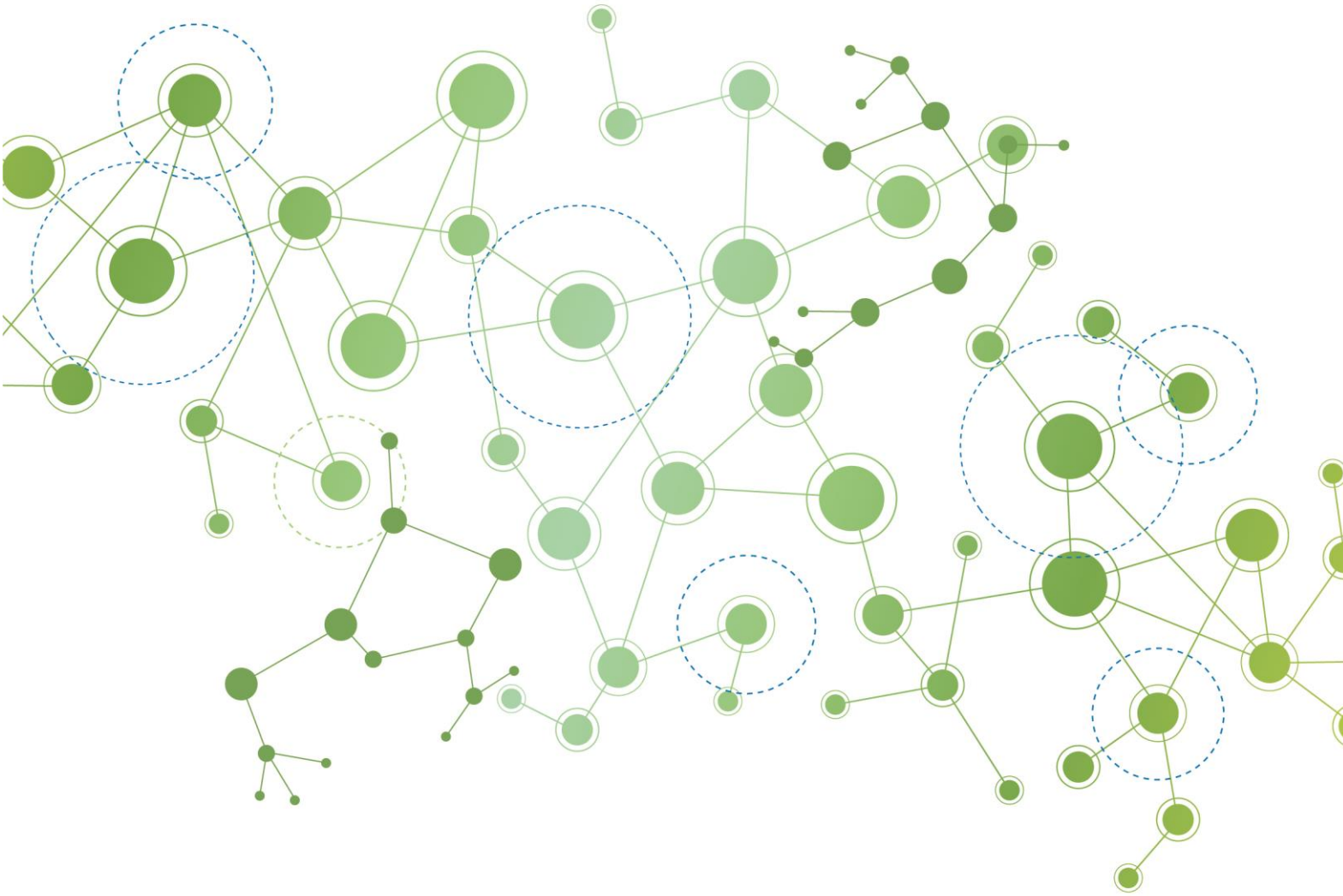
Capturing new fixed dose combination TLD (Tenofovir, Lamivudine and Dolutegravir) into the TB/HIV information system guidance



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Document control

Document name:	GUIDANCE ON CAPTURING NEW FIXED DOSE COMBINATION TLD (TENOFOVIR, LAMIVUDINE AND DOLUTEGRAVIR) INTO THE TB/HIV INFORMATION SYSTEM
Compiled by:	TB/HIV information System Implementation Team (NIT)
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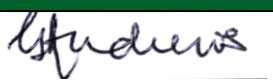
Version control

Date updated	Version	Updated by	Comment on changes
February 2020	1.0	NIT	New document

Approvals

Date approved	Version	Approved by	
February 2020	1.0	Dr. Gail Andrews	

Background

On 01 December 2020, the Minister of Health launched a new first line fixed drug combination therapy to be used by the South African HIV programme to treat HIV. The 3 in 1 pill, referred to as TLD, is a combination of 3 drugs, including Tenofovir (TDF), Lamivudine (3TC), and Dolutegravir (DTG).

DTG is associated with a more rapid viral suppression and higher genetic resistance barrier (WHO, 2018) and although there are increased outcome benefits, there is a reported risk of neural tube defects in women of childbearing potential, increased weight gain and the requirement of a booster dose of DTG for TB patients. It is therefore critical to ensure that this information is accurately documented and accounted for in the clinical stationery. However, not all information is required for capturing into the TB/HIV information system.

Monitoring patients initiated onto or switched to TLD is a critical component of HIV and TB programme management This document provides guidance on how to account the initiation and/or switching of patients onto TLD.

Guiding principles:

TLD implementation can be monitored by applying the same principles used in the rollout of the previous Fixed Dose Combination (FDC) regimen, TFE (Tenofovir, Emtricitabine, Efavirenz). Acknowledging the need to monitor the implementation of TFE, the National Department of Health developed guidance for clinicians on how to document changes from existing drug regimens to the FDC, using existing HIV clinical stationery and subsequent capture in TIER.Net

It is important to note, that whilst the introduction of FDC did not require the modification or introduction of new clinical stationery, clinical instruction and guidance was required. The same approach that was taken for the rollout of TFE should be applied to the rollout of TLD.

Clinical Documentation

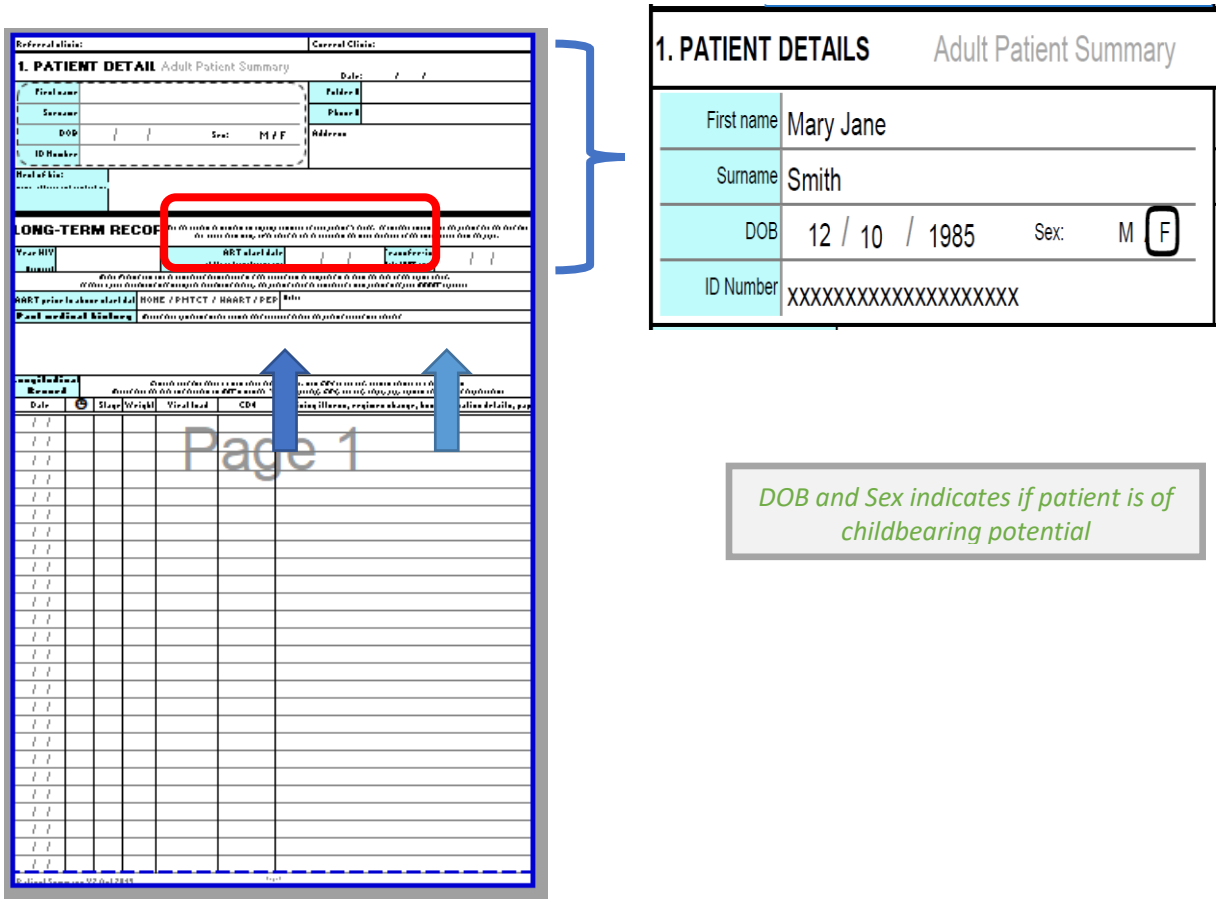
Recording a patient initiated onto TLD

In the HIV clinical stationery, the clinician is to complete/record the following:

- Verification of sex/age of HIV+ patient
- Patient's current pregnancy and contraception status
- Explanation of the potential risk of Neural Tube Defects associated with DTG in woman of childbearing potential
- Acknowledgement by the patient of her awareness and understanding of associated risks
- Patient acceptance/refusal of contraception, if pregnancy or current contraception status, is null
- Confirmation by patient of decision to commence TLD treatment if contraception is declined
- Prescription for TLD - Fixed Dose Combination Regimen
- Type of regimen
- Date of initiation
- FDC combination (to be documented on one line)
- Record 3 letter abbreviation for the drugs and the dosages

Patient details

To verify if an HIV + patient is female and of childbearing potential, the clinician is to document the sex and age of the patient in the corresponding fields below.

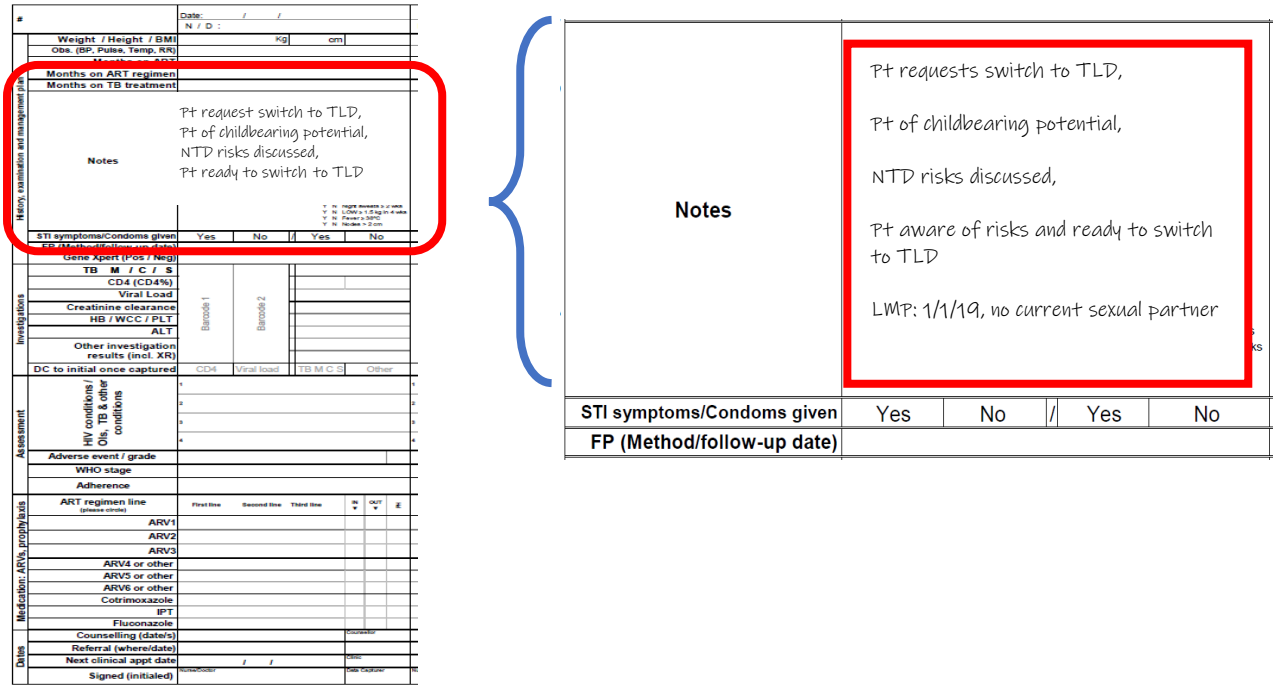


DOB and Sex indicates if patient is of childbearing potential

Notes section

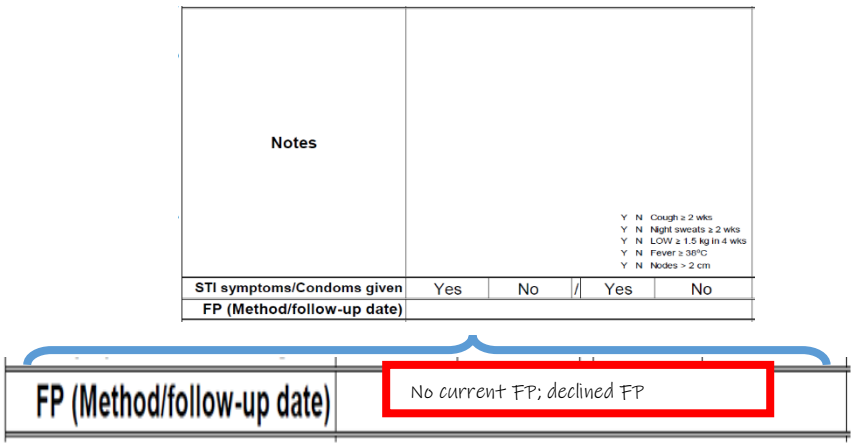
The notes section to document the following:

- Clinical assessment of patient's current pregnancy and contraception status
- Explanation by clinician of potential risk of Neural Tube Defects associated with DTG
- Acknowledgement by the patient the awareness and understanding of associated risks



Family Planning section

The clinician to indicate in this section that family planning (contraception) has been discussed, offered and accepted/declined by patient.



Assessment section

The current adherence section can be used to indicate that the patient consented to switching/being initiated on TLF despite being aware of the potential Neural Tube Defect risks associated with DTG

Assessment		
	HIV conditions / OIs, TB & other conditions	1 2 3 4
	Adverse event / grade	
	WHO stage	
	Adherence	*pt aware of DTG risk, consented to TLD switch*

Medication section

This section should be used to indicate initiation or switching from their current regimen to Fixed Dose Combination, TLD.

Switching to TLD:

The clinician to record the following:

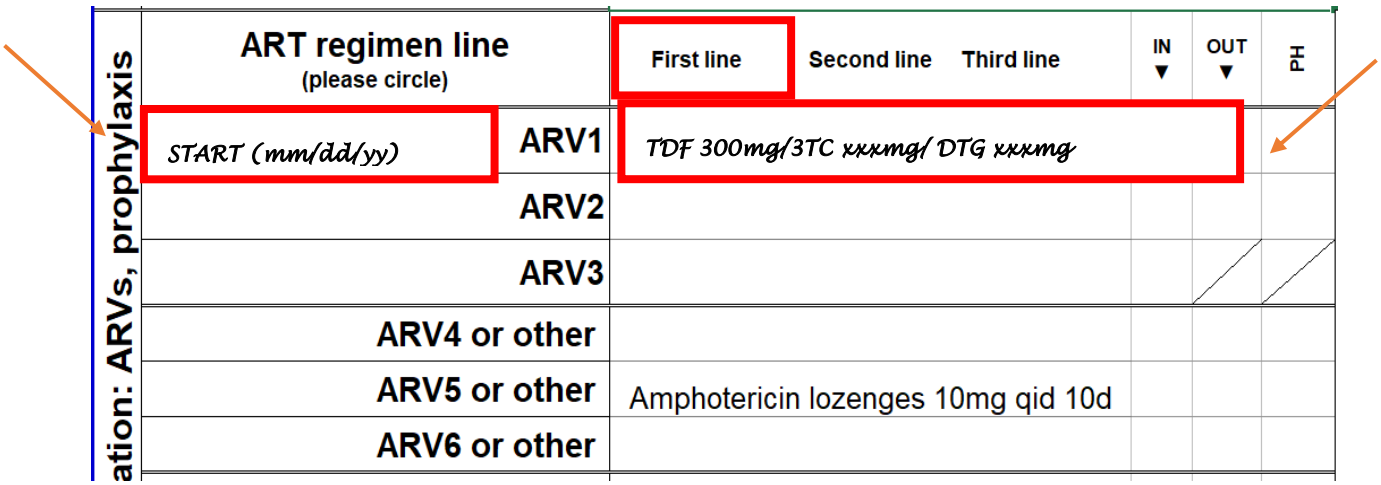
- The name of drugs to be 'Stopped' in ARV line 1
- START and the date the patient was started on the regimen
- Type of regimen – first line, second line or third line.
- The FDC combination by providing 3 letter abbreviation for the drug and the dosage.

FIGURE 1. DOCUMENTING THE SWITCH IN REGIMENS IN THE CLINICAL STATIONERY

ation: ARVs, prophylaxis	ART regimen line (please circle)	First line Second line Third line	IN ▼	OUT ▼	PH
	START (mm/dd/yy) ARV1	*STOP current regimen (mm/dd/yy)*			
	ARV2	*TDF 300mg/3TC xxxmg/ DTG xxxmg*			
	ARV3				
	ARV4 or other				
	ARV5 or other	Amphotericin lozenges 10mg qid 10d			
	ARV6 or other				

Recording the initiation of a patient onto TLD:

- START and the date the patient was started on the regimen
- Type of regimen – first line, second line or third line.
- The FDC combination by providing 3 letter abbreviation for the drug and the dosage.

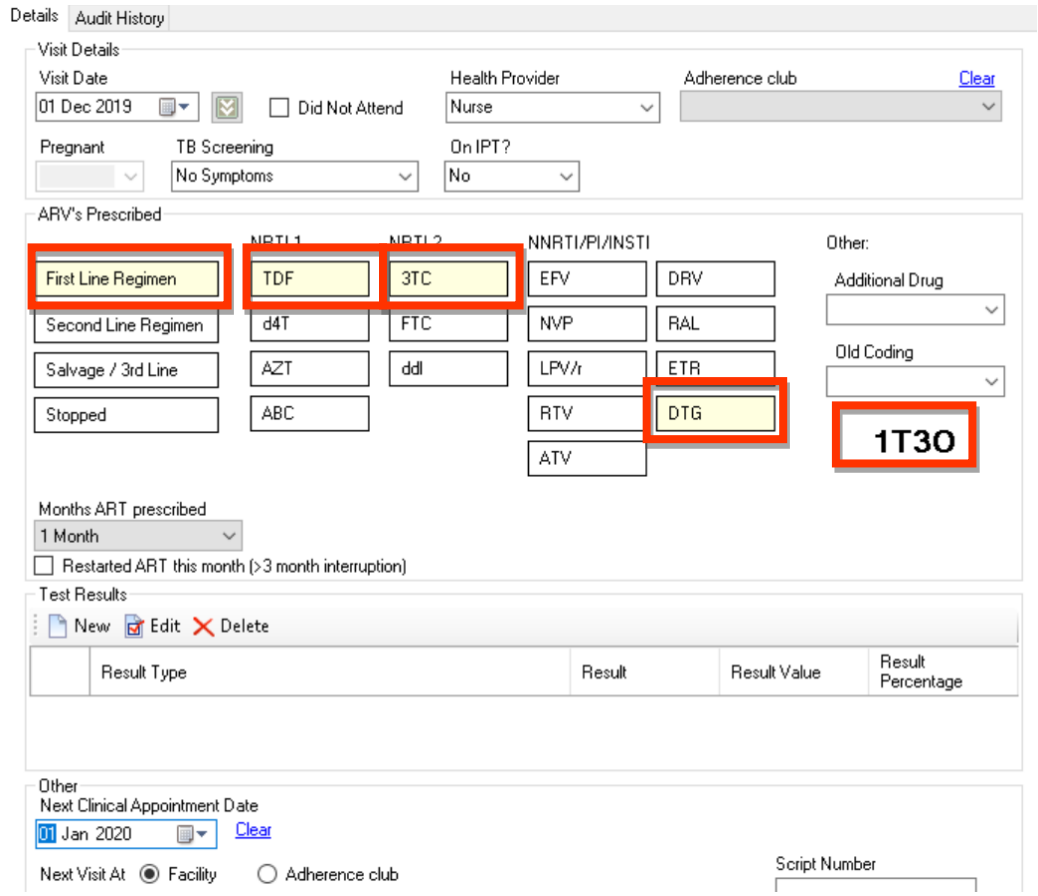


Capturing a new patient initiated on TLD into the TB/HIV information system

NB: To identify the name of the drug, when capturing, place the mouse over the box containing the name of the drug, information regarding the generic and trade drug name will appear.

- The drug code for the TLD fixed dose combination will appear in TIER.Net as:
    - Regimen 1 – Tenofovir (TDF); Lamivudine (3TC); Dolutegravir (DTG)
- To capture select the corresponding drug from the clinical stationery
    - For TLD, select the following:
        - Select First line Regimen
        - Select: TDF – Tenofovir
        - Select 3TC – Lamivudine
        - Select DTG – Dolutegravir

FIGURE 2. CAPTURING NEW DRUG REGIMEN FOR DOLUTEGRAVIR BASED FDC



NB: Although the abbreviation for the new Fixed Dose Combination is TLD, in TIER.Net, the drugs combination will appear as - ***1T3O****. The reason for this is that the the letters "L" and "D" are already in use in TIER.Net. L references Lopinovir and D references Didanosine.*

Switching from current FDC – TFE to TLD

In most instances, a change of 2 or more drugs in a patients ART regimen constitutes a switch from first line to second line treatment therapy (in addition to other clinical determinations,including but not limited to 2 consecutive unsuppressed Viral Loads).

NB: Unless clearly documented as a switch by the clinician, the switch from Fixed Dose Combination TFE (Tenofovir, Emtricitabine, Efavirenz) to TLD does not require a switch in regimen.

- Open TIER.Net
- Select the patient
- Open a new visit, the previous drug regimen will appear greyed out
- Change the existing drugs to reflect the new fixed dose combination – TLD
    - Change FTC to 3TC
    - Change EFV to DTG

FIGURE 3. PREVIOUS DRUG REGIMEN

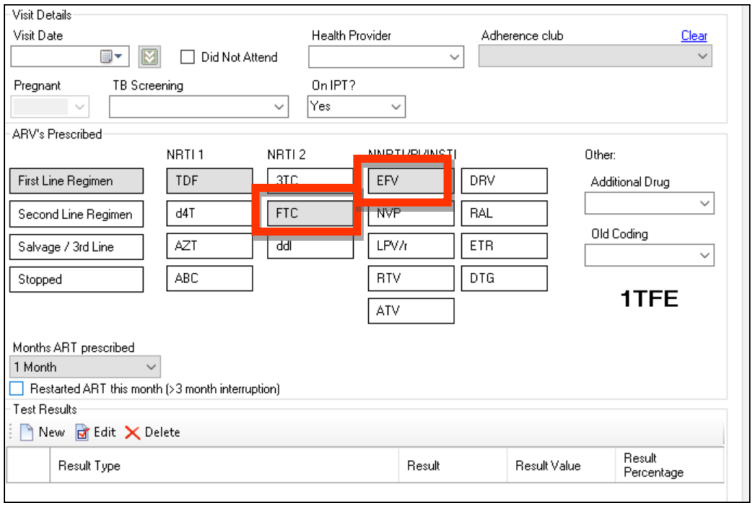
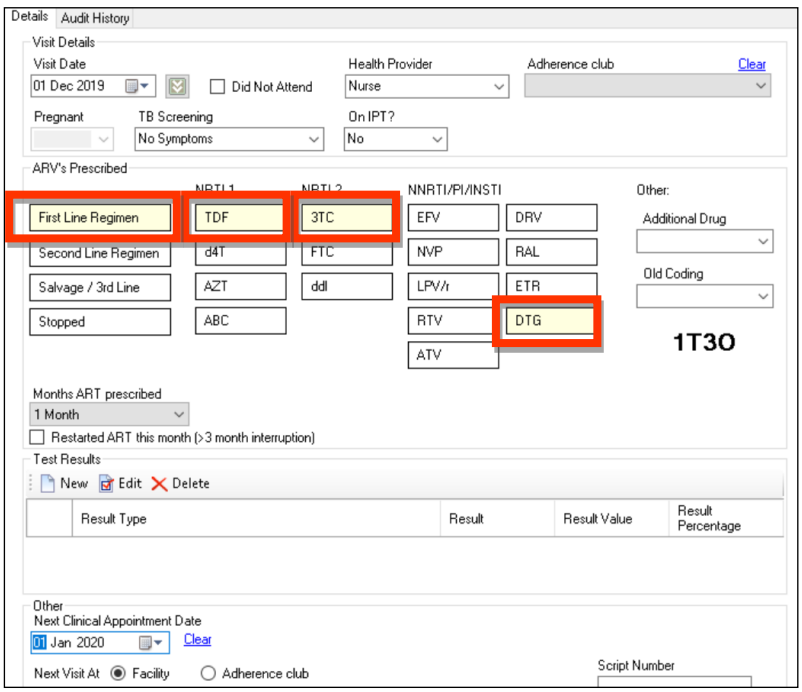
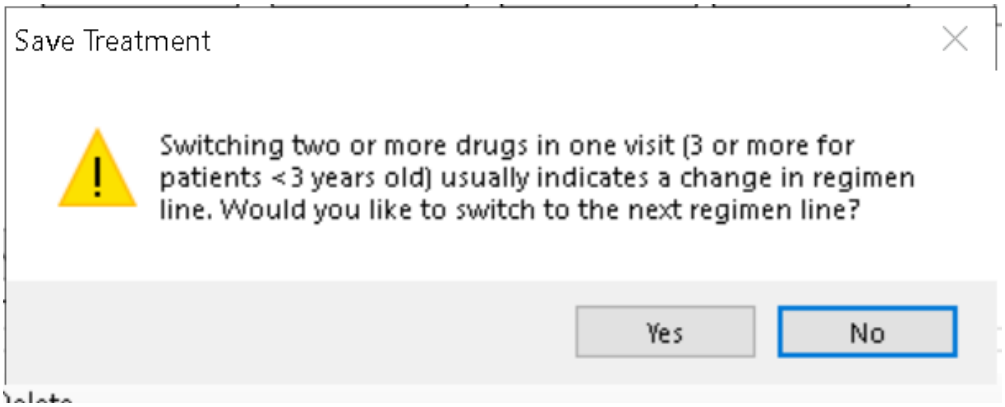


FIGURE 4. REVISED DRUG REGIMEN REFLECTING TLD



- When accounting for the switch in TIER.Net – a pop-up verification notice will appear with the following message;



- Unless the clinician has clearly documented a switch from Regimen 1 to Regimen 2, with either the Adverse Events or proof of 2 consecutive unsuppressed Viral Loads, *select* **NO**

Accounting for extra dose of DTG with TB patients

The 1.12 version of TIER.Net does not enable the capture of duplicates of drugs. Therefore, accounting for the additional dose of DTG cannot be done at this time. The ability to capture a 4th drug has been logged for correction in the next version release of the software. However, patients who are on an extra dose of DTG can be identified via indication of an active TB episode.

Accounting for women of childbearing potential

The clinical stationery will account for whether a woman of childbearing potential has been informed about the risk associated with DTG and whether the woman is on birth control. Importantly, the stationery will indicate if the woman has agreed to either initiating or switching of medication.