health
Department:
Health
REPUBLIC OF SOUTH AFRICA

STANDARD OPERATING PROCEDURE

TITLE	**CCMDD: TENOFOVIR & LAMIVUDINE & DOLUTEGRAVIR (TLD) - PATIENT REGISTRATION OR TRANSITION**		
INSTITUTION	NATIONAL DEPARTMENT OF HEALTH		
REFERENCE NUMBER	CCMDD SOP-16	**EFFECTIVE DATE**	December 2019

PURPOSE

Outlines the process for switching stable adult patients on ART from first line regimen **TEE (Tenofovir + Emtricitabine + Efavirenz)** to **TLD (Tenofovir + Lamivudine + Dolutegravir)** in the CCMDD programme and the process for registration of new patients into CCMDD with regards to TLD.

PERSONS AFFECTED

- Health Facility staff
- Authorised Prescribers
- Patients
- CCMDD service provider staff

APPLICABLE POLICIES

- Medicines and Related Substances Act 101 of 1965 as amended, and the regulations and guidelines published in terms of this Act (the **'Medicines Act'**)
- Pharmacy Act 53 of 1974 as amended, and the regulations and rules published in terms of this Act (the **'Pharmacy Act'**)
- National Health Act 61 of 2003 as amended, and regulations issued in terms of the Act
- 2019 ART Clinical Guidelines for the management of HIV in adults, pregnancy, adolescents, children, infants and neonates
- Adherence guidelines for HIV, TB and NCDs
- Standard treatment guidelines and essential medicine list of South Africa
- The South African Nursing Act 50 0f 1978 as amended, and the regulations and guidelines in terms of this Act (the **'Nursing Act'**)

ABBREVIATIONS

- **ABCDE:** Adherence Problems, Bugs, In-Correct ART dosage, Drug Interactions, Resistance
- **ART:** Antiretroviral therapy
- **CCMDD**: Central Chronic Medicine Dispensing and Distribution
- **DTG**: Dolutegravir
- **EFV**: Efavirenz
- **HIV**: Human Immunodeficiency Virus
- **TB**: Tuberculosis
- **TEE**: Tenofovir + Emtricitabine + Efavirenz
- **TLD:** Tenofovir + Lamivudine + Dolutegravir
- **NCD:** Non communicable diseases
- **SP:** Service provider
- **VL:** Viral load
- **WOCP:** Women of Childbearing Potential/ Women of Childbearing Age

NOTES

- **Only patients with a valid ID Number /Passport Number/ Asylum Seeker number** can be registered on the CCMDD programme

- Only prescriptions completed and signed by **authorised** prescribers are valid and can be submitted to the SP
- A list of authorised prescribers must be maintained by the health facility, district and province. The list per health facility must be submitted to the SP
- Patients that are virally suppressed with co-morbidities taking medication with **no known drug interactions** as listed below in the safety warning **may be switched to TLD** and/or enrolled onto CCMDD
- Patients that are virally suppressed with co-morbidities taking medication **with known drug interactions** as listed below wanting to switch to TLD for the first time **should not be enrolled** onto CCMDD for now
- When prescribing TLD, the acronym TLD should not be used, use one of the following:
  - Tenofovir 300mg + Lamivudine 300mg + Dolutegravir 50mg, or
  - TDF 300mg, DTG 50mg & 3TC 300mg

SAFETY WARNINGS

- Patients should be given the choice to switch to the DTG containing regimen
- Patients must be provided appropriate counselling on risks and benefits of DTG and EFV-containing regimens
- WOCP must be counselled on the importance of dual contraception
- WOCP must be counselled on the risk of neural tube defects if DTG is used in the first six weeks of pregnancy
- DTG has the following known drug interactions:
  - Anticonvulsants (Carbamazepine, Phenobarbital, Phenytoin) decreases DTG levels, therefore co-administration should be avoided if possible. Anticonvulsants that do not interact with DTG include Valproate, Lamotrigine, Levetiracetam, and Topiramate. Please note that Valproate is contra-indicated during pregnancy. Double DTG dose to 50mg 12-hourly for Carbamazepine if alternative anticonvulsant cannot be used
  - Increases **Metformin** levels, therefore it is recommended that Metformin should not exceed a dose of 500mg 12-hourly
  - **Antacids, sucralfate, multivitamin and nutritional supplements** (Magnesium, Iron, Aluminium, Zinc and Calcium) decreases the absorption of DTG. Therefore, DTG should be taken 2 hours before or 6 hours after consumption of antacids, sucralfate, multivitamins and nutritional supplements.
- Refer to the National ART Guidelines for recommendations and other interactions

No	PROCEDURE/ PROCESS	RESPONSIBILITY
Patient identification		

1	Eligible patients for **new** enrolment onto CCMDD are the following patients:
	• Patients without co-morbidities;
	  ○ Patients on ART treatment, and
	  ○ Have a VL < 50c/mL
	• Patients with co-morbidities:
	  ○ Patients on ART treatment, and
	  ○ Have a VL < 50c/mL, and
	  ○ On medication for NCDs that **do not have a known drug interaction** as listed in the safety warning above
		Authorised prescriber

2	**Existing** patients on CCMDD are eligible for switching from TEE to TLD if: • Their VL has been taken in the last 6 months and is less than 50c/mL or, • Two consecutive VL done in the last 6 months (within 3 months of each other), are both between 50 – 999c/mL (provided the client has	Authorised prescriber

	had an assessment of causes (ABCDE) and gone through enhanced adherence counselling) And, • On medication for NCDs that **do not have a known drug interaction** as listed in the safety warning above If a patient has co-morbidities and **taking medication that has a known drug interaction** as listed in the safety warning above, the patient should be given the option of a.) remaining on their current regimen and remaining on CCMDD, or b.) switch to TLD and deactivate from CCMDD due to drug interactions that may affect the control of their chronic conditions. Patient will be reassessed after 3-6 months. If they are found to be: a.) clinically stable on adjusted chronic medication dosages, **and** b.) VL < 50 c/mL in last 6 months, the patient can be re-registered onto CCMDD. Any client on CCMDD who has a VL between 50 and 999 c/ml can remain on CCMDD, but should be referred back to a clinician for an appropriate assessment (ABCDE), enhanced adherence counselling, and a repeat VL as appropriate. Patients with a **VL ≥ 1000c/mL** should be deactivated from CCMDD and the viral load monitoring guideline should be followed.	
Patient consultation and assessment		

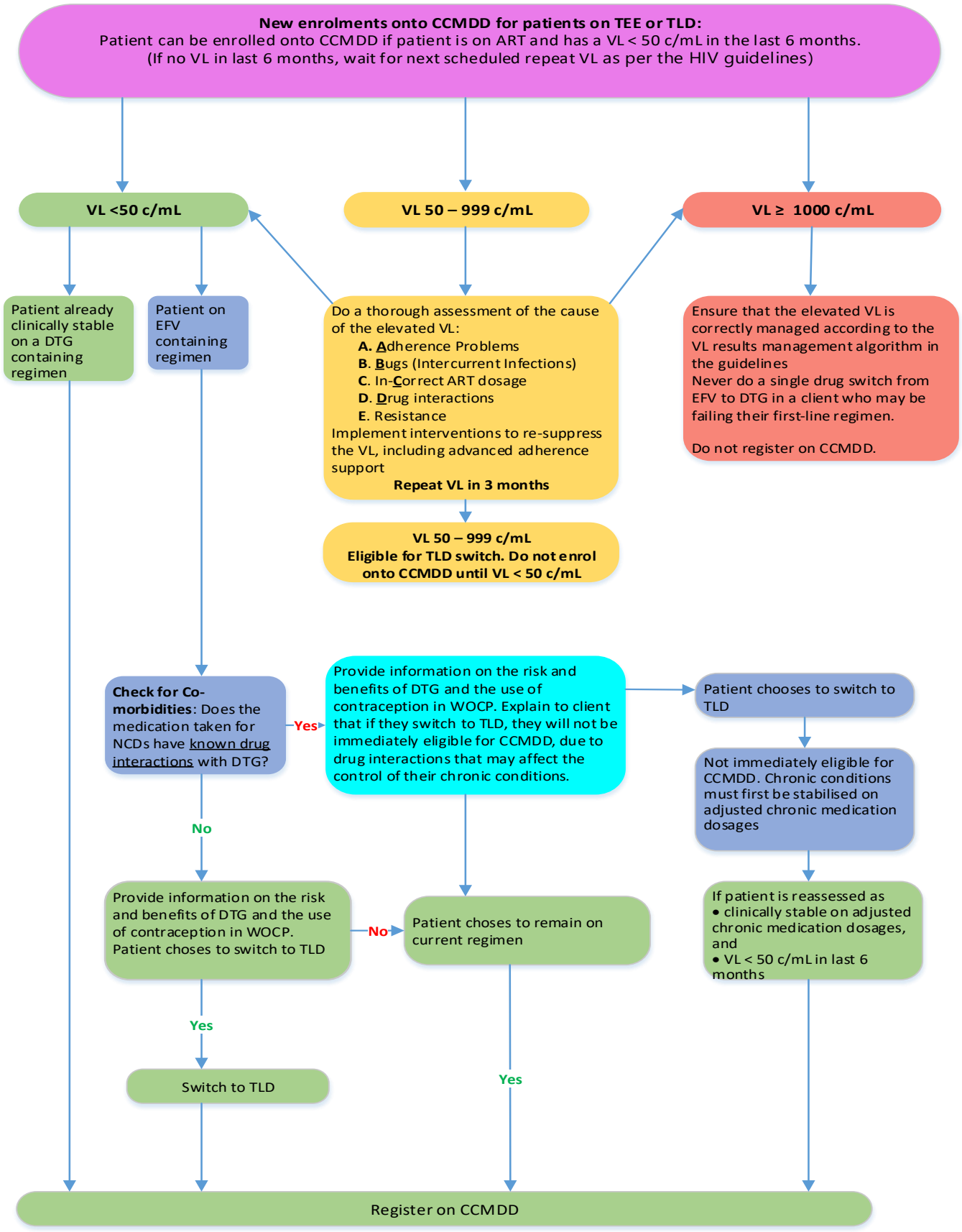
3	Consult all WOCP and consider the following:
	• Be cautious about using DTG in the following women:
	  ○ women actively wanting to **conceive in the near future**,
	  ○ pregnant women in the **1st** six weeks of pregnancy. (However, pregnant women are no longer eligible for CCMDD)
	• It is recommended that WOCP that do not currently wish to become pregnant, **use dual contraception** if using DTG
	• Respect women's autonomy in decision-making about their health and enable women to make **informed choices by**
	  ○ Understanding her fertility intentions
	  ○ Providing information on the risks and benefits of DTG vs EFV
	  ○ Providing her with contraception options
	• The patient should be informed of the following possible side effects:
	  • Insomnia, headache, GIT disturbances, weight gain. Insomnia can be managed by taking the DTG regimen in the morning.
	  • Counsel the patient to return to the facility if side effects are severe and not self-limiting
		Authorised prescriber

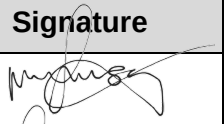
4	The transition to TLD must be integrated into existing processes and routine monitoring schedules. Patient to remain in CCMDD cycle.	Health facility
CCMDD: TLD		
5	Patients whose last viral load was done *more than six months ago* and still stable, should get a 6-month CCMDD repeat prescription on the current regimen and only be switched in the next cycle after a subsequent viral load has been done and confirmed to be < 50 c/mL. *Eligibility of these patients will be determined at their next review*	Authorised prescriber

7	The patient will be contacted by the SP to enquire whether the patient has encountered any side effects on DTG. If the patient does complain about side effects the patient will be advised to revisit the facility.	Service provider
8	All other processes according to CCMDD SOPs mainly SOPs for enrolment, issuing of a new prescription and entering of patient data on TIER.Net must still be followed.	Health facility

Algorithm for switching CCMDD patients to TLD

Algorithm for new enrolments into CCMDD for patients on TEE or TLD



SOP REVIEW AND AUTHORISATION				
Date	**Initials & Surname**	**Designation**	**Signature**	**Comments**
27/02/2020	M Munsamy	NHI: TS: Head: CCMDD		Removed SAHPRA risk form and criteria for co-morbidities
31/03/2020	M Munsamy	NHI:TS: Head: CCMDD		Revised the algorithms