeding years</p> <p>Reference: [TLD and TL&D] Costing .pdf</p> <p><i>*viral load testing conducted twice in the first year</i> <i>**viral load testing conducted thrice (minimum) in the first year</i></p>
<p>Tenofovir + Lamivudine 300mg / 300mg tablet</p> <p>In combination with</p> <p>Dolutegravir 50 mg tablet</p> <p>as HIV treatment for treatment-experienced people living with HIV (PLHIV) (including those that are stable in their current regimen)</p>	<p>Strong recommendation by DOH Omnibus Health Guidelines for Adults (2023) to wit:</p> <p><i>“Pharmacologic Therapy. Offer antiretroviral treatment (ART) to all patients diagnosed to have HIV infection after thorough clinical and laboratory evaluation.</i></p> <ul style="list-style-type: none"> ● <i>First-line. Offer the following first-line regimens to eligible patients (strong recommendation).</i> <ul style="list-style-type: none"> - <i>Tenofovir Disoproxil Fumarate (TDF) + lamivudine (3TC) + Dolutegravir (DTG) 300 mg once daily, 150 mg twice daily or 300 mg once daily, 50 mg once daily”</i> <p>Reference: Omnibus Health Guidelines for Adults Version 2023.pdf WHO consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring (2021).</p>	<p>Included in the WHO EML as fixed-dose combination formulation of dolutegravir + lamivudine + tenofovir disoproxil fumarate</p> <p>Indication: - Human immunodeficiency virus disease without mention of associated disease or condition, clinical stage unspecified - Adolescents and adults</p> <p>Formulation: 50 mg + 300 mg + 300 mg (tenofovir disoproxil fumarate equivalent to 245 mg tenofovir disoproxil)</p> <p>References:</p> <ul style="list-style-type: none"> ● WHO List of Essential Medicines ● WHO, 2016 ● WHO CDS HIV 	<p>PHP 15,582.95 per patient if virologically suppressed* in the first year of administration</p> <p>PHP 20,582.95 per patient if with poor adherence to treatment** in the first year of administration</p> <p>PHP 10,582.95 per patient in the succeeding years</p> <p>Reference: [TLD and TL&D] Costing .pdf</p> <p><i>*viral load testing conducted twice in the first year</i> <i>**viral load testing conducted thrice (minimum) in the first year</i></p>