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Ref No: MOH/1/2/30

Date: 12th September 2024

All County Directors for Health

Thro'

Ms. Mary Mwiti
Chief Executive Officer
Council of Governors
Delta House
NAIROBI

RE: GUIDANCE FOR INTRODUCTION OF FIXED DOSE COMBINATION (FDC) OF TENOFOVIR ALAFENAMIDE 25MG/LAMIVUDINE 300MG/ DOLUTEGRAVIR 50MG (TAF-LD) FOR CLINICALLY ELIGIBLE PEOPLE LIVING WITH HIV IN KENYA

The National AIDs & STI Control Program (NASCOP) through **the *Kenya HIV Prevention and Treatment Guidelines 2022*** envisioned the optimization of HIV treatment services for people living with HIV through introduction of safer and efficacious regimen in line with global recommendations. The guidelines recommended the use of Tenofovir Alafenamide (TAF) as an option in the Nucleoside Reverse Transcriptase Inhibitors (NRTI) ART backbone once fixed-dose combinations were available and registered in Kenya.

The World Health Organization (WHO) has recommended the use of TAF-LD for priority groups including adult and adolescents with established impaired renal function and/or osteoporosis. Clinical studies conducted in Kenya on use of TAF among PLHIV have shown that it has more favorable renal and bone safety profiles

compared to TDF. Previously, these sub-populations were using dose-adjusted Abacavir and Lamivudine as single molecules. However, the use of single molecules has declined globally hence manufacturers and suppliers have had difficulty in availing such small quantities when needed leading to stock outs.

The Country has procured initial quantities of TAF-LD which will be prioritised for People Living with HIV (PLHIV) on ART who have renal insufficiency and/or established following the eligibility criteria below:-

(i) All PLHIV new or currently on ART (Children, Adolescents and Adults) weighing ≥ 30 kgs with renal impairment (Creatinine clearance <60 ml/min)
(ii) All PLHIV new or currently on ART (Children, Adolescents and Adults) weighing ≥ 30 kgs with osteoporosis

PLHIV on ART who meet the above criteria should be transitioned as follows:

(a) PLHIV Currently on ART

	Current Regimen	**Transition to:**
(i)	TDF/3TC/DTG	TAF/3TC/DTG (TAF-LD)
(ii)	ABC/3TC/DTG	TAF/3TC/DTG (TAF-LD)
(iii)	AZT/3TC/DTG	TAF/3TC/DTG (TAF-LD)

(b) PLHIV Newly initiating ART with renal insufficiency and/or osteoporosis at baseline

Criteria	**Initiate on:**
≥30 Kgs of weight with CrCl<60 ml/min	TAF/3TC/DTG (TAF-LD)

All PLHIV initiating and currently on ART should be screened for renal insufficiency and other co-morbidities and managed appropriately as part of the package of care prescribed in the national guidelines.

NOTE:

- Due to drug-drug interactions, TAF-LD should NOT be used in TB co-infected PLHIVs taking Rifampicin-containing Anti-TBs.
- Although TAF can be used for PLHIV weighing 25 Kgs and above, the 30 Kg cut off has been used to harmonize with the current guidelines on transitioning from ABC to TDF.
- All PLHIV starting TAF-LD should be closely monitored for any adverse events (AEs) and promptly reported on the Pharmacy and Poisons Board (PPB) portal **https://pv.pharmacyboardkenya.org** and the Kenya EMR.

- A comprehensive sensitization on TAF-LD introduction will be conducted by National AIDS and STI Control Program.

The supply of TAF-LD to health facilities will be done through the existing distribution mechanism for ARVs.

For any further clarification kindly reach out to Dr. Rose Wafula at **head@nascop.or.ke** and copy **carentreatmentmanager@nascop.or.ke.**

Dr. Patrick Amoth, EBS
DIRECTOR GENERAL FOR HEALTH