CALL FOR STAKEHOLDER COMMENTS ON THE PRELIMINARY RECOMMENDATION OF THE HEALTH TECHNOLOGY ASSESSMENT (HTA) COUNCIL ON *RETEPLASE for ST-ELEVATION MYOCARDIAL INFARCTION*

Published as of 01 October 2024

As of 23 September 2024, the Health Technology Assessment (HTA) Council has completed the evidence appraisal on the assessment of *Reteplase (10 units lyophilized powder for IV injection) for ST-Elevation Myocardial Infarction (STEMI) Patients* for possible inclusion in the Philippine National Formulary (PNF). As such, the HTA Council hereby makes public its preliminary recommendation on the non-government financing of reteplase through its non-inclusion in the PNF, for stakeholder feedback/comments.

The population, intervention, comparator, and outcomes (PICO) set by the HTA Council for the said evaluation are shown in the table below, for your reference:

	Reteplase for adult patients with STEMI	
Population	Adult patients with STEMI	
Intervention	Reteplase [with or without background therapy e.g. parenteral anticoagulants (PAC) such as unfractionated heparin, low-molecular-weight heparin, anti Xa inhibitors, and direct thrombin inhibitors]	
Comparator	Alteplase (with or without background therapy)	
	Streptokinase (with or without background therapy)	
Outcomes	Efficacy: ● Cardiovascular morbidity ○ Reinfarction (including rescue PCI, refractory ischemia, etc.) ○ Cardiogenic shock ○ Malignant arrhythmia ● Stroke (non-fatal, total) ● Length of hospital/ intensive care unit (ICU) stay* **LoS is not reported in the scoped evidence*	Safety: ● Bleeding (all bleeding, major bleeding, and intracranial hemorrhage) ● Other adverse events (e.g., severe allergy)

The HTA Council's preliminary recommendation on the non-government financing of reteplase through its non-inclusion in the PNF was based on the following reasons:

- Reteplase vs streptokinase: In terms of efficacy, the evidence comparing reteplase + PAC vs streptokinase + PAC showed inconclusive results. However, in terms of safety, while there is a decreased risk of serious allergic reaction *(high certainty of evidence)*, the increased risk of hemorrhagic stroke compared to streptokinase + PAC is twice as high *(moderate certainty of evidence)*. The HTA Council gave higher value to the outcome of hemorrhagic stroke over serious allergic reactions, albeit both being critical outcomes.
- Reteplase vs alteplase: In terms of efficacy and safety, the evidence comparing reteplase + PAC versus accelerated or non-accelerated + PAC showed inconclusive results.
- There are no guidelines that recommend the use of reteplase preferentially over other fibrinolytic agents, such as streptokinase and alteplase, in the management of STEMI. Further, reteplase is not listed in the WHO Essential Medicines List.

For the supporting evidence reviewed and discussed by the HTA Council, please refer to: https://tinyurl.com/PrelimRecommReteplase. All comments, inputs, and/or appeals on the above preliminary recommendation may be submitted until **15 October 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 loc 2410*.

Thank you very much and best regards.

On behalf of the HTA Philippines:

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