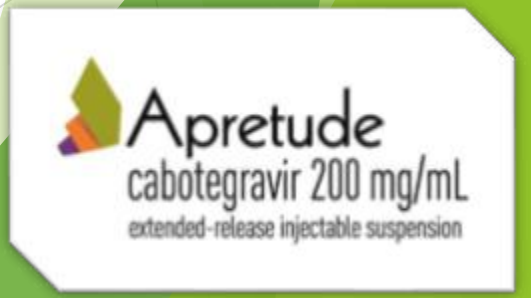
TO BE OR NOT TO BE...

ORAL LEAD-IN FOR THE TRANSITION FROM ORAL PREP TO EXTENDED-RELEASE CABOTEGRAVIR

Julena Maurer, PharmD

PGY-1 Pharmacy Resident | UPMC Shadyside Hospital



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Learning Objectives

- Identify the pharmacologic options for pre-exposure prophylaxis (PrEP) of human immunodeficiency virus (HIV)
- Describe place in therapy of intramuscular cabotegravir for PrEP
- Discuss the risks and benefits of oral lead-in during the transition from oral to extended-release intramuscular cabotegravir

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Other health care professionals will receive a certificate of attendance confirming the number of contact hours commensurate with the extent of participation in this activity.

Continuing Education Information

- This presentation is intended for practicing pharmacists involved in the planning, implementation, and/or monitoring of cabotegravir treatment regimens
- By the end of this presentation, active learners will be able to...
  - Identify the pharmacologic options for pre-exposure prophylaxis (PrEP) of human immunodeficiency virus (HIV)
  - Describe place in therapy of intramuscular cabotegravir for PrEP
  - Discuss the risks and benefits of oral lead-in during the transition from oral to extended-release intramuscular cabotegravir

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Abbreviations

- "BBW" black box warning
- "BMD" bone mineral density
- "HIV" human immunodeficiency environment
- "PK" pharmacokinetics
- "PrEP" pre-exposure prophylaxis
- "TAF-FTC" tenofovir alafenamide-emtricitabine
- 'TDF-FTC" tenofovir disoproxil-emtricitabine
- "TGW" persons assigned male sex at birth whose gender identification is female
- "MSM" men who have sex with men

Prevalence of HIV

What role can we as pharmacists play in the prevention of HIV infections

WHO, 2022

Learning Objective #1

Identify the approved pharmacologic options for pre-exposure prophylaxis (PrEP) of human immunodeficiency virus (HIV)

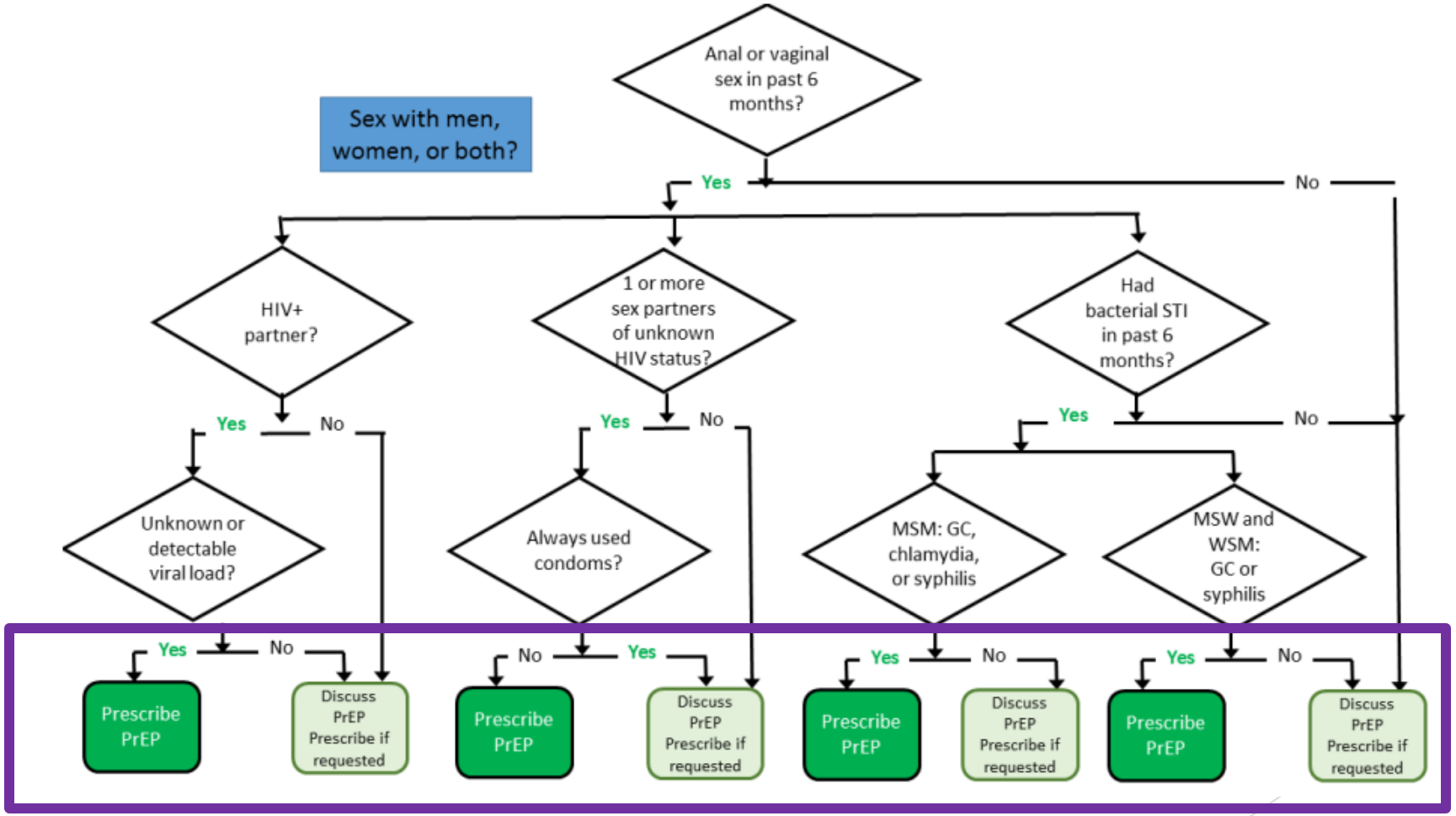
Clinical Practice Guidelines

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES

2021

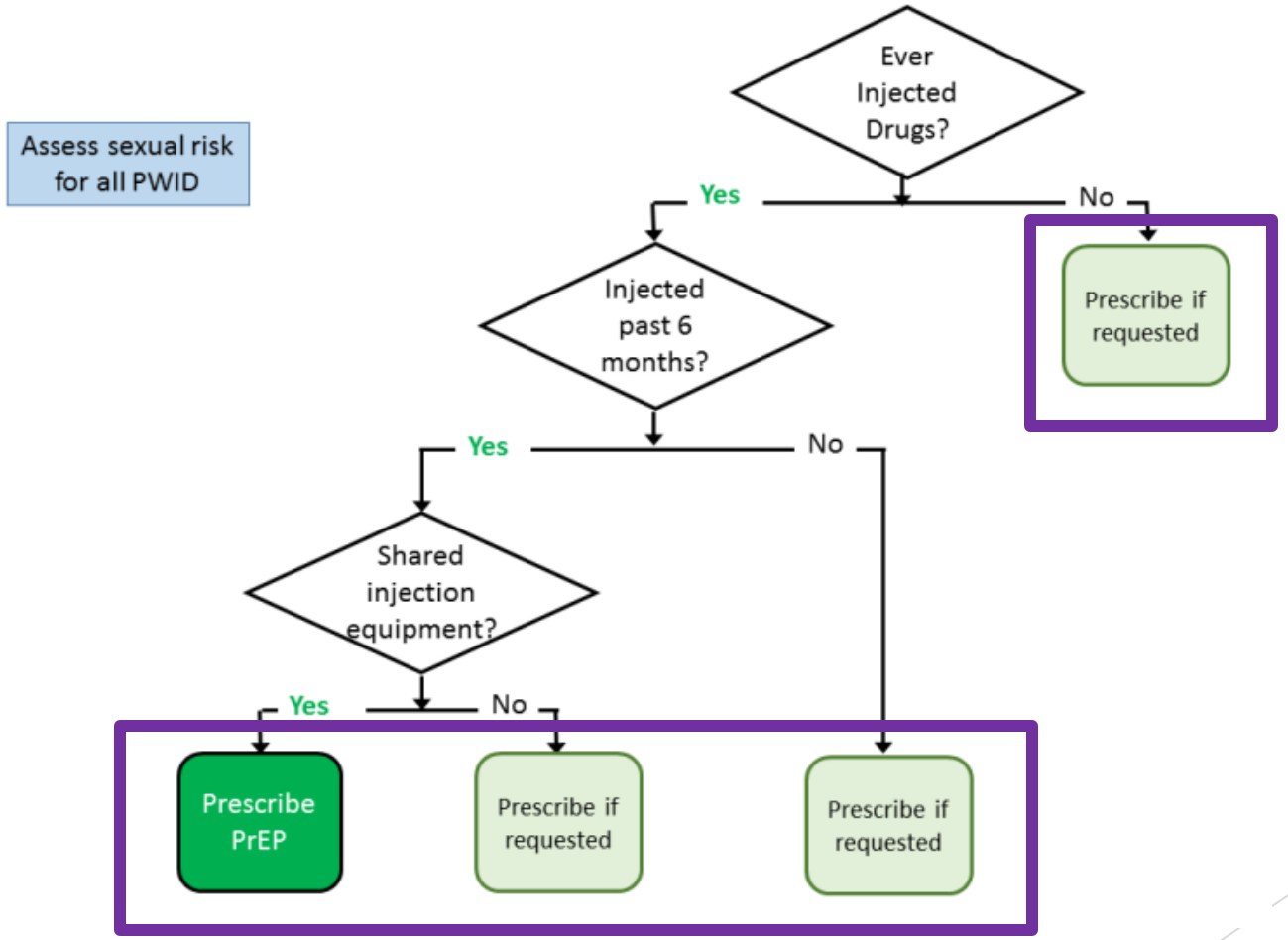
CDC, 2021

Assessing Indications for PrEP in Sexually Active Persons



CDC, 2021

Assessing Indications for PrEP in Persons who Inject Drugs



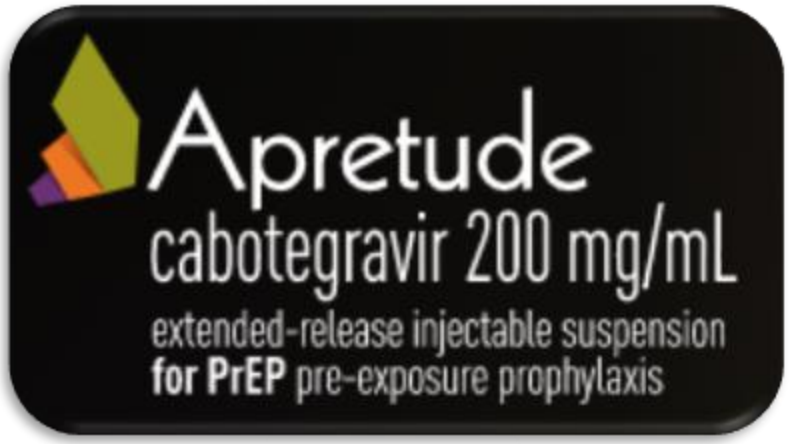
CDC, 2021

FDA Approved Pharmacologic Options for PrEP

TDF-FTC

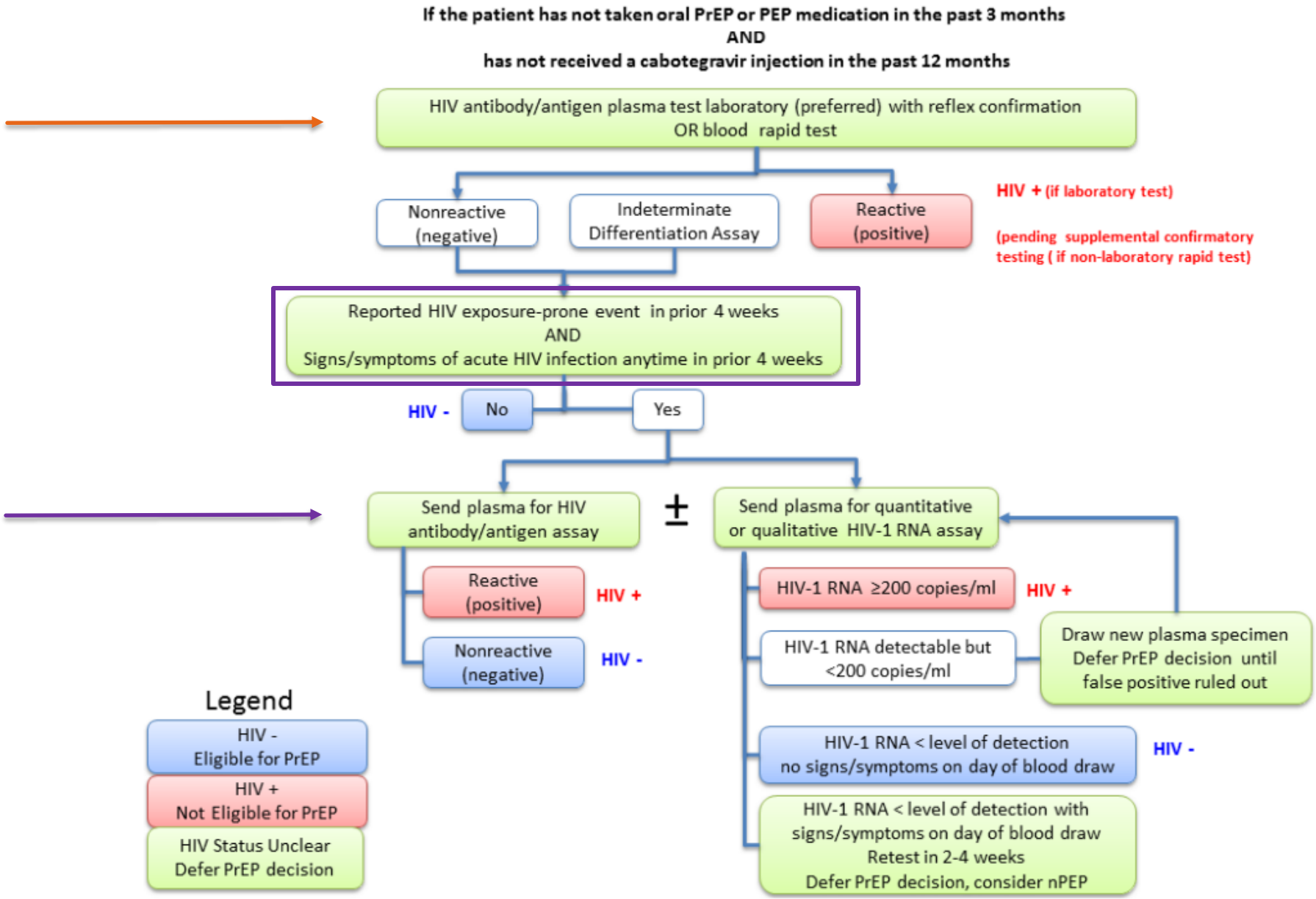
TAF-FTC

CAB



Gilead Sciences, 2022
Gilead Sciences, 2022
ViiV Healthcare, 2022

Prior to Therapy... Clinical Determination of HIV Status

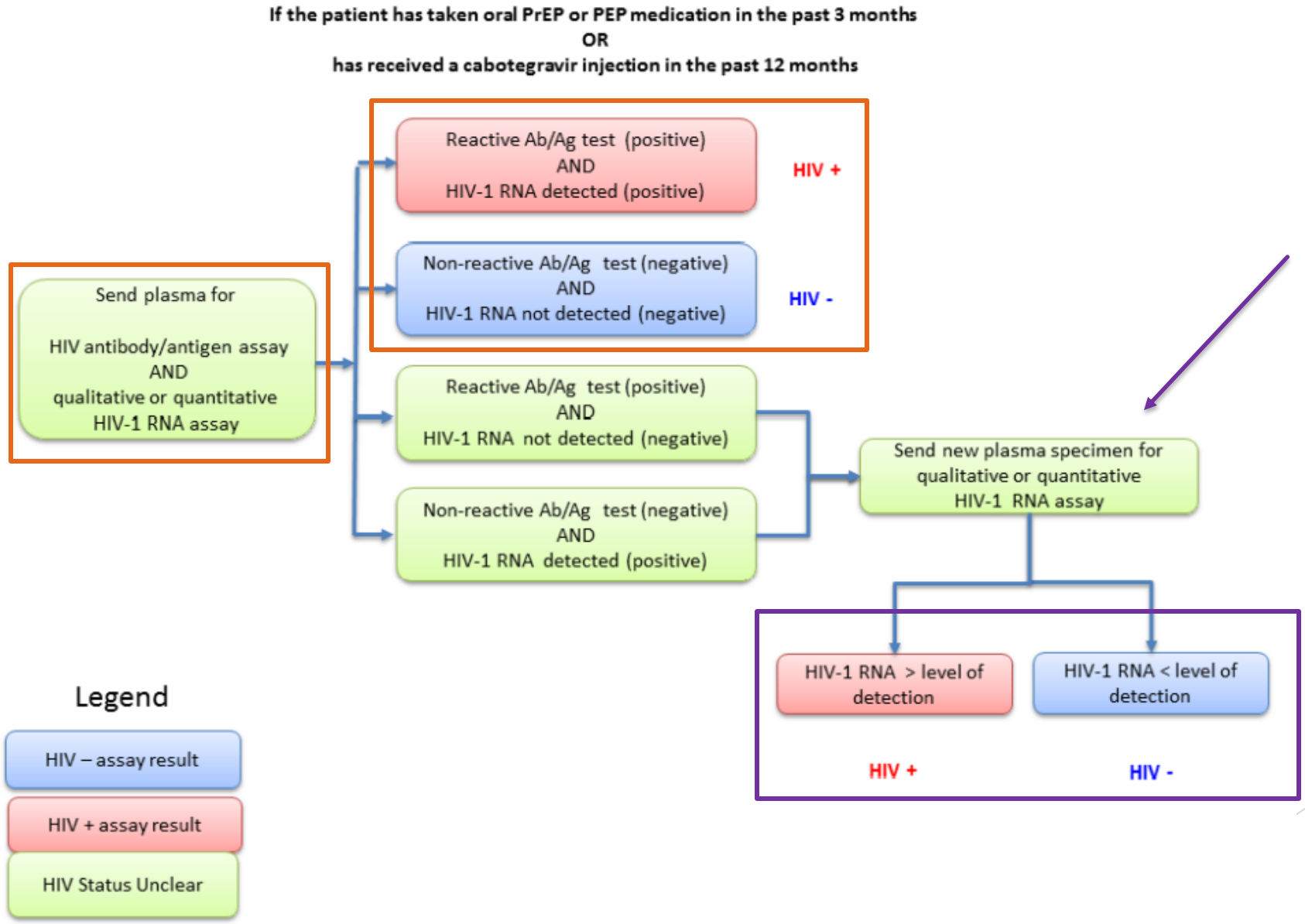


Without recent antiretroviral prophylaxis use

CDC, 2021

Prior to Therapy... Clinical Determination of HIV Status

With recent antiretroviral prophylaxis use



CDC, 2021

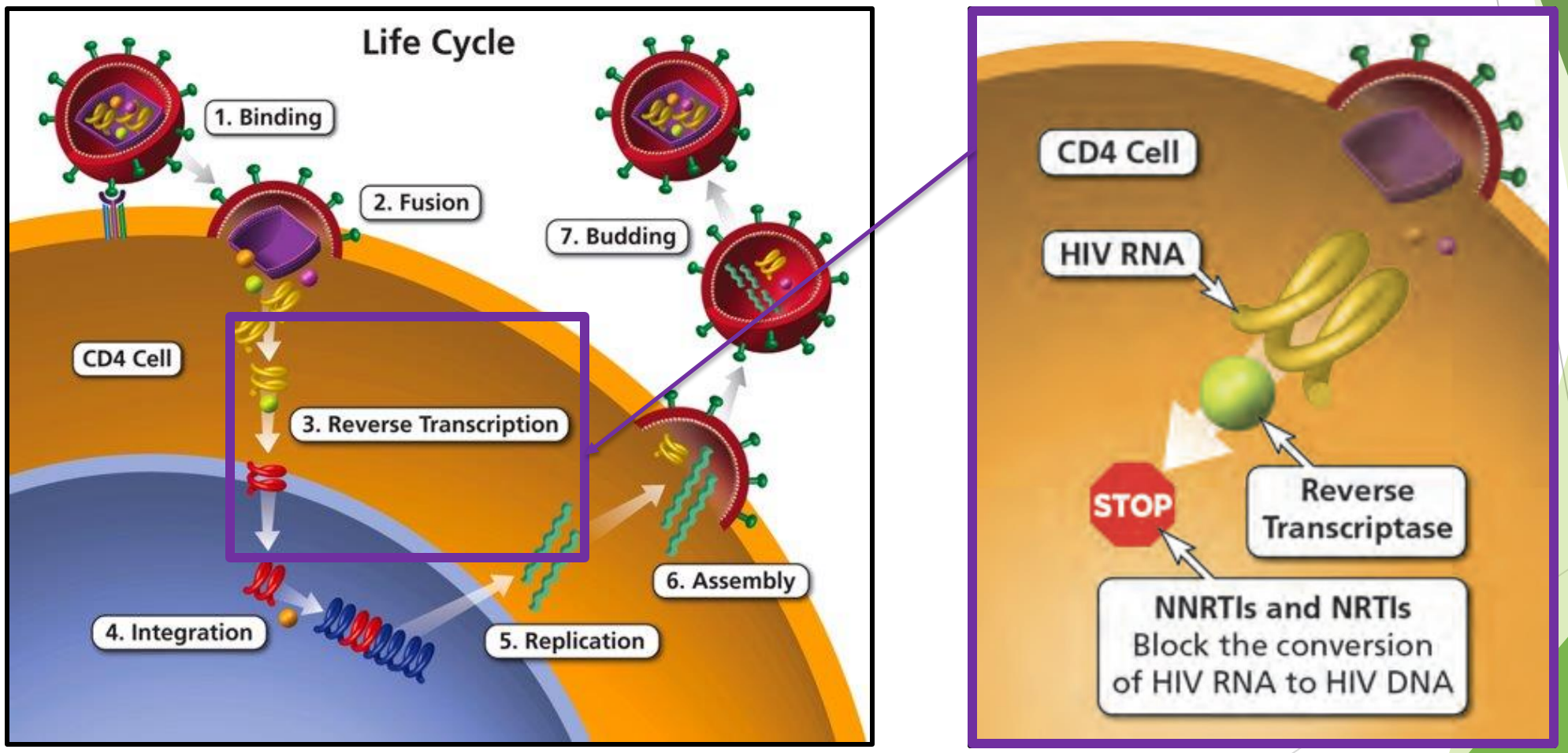
Oral PrEP Therapies

TDF-FTC

TAF-FTC

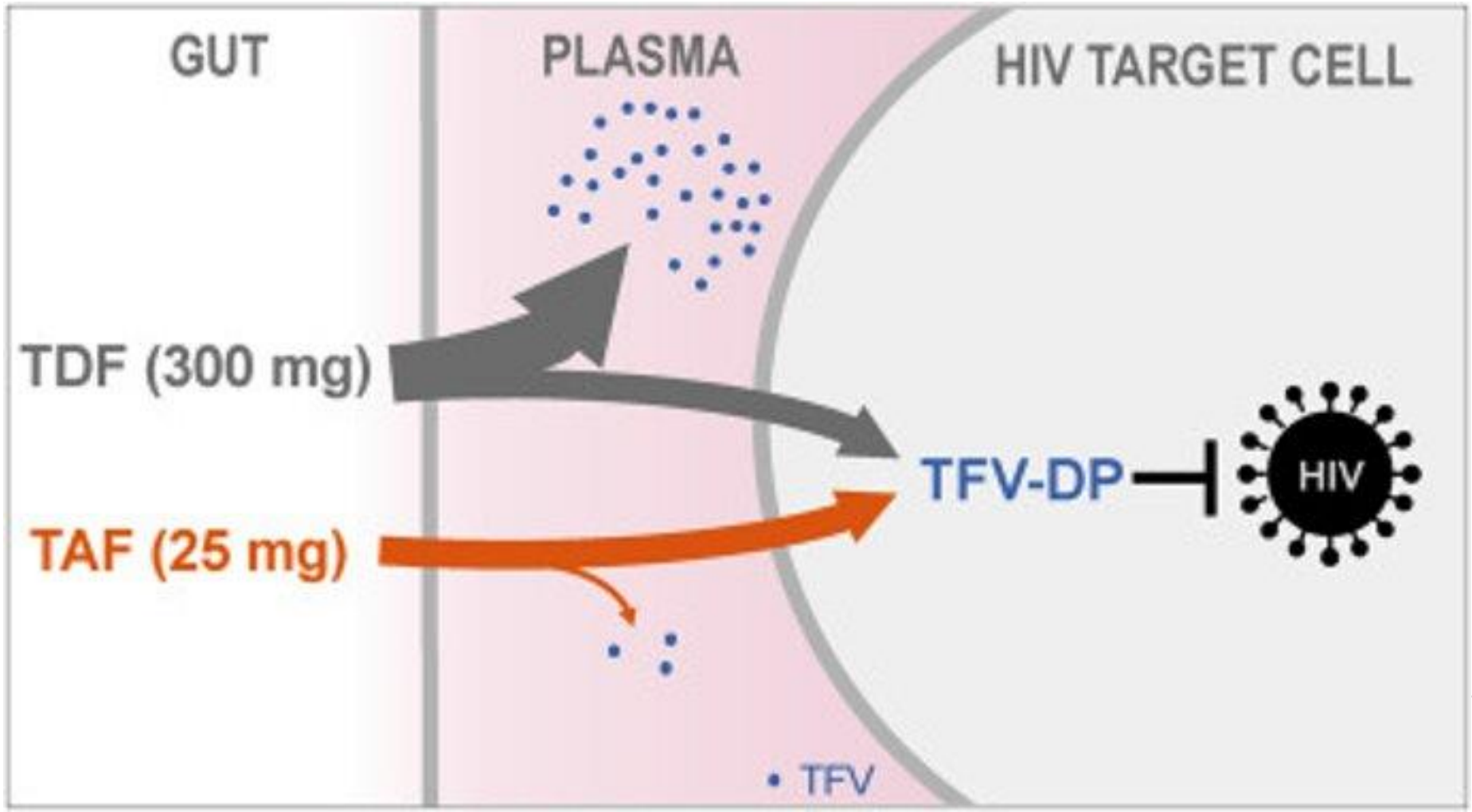
Gilead Sciences, 2022
Gilead Sciences, 2022

Oral PrEP Therapies: Mechanism of Action



NIH, 2021

Oral PrEP Therapies: Mechanism of Action



Ray, 2015

Oral PrEP Therapies: Indication

TDF-FTC (Truvada)	TAF-FTC (Descovy)
Adults and **adolescents,** weighing at least 35 kg, at high risk for acquiring HIV	**Adult cis-men and TGW,** at high risk of acquiring HIV

Gilead Sciences, 2019
Gilead Sciences, 2020

Oral PrEP Therapies: BBW

TDF-FTC (Truvada)	TAF-FTC (Descovy)
Risk of drug resistance with use for preexposure prophylaxis Posttreatment acute exacerbation of hepatitis B	

Gilead Sciences, 2019
Gilead Sciences, 2020

Oral PrEP Therapies: Dosing

TDF-FTC (Truvada)	TAF-FTC (Descovy)
300/200 mg daily CrCl 30-49 mL/min 1 tablet Q48H CrCl < 30 mL/min: NOT recommended for use	**200/25 mg daily** CrCl < 30 mL/min: NOT recommended for use

Gilead Sciences, 2019
Gilead Sciences, 2020

Oral PrEP Therapies: Administration

TDF-FTC (Truvada)	TAF-FTC (Descovy)
• Oral tablet • Without regard to food	

Gilead Sciences, 2019
Gilead Sciences, 2020

Oral PrEP Therapies: Adverse Effects

TDF-FTC (Truvada)	TAF-FTC (Descovy)
Common Side Effects Headache Abdominal pain Weight loss *Serious Side Effects* **Decreased BMD** **Kidney injury**	*Side Effects* *(2-5% occurrence rate)* Abdominal pain Diarrhea Nausea Fatigue Headache Other Side Effects **Weight gain** **Dyslipidemia**

Gilead Sciences, 2019
Gilead Sciences, 2020

Checkpoint #1

Which of the following are FDA approved pharmacologic options for HIV pre-exposure prophylaxis? (Select all that apply)

a. Emtricitabine / Tenofovir disoproxil (Truvada)
b. Emtricitabine / Tenofovir alafenamide (Descovy)
c. Cabotegravir (Apretude)
d. Cabotegravir-rilpivirine (Cabenuva)

Which of the following are FDA approved pharmacologic options for HIV pre-exposure prophylaxis? (Select all that apply)

a. Emtricitabine / Tenofovir disoproxil (Truvada)
b. Emtricitabine / Tenofovir alafenamide (Descovy)
c. Cabotegravir (Apretude)
d. Cabotegravir-rilpivirine (Cabenuva)

Cabotegravir (CAB)

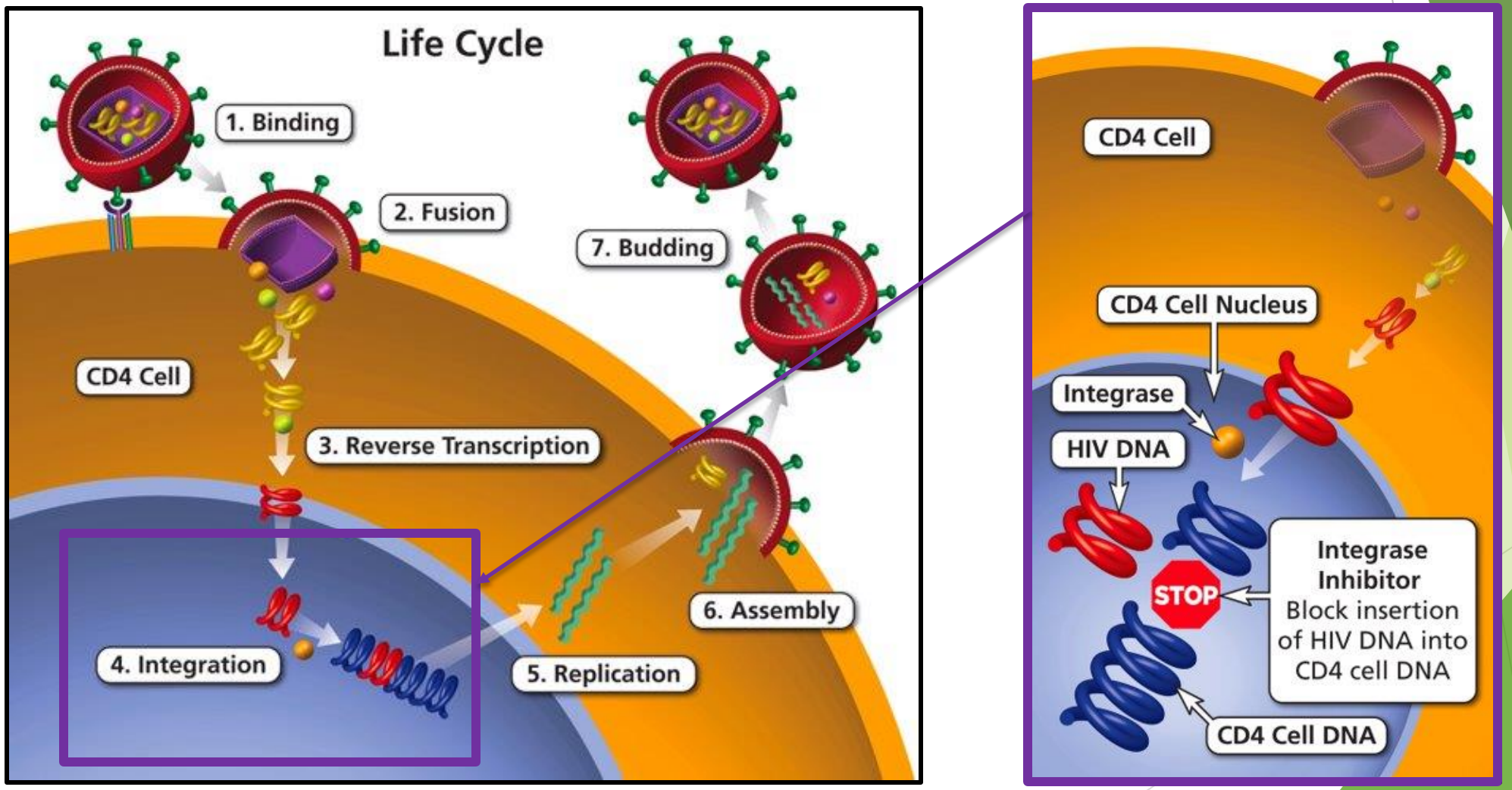
Apretude

Viiv Healthcare, 2022

Learning Objective #2

Describe place in therapy of intramuscular cabotegravir

Cabotegravir (CAB): Mechanism of Action



NIH, 2021

Cabotegravir (CAB): Indication

Indicated for adults
(> 18 years old),
weighing > 35 kg,
at high risk for acquiring HIV

Viiv Healthcare, 2022

Strength of Recommendation Taxonomy (SORT)

Study quality	*Diagnosis*	*Treatment/prevention/screening*	*Prognosis*
Level 1—good-quality patient-oriented evidence	Validated clinical decision rule SR/meta-analysis of high-quality studies High-quality diagnostic cohort study†	SR/meta-analysis of RCTs with consistent findings High-quality individual RCT‡ All-or-none study§	SR/meta-analysis of good-quality cohort studies Prospective cohort study with good follow-up
Level 2—limited-quality patient-oriented evidence	Unvalidated clinical decision rule SR/meta-analysis of lower-quality studies or studies with inconsistent findings Lower-quality diagnostic cohort study or diagnostic case-control study§	SR/meta-analysis of lower-quality clinical trials or of studies with inconsistent findings Lower-quality clinical trial‡ Cohort study Case-control study	SR/meta-analysis of lower-quality cohort studies or with inconsistent results Retrospective cohort study or prospective cohort study with poor follow-up Case-control study Case series
Level 3—other evidence	Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), or case series for studies of diagnosis, treatment, prevention, or screening		

Ebell, 2004

Strength of Recommendation Taxonomy (SORT)

Strength of recommendation	*Definition*
A	Recommendation based on consistent and good-quality patient-oriented evidence.*
B	Recommendation based on inconsistent or limited-quality patient-oriented evidence.*
C	Recommendation based on consensus, usual practice, opinion, disease-oriented evidence,* or case series for studies of diagnosis, treatment, prevention, or screening.

**—Patient-oriented evidence measures outcomes that matter to patients: morbidity, mortality, symptom improvement, cost reduction, and quality of life. Disease-oriented evidence measures intermediate, physiologic, or surrogate end points that may or may not reflect improvements in patient outcomes (e.g., blood pressure, blood chemistry, physiologic function, pathologic findings).*

Ebell, 2004

HPTN 083 and 084: Overview

Cabotegravir vs. TDF-FTC

Characteristic	HPTN 083	HPTN 084
Design	Phase 3, Randomized, Double-blind, Active control trial	Phase 3, Randomized, Double-blind, Active control trial
Location	Argentina, Peru, Brazil, Thailand, Vietnam, South Africa, Unites States	Botswana, Eswatini, Kenya, Malawi, South Africa, Uganda, Zimbabwe
Population	Cis-male, TGW Sex with male within 6 months preceding enrollment	Women Sex with male within 6 months preceding enrollment
Intervention	Cabotegravir vs. TDF-FTC Lead-in phase: 30mg cabotegravir oral daily x5 weeks vs. Placebo 600mg cabotegravir IM at weeks 5 and 9, then every 8 weeks vs. TDF-FTC daily	Cabotegravir vs. TDF-FTC Lead-in phase: 30mg cabotegravir oral daily x5 weeks vs. Placebo 600mg cabotegravir IM at weeks 5 and 9, then every 8 weeks vs. TDF-FTC daily
Outcomes	Incident HIV infection	Incident of HIV infection
Follow-up	48 weeks	48 weeks

Landovitz et al, 2021
Delaney, 2022

HPTN 083, 084: Results

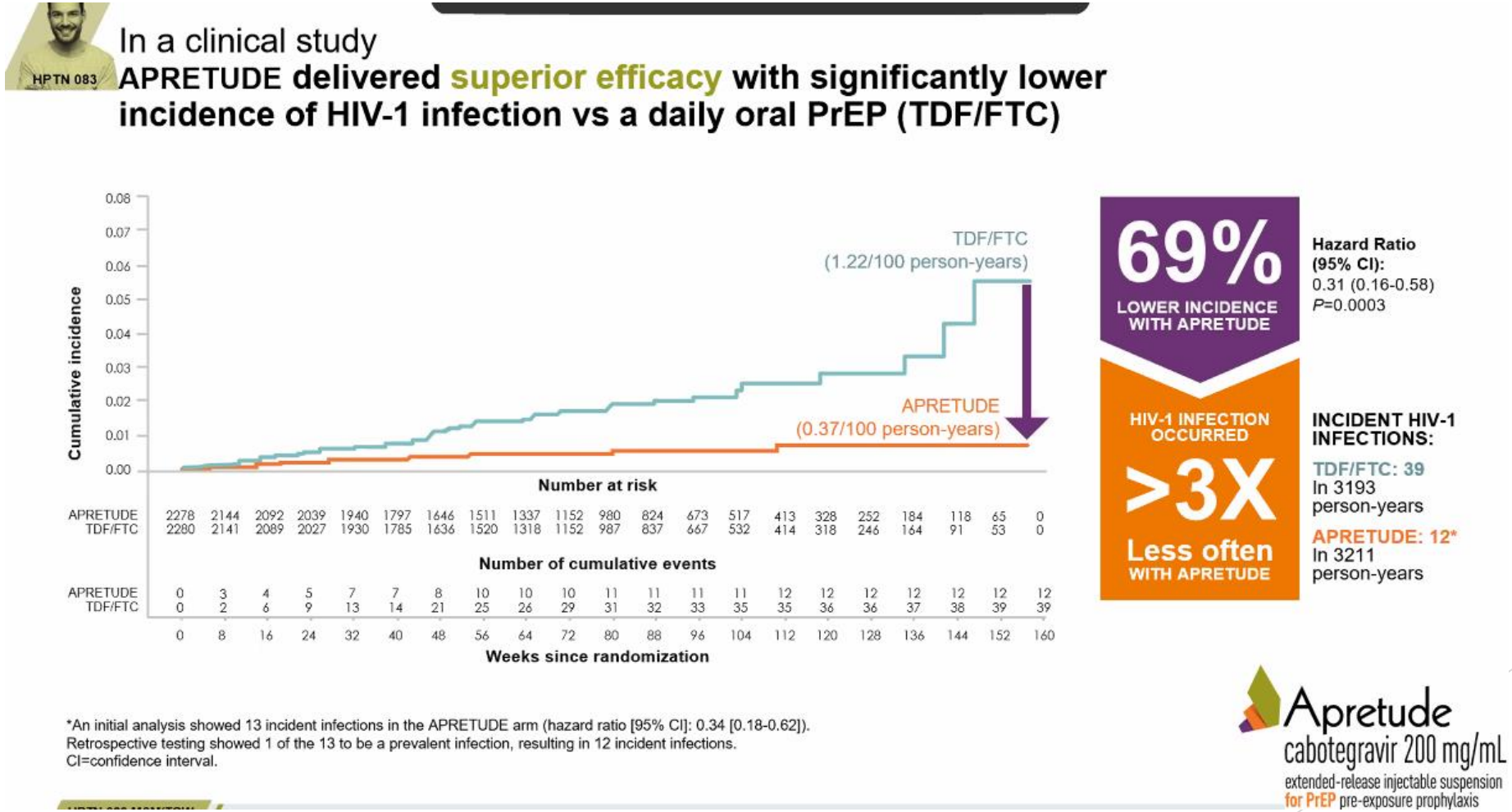
Cabotegravir vs. TDF-FTC

Outcome	HPTN 083 (CAB) N = 2282	HPTN 083 (TDF-FTC) N = 2284	HPTN 084 (CAB) N = 1614	HPTN 084 (TDF-FTC) N = 1610
Incident HIV infection (n (%))	13 (0.52)	39 (1/71)	4 (0.25)	36 (2.24)
Adherence rate (%)	91.5 (concentration)	96.6 (pill count) 74.2 (concentration)	93.1 (concentration)	41.9 (concentration)
Injection site reaction rate (%)	81.4	31.3	38	10.8

Landovitz et al, 2021
Delaney, 2022

HPTN 083, 084: Results

Cabotegravir vs. TDF-FTC

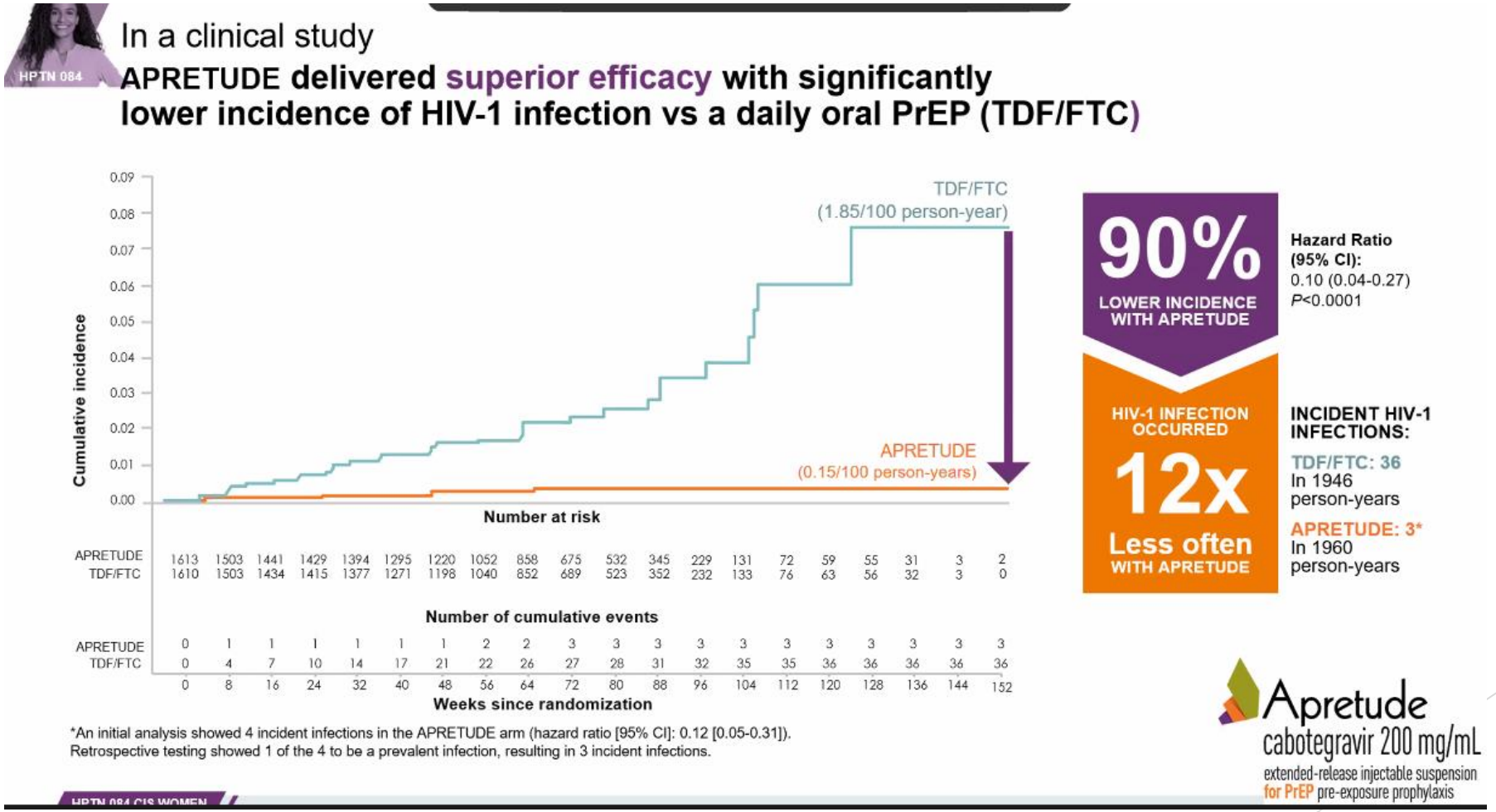


*An initial analysis showed 13 incident infections in the APRETUDE arm (hazard ratio [95% CI]: 0.34 [0.18-0.62]).
Retrospective testing showed 1 of the 13 to be a prevalent infection, resulting in 12 incident infections.
CI=confidence interval.

Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension
for PrEP pre-exposure prophylaxis

HPTN 083, 084: Results

Cabotegravir vs. TDF-FTC



HPTN 083, 084: Conclusions

Cabotegravir (CAB) vs. TDF-FTC

- Cabotegravir is effective in preventing HIV infection
- Cabotegravir is superior to TDF-FTC in preventing HIV infection

Grade 2B

Landovitz et al, 2021
Delaney, 2022

Cabotegravir: BBW

CAB (Apretude)

Risk of drug resistance with use for preexposure prophylaxis

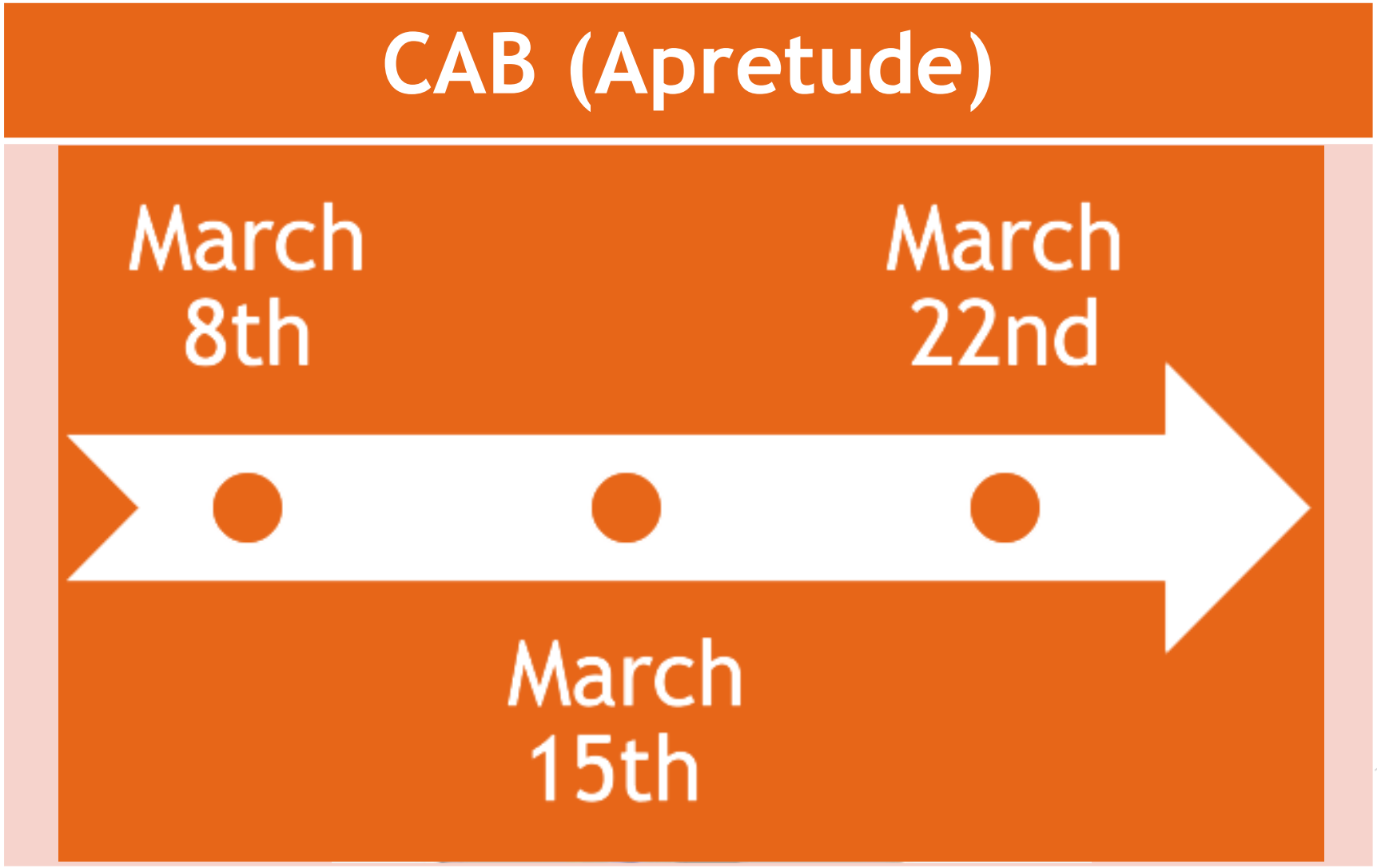
~~**Posttreatment acute exacerbation of hepatitis B**~~

Viiv Healthcare, 2022

Cabotegravir: Dosing

ViiV Healthcare, 2022

Cabotegravir: Administration



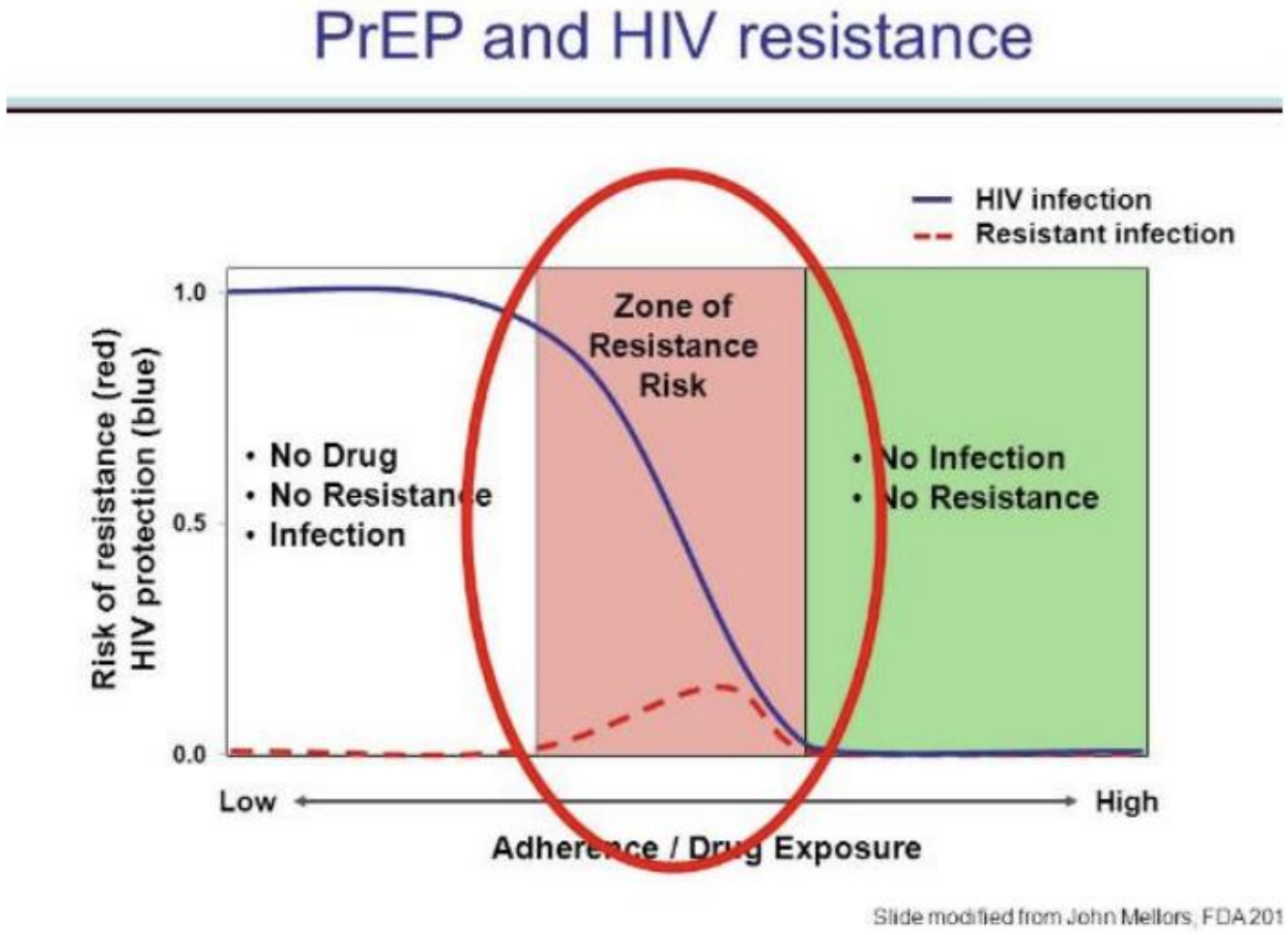
Viiv Healthcare, 2022

Cabotegravir: Administration

Dose Missed	Time since Previous Dose	Recommendation
Second Injection	<2 months	Administer dose as soon as possible, continue as scheduled
	>2 months	Restart initial dosing regimen
Third injection or later	<3 months	Administer dose as soon as possible, continue as scheduled
	>3 months	Restart initial dosing regimen

Viiv Healthcare, 2022

The Tail-phase



CDC, 2021

Cabotegravir: Adverse Effects

CAB (Apretude)

Most Common:

- Local site reactions
- Headache
- Elevated CPK

Rare:

- Depressive disorder
- Hepatotoxicity

Viiv Healthcare, 2022

Drug Interactions

	CAB (oral)	CAB LA, PrEP	FTC/TAF (PrEP)	FTC/TDF
Carbamazepine	●	●	●	◆
Ibuprofen	◆	◆	◆	■
Orlistat	▲	◆	▲	▲
Oxcarbazepine	●	●	●	◆
Phenobarbital (Phenobarbitone)	●	●	●	◆
Phenytoin	●	●	●	◆
Rifampicin	●	●	■	◆
Rifapentine	●	●	■	◆
St John's Wort	●	●	●	◆
Tacrolimus	◆	◆	◆	▲

● Do Not Coadminister ■ Potential Interaction ▲ Potential Weak Interaction ◆ No Interaction Expected

University of Liverpool, 2023

Monitoring Parameters

Testing	Baseline	1 month visit	Every 2 months	Every 3 months	Every 4 months	Every 6 months	Every 12 months	When stopping therapy
HIV	X	^	^	X				X
SCr (eCrCl)	*					≥50yo or <90mL/min at initiation	*	*
Syphilis	X			*MSM *TGW	^MSM ^TGW	^ ^Heterosexual men and women	^	MSM TGW
Gonorrhea	X			*MSM *TGW	^MSM ^TGW	* ^Heterosexual women	^	MSM TGW
Chlamydia	X			*MSM *TGW	^MSM ^TGW	*	^Heterosexual men and women	MSM TGW
Lipid panel	*						*	
HepB	*							
HepC	*MSM *TGW *PWID						MSM TGW PWID	

"X" All PrEP patients
^CAB therapy only
*Oral PrEP only

CDC, 2021

Cost

Type of Coverage	CAB (Apretude)	CAB (Vocabria)	TDF-FTC (Truvada)	TAF-FTC (Descovy)
No insurance	$1,502/injection	$23.78 ($665.84 for 28 tablets)	Generic: $2.34-70.1/tablet ($70.2-2,103 for 30 tablets) Brand: $73.69/tablet ($2,210.70 for 30 tablets)	$86.36/tablet ($2,590.80 for 30 tablets)
State (PA) Preferred Drug-list	Listed	Not listed	Listed	Listed
UPMC For You	NF	NF	NF	NF
UPMC Your Choice	Tier 2	NF	Generic: Tier 1 Brand: NF	Tier 2

Uptodate, 2023
PA Department of Human Services, 2023
UPMC Health Plan, 2023

UPMC Hospital Formulary

Formulary Coverage	CAB (Apretude)	CAB (Vocabria)	TDF-FTC (Truvada)	TAF-FTC (Descovy)
UPMC	Formulary Restricted to outpatient use only	Formulary	Formulary	Formulary

UPMC Systems Formulary, 2023

What does the information we have reviewed about our PrEP options tell us?

- Who may benefit from cabotegravir use?
- Who may NOT benefit from cabotegravir use?

Learning Objective #2:

Describe place in therapy of intramuscular cabotegravir

Pros	Cons
Indicated for all persons ≥ 18 yo weighing ≥ 35 kg	Must be administered by a healthcare professional
Dosing frequency every 2 months vs daily	Lab testing required every 2 months
Cost	Cost
No renal dose adjustments	Tail-period
No association with decreased bone mineral density	Drug-interactions

Checkpoint #2

Which of the following is **not** true about cabotegravir?

a. Cabotegravir must be administered by a healthcare provider
b. Cabotegravir requires a negative HIV test prior to each administration
c. Cabotegravir is not approved for persons whose main risk for HIV is receptive vaginal sex
d. Cabotegravir can remain in the body for over 40 weeks after injection

Which of the following is **not** true about cabotegravir?

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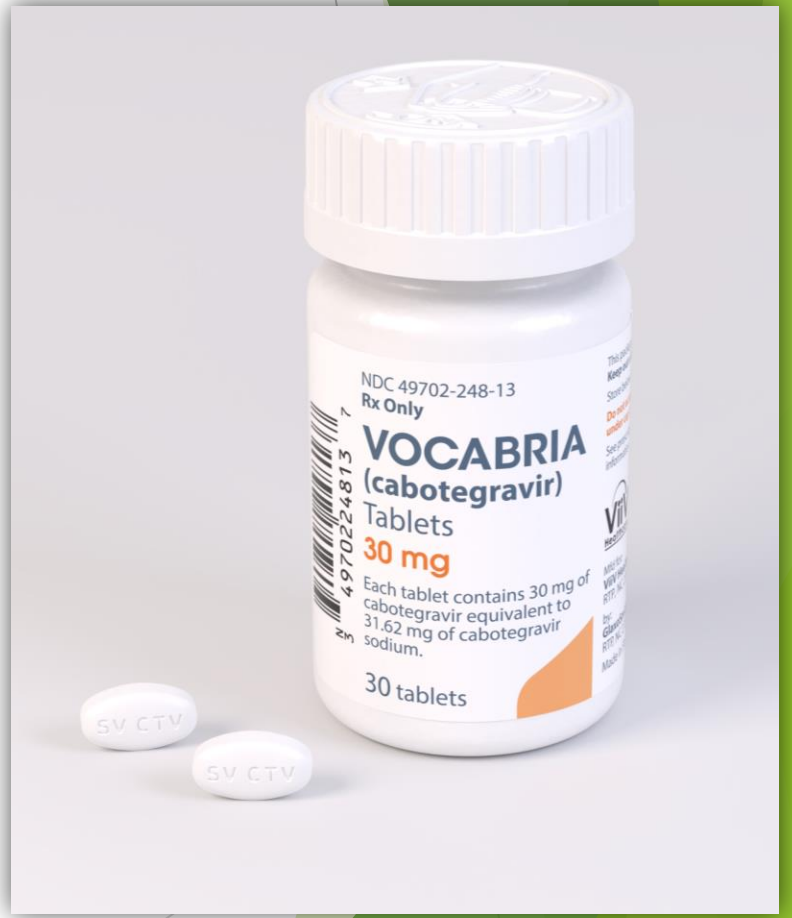
Which of the following is **not** true about cabotegravir?

a. Cabotegravir must be administered by a healthcare provider
    a. This is true!
b. Cabotegravir requires a negative HIV test prior to each administration
    a. Testing required for oral PrEP, but NOT for cabotegravir includes renal function, lipid panel, hepatitis C and hepatitis B
c. Cabotegravir is not approved for persons whose main risk for HIV is receptive vaginal sex
    a. No. This relates to TAF-FTC (Descovy)
d. Cabotegravir can remain in the body for over 40 weeks after injection
    - In the HPTN 077 trial, cabotegravir levels were detectable for up to 44 weeks for men and 67 weeks for women
    - Remember, cabotegravir levels do not remain therapeutic for the duration of the "tail=phase"

So where is the controversy....

Oral Lead-in for Cabotegravir (Apretude)

Cabotegravir (Vocabria)
1 tablet (30mg) **by mouth** daily
for at least 28 days



Viiv Healthcare, 2022

Oral Lead-in for Cabotegravir (Apretude)

----------DOSAGE AND ADMINISTRATION----------

- HIV-1 Screening: Screen all individuals for HIV-1 infection immediately prior to initiating APRETUDE for HIV-1 PrEP and prior to each injection while taking APRETUDE. (2.2)
- Prior to initiating APRETUDE, an oral lead-in dosing may be used for approximately 1 month with the recommended dosage to assess the tolerability of APRETUDE. (2.4)
- For gluteal intramuscular injection only. (2.5, 2.6)
- Recommended Dosing Schedule: Initiate APRETUDE with a single 600-mg (3-mL) injection given 1 month apart for 2 consecutive months on the last day of an oral lead-in if used or within 3 days and continue with the injections every 2 months thereafter. (2.5)

2.4 Optional Oral Lead-in Dosing to Assess Tolerability of APRETUDE

The healthcare provider and individual may decide to use an oral lead-in with oral cabotegravir prior to the initiation of APRETUDE to assess the tolerability of cabotegravir or the healthcare provider and individual may proceed directly to injection of APRETUDE without the use of an oral lead-in *[see Dosage and Administration (2.5)]*.

Viiv Healthcare, 2022

Missing Guidance

"No data available from clinical trials in men or women to estimate the time from initiation of CAB injections to maximal protection against HIV acquisition."

CDC, 2021

The question is...

When patients transition from an oral PrEP therapy to cabotegravir, are they continuously protected following the first injection without an oral lead-in period?

What are clinicians asking?

Posted 03-28-2022 09:08

Reply | Reply Privately

A patient who was taking TDF/FTC for PrEP and is switching to injected Cabotegravir, and who opted to skip the oral CAB lead-in, asked me an excellent question. After reading that the precise lag time from CAB injection to adequate protection is unknown, he asked whether he should continue the TDF/FTC for a few days to overlap the first CAB injection. Any thoughts about how you will advise people making this switch?

Posted 03-28-2022 17:09

Reply | Reply Privately

That's correct, Julia. We don't know how much time it takes after injection to reach adequate tissue levels for Apretude to prevent HIV infection, and there is no guidance currently in the package insert. So, maybe it would be smart to continue oral PrEP for a week or so after the initial injection, if possible. Or, perhaps encourage consistent condom use, at least during that time period. We do know that in the HPTN trials, seroconversion soon after the initial injection (in those newly started on PrEP) was rare. So, that is certainly comforting.

I've been following this conversation as I think these concerns and questions are being discussed by a lot of clinicians who are unsure how to move forward with the recommendation for patients to opt out of the oral lead-in. I'm very concerned about this and Dan Scales thank you for making this make sense and presenting the real challenge with CAB for PrEP.

So, with data showing seroconversion in CAB having delayed diagnosis is this a wise decision to opt out of the oral lead in given the tight window Dan Scales presented? I'm not sure how I feel about this as we have no data to support skipping oral lead in as a good idea.

Cooper, 2022

Learning Objective #3

Discuss the risks and benefits of oral lead-in during the transition from oral to extended-release intramuscular cabotegravir

Pharmacokinetic Evaluation of Long-acting Cabotegravir in Healthy Adults for HIV Exposure Prophylaxis

Phase I, open-label, study

Johns Hopkins Hospital and the University of Pittsburgh Medical Center

19 participants enrolled

- 16 participants completed the study through 52 weeks

Interventions

- 28-day oral lead-in
- 14-42 day washout period
- Cabotegravir 600mg single injection

Follow-up

- Plasma, cervical and rectal tissue/fluids
  - Day 29 of oral dosing period
  - Day 3 and 8, plus weeks 4, 8, and 12 following injection
- Plasma
  - Day 1 and 5, plus weeks 24, 36, and 52 following injection

Primary outcome

- Cabotegravir concentrations in plasma, rectal tissue and fluid, cervical tissue*, and cercovaginal fluid*

Shaik et al. 2021

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  - Day 1 and 5, plus weeks 24, 36, and 52 following injection

Primary outcome

- Cabotegravir concentrations in plasma, rectal tissue and fluid, cervical tissue*, and cercovaginal fluid*

Shaik et al. 2021

Pharmacokinetic Evaluation of Long-acting Cabotegravir in Healthy Adults for HIV Exposure Prophylaxis

Phase I, open-label, study

Johns Hopkins Hospital and the University of Pittsburgh Medical Center

19 participants enrolled

- 16 participants completed the study through 52 weeks

Interventions

- 28-day oral lead-in
- 14-42 day washout period
- Cabotegravir 600mg single injection

Follow-up

- Plasma, cervical and rectal tissue/fluids
  - Day 29 of oral dosing period
  - Day 3 and 8, plus weeks 4, 8, and 12 following injection
- Plasma
  - Day 1 and 5, plus weeks 24, 36, and 52 following injection

Primary outcome

- Cabotegravir concentrations in plasma, rectal tissue and fluid, cervical tissue*, and cercovaginal fluid*

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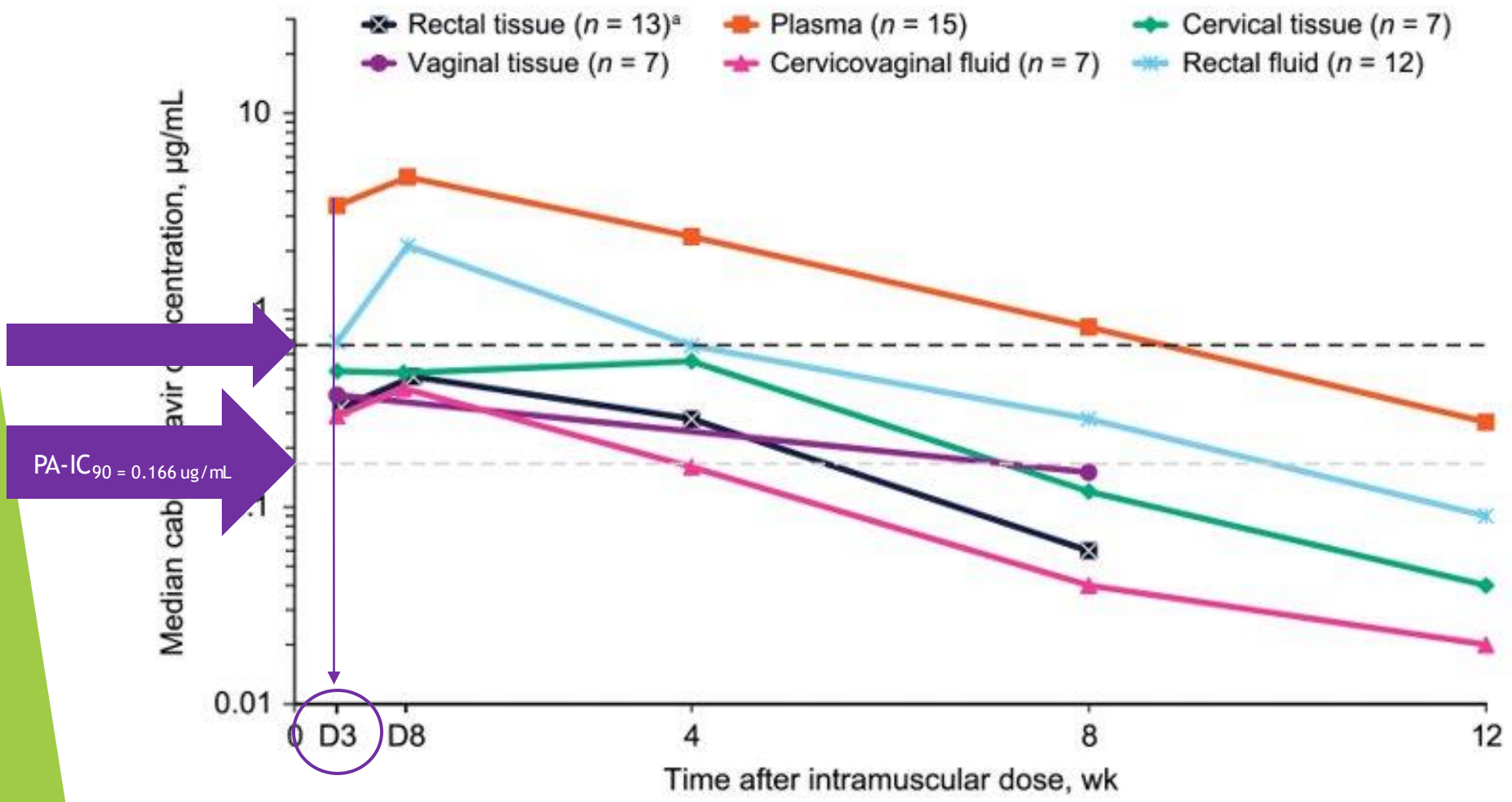
Pharmacokinetic Evaluation of Long-acting Cabotegravir in Healthy Adults for HIV Exposure Prophylaxis

Results



Shaik et al. 2021

Pharmacokinetic Evaluation of Long-acting Cabotegravir in Healthy Adults for HIV Exposure Prophylaxis

Conclusions

- Following a single extended-release intramuscular injection, cabotegravir was detected in tissues and fluids of anatomical sites associated with sexual HIV-1 transmission
- Tissue and fluid cabotegravir concentrations were proportional to plasma over time

Grade 3C

Shaik et al. 2021

How does this apply to our controversy?

It is all about the Pharmacokinetics!!!

Characterizing HIV-Preventive, Plasma Tenofovir Concentrations

Pooled participatnt-level data analysis

Infectious Disease Society of America (IDSA)

N = 2950

- IPREx
- VOICE
- Partners PrEP

Intervention

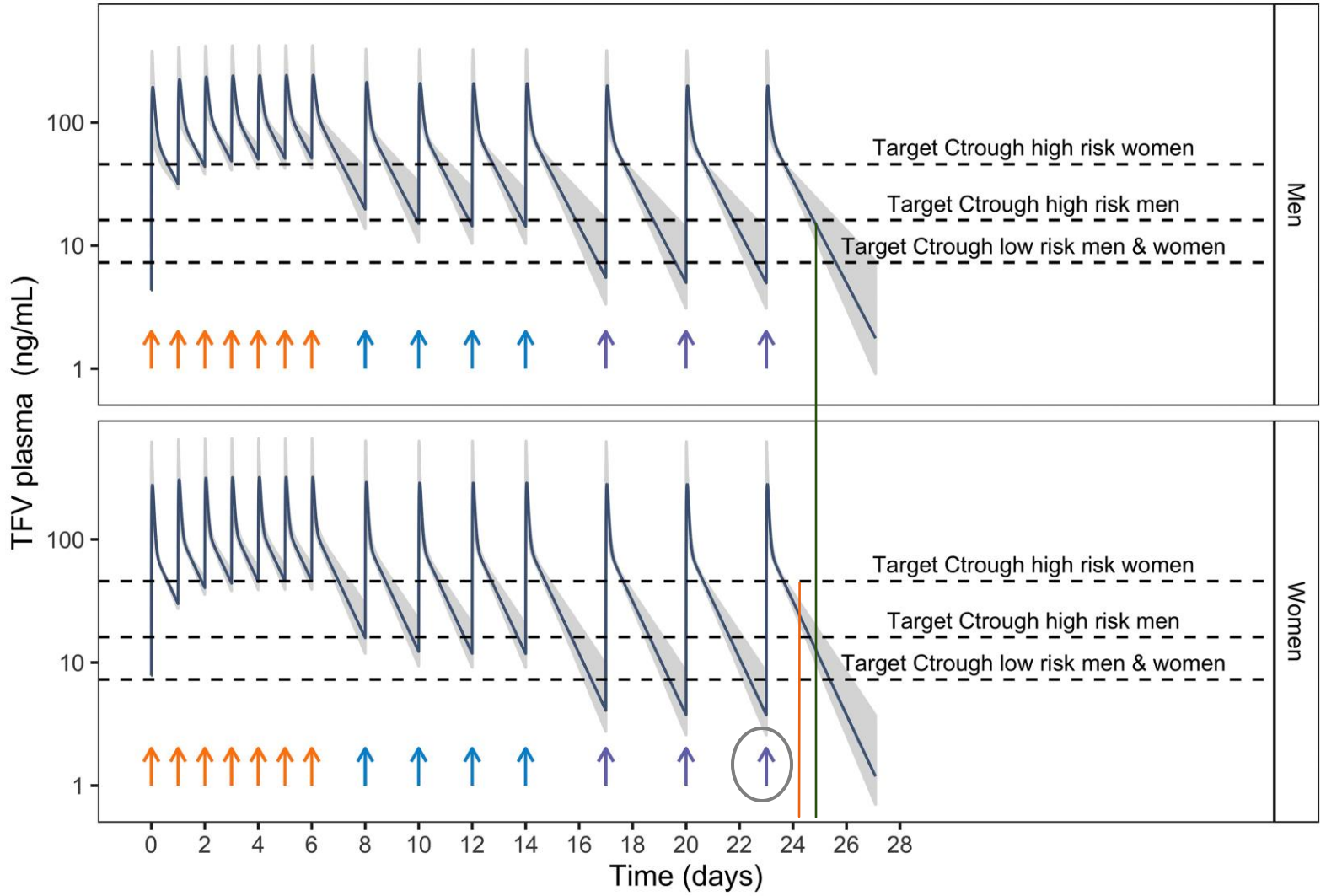
- Tenofovir disoproxil fumarate

Outcomes

- Longitudinal pharamcokinetics
- HIV outcmes
- Individual risk scores
- Effect of sex at birth

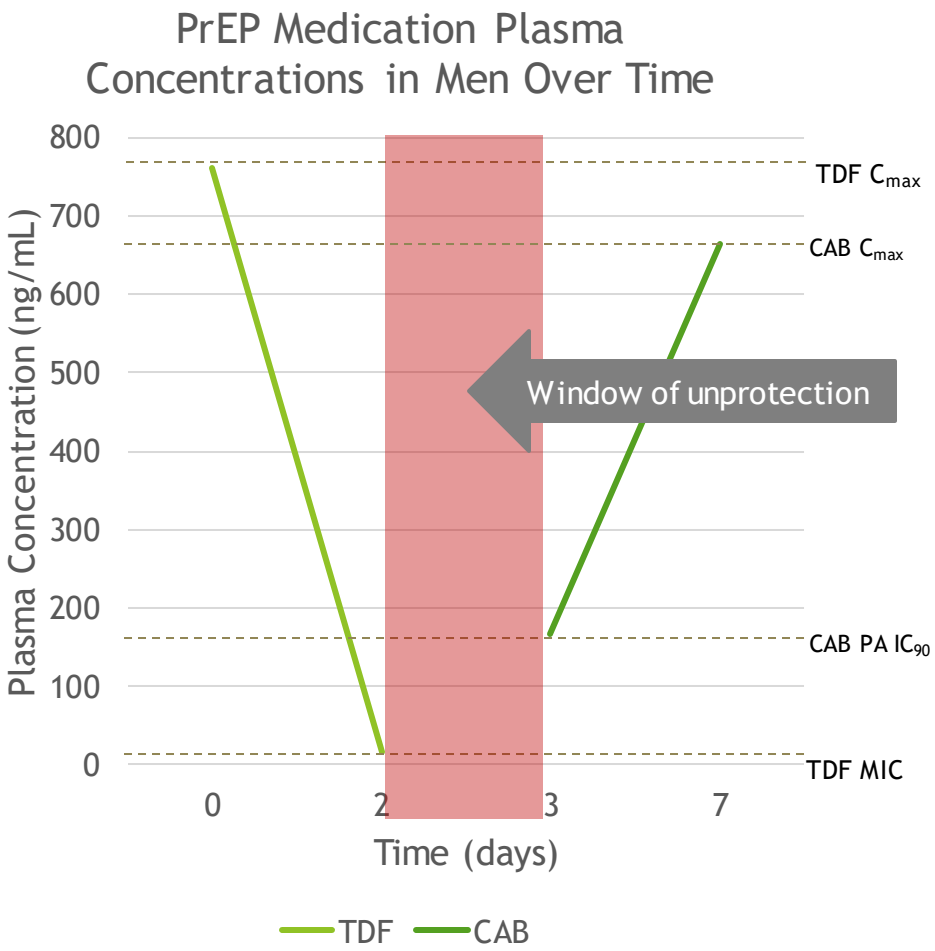
Garcia-Cremades et al, 2022

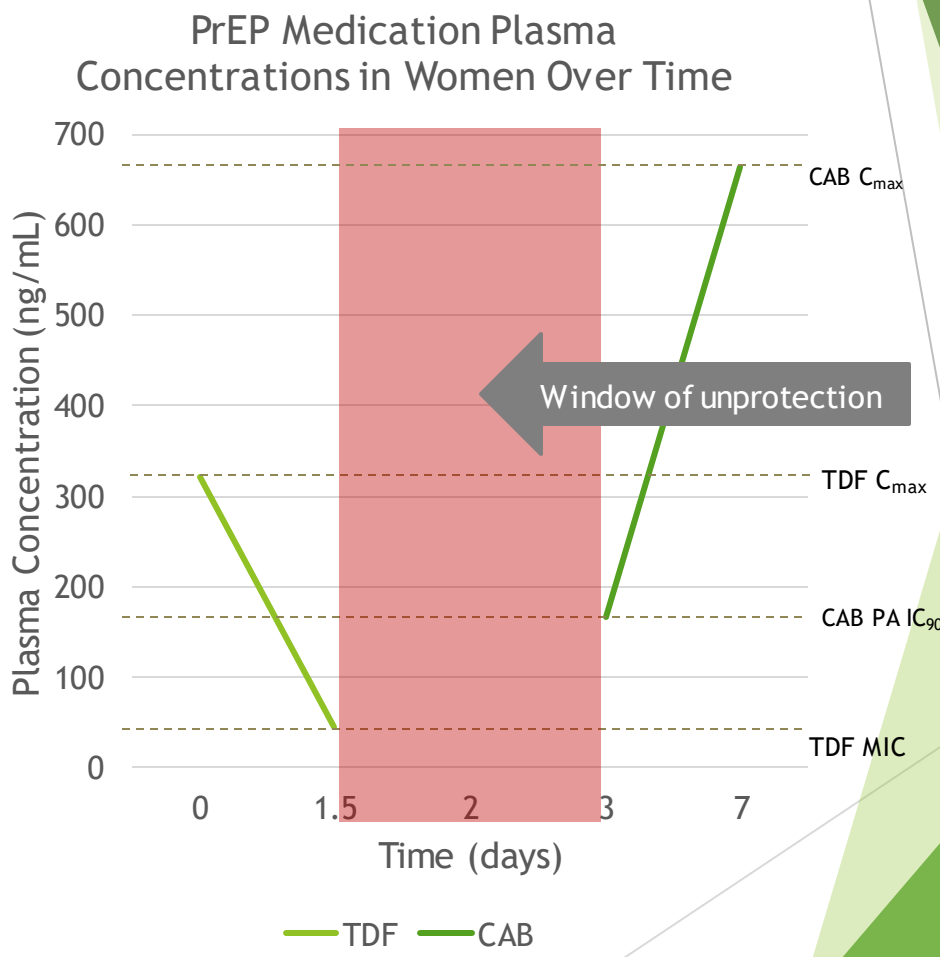
Tenofovir Pharmacokinetics



Garcia-Cremades et al, 2022

Pharmacokinetic Comparisons



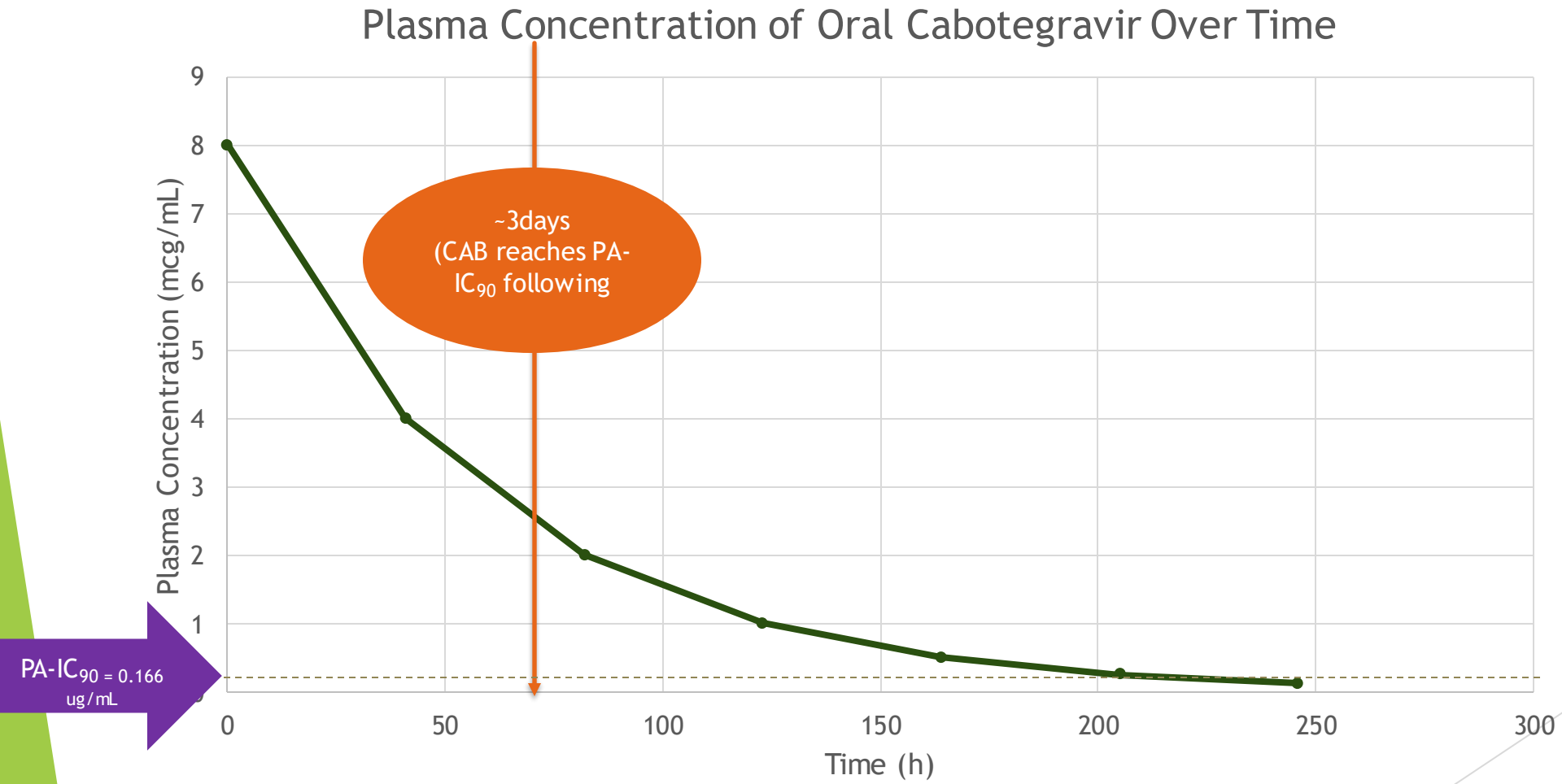


Garcia-Cremades et al, 2022

Cabotegravir (Vocabria) Pharmacokinetics

Half Life (t1/2)	Time (hours)
Cabotegravir (Vocabria)	41

Cabotegravir (Vocabria) Pharmacokinetics



ViiV Healthcare, 2021
Orkin et al, 2020
Overton et al, 2020

HPTN 083, 084: Results

Cabotegravir vs. TDF-FTC

Outcome	HPTN 083 (CAB) N = 2282	HPTN 083 (TDF-FTC) N = 2284	HPTN 084 (CAB) N = 1614	HPTN 084 (TDF-FTC) N = 1610
Incident HIV infection (n (%))	13 (0.52)	39 (1.71)	4 (0.25)	36 (2.24)
Adherence rate (%)	91.5 (concentration)	96.6 (pill count) 74.2 (concentration)	93.1 (concentration)	41.9 (concentration)
Injection site reaction rate (%)	81.4	31.3	38	10.8

The question is...

When patients transition from an oral PrEP therapy to cabotegravir, are they continuously protected following the first injection of CAB without oral lead-in?

What does this mean for clinical practice?

Oral lead-in for extended-release cabotegravir initiation is not necessary for adequate protection

Oral lead-in or oral PrEP therapy overlap might be an appropriate option for some patients

Let’s look at a patient case…

Patient EP, 28 yo, TGM

CC
Presents to the health center today asking if he can be switched to the new injection medication for PrEP he has heard about from some friends.

PMH
None

Social History
- Tobacco use: denies
- Alcohol use: social
- Illicit drug use: marijuana
- Living with HIV positive partner x5 years – partner is out of town on a business trip until March 17th

Current medications
- Emtricitabine/tenofovir disoproxil (Truvada) 300/200mg once daily
- Etonogestrel/ethinyl estradiol (Nuvaring) 11.7/2.7mg vaginally x3 weeks

Medication adherence
2-3 missed doses per week of oral medications

Most recent screen for HIV: negative (March 1, 2023)
Most recent screen for Hepatitis B: negative (January 2018)
Most recent screen for Gonorrhea, Chlamydia, and Syphilis: negative (March 1, 2023)

Vitals	Value	Date
Ht	170 cm	3/8/23
Wt	85 kg	3/8/23
BP	132/78 mmHg	3/8/23
HR	67	3/8/23
RR	16	3/8/23

Labs	Value	Date
SCr	1.1	3/1/23
CrCl	85 mL/min	3/1/23
BUN	18 mmol/L	3/1/23
LDL	70 mg/dl	3/1/23
HDL	60 mg/dl	3/1/23
TG	112 mg/dl	3/1/23
TC	150 mg/dl	3/1/23

The doctor asks you what would be the best plan to transition the patient to cabotegravir (Apretude) for PrEP?

a) The patient is not eligible for cabotegravir therapy. Instead, discontinue Truvada and start Descovy today

b) Give the first injection of cabotegravir (Apretude) today and continue oral PrEP therapy for 7 days.

c) Give the first injection of cabotegravir (Apretude) and discontinue oral PrEP therapy today.

d) Discontinue Truvada and start cabotegravir (Vocabria) 30mg oral daily today. The day after oral lead-in is completed, give the first injection of cabotegravir (Apretude).

The doctor asks you what would be the best plan to transition the patient to cabotegravir (Apretude) for PrEP?

a) The patient is not eligible for cabotegravir therapy. Instead, discontinue Truvada and start Descovy today.

b) Give the first injection of cabotegravir (Apretude) today and continue oral PrEP therapy for 7 days.

c) Give the first injection of cabotegravir (Apretude) and discontinue oral PrEP therapy today.

d) Discontinue Truvada and start cabotegravir (Vocabria) 30mg oral daily today. The day after oral lead-in is completed, give the first injection of cabotegravir (Apretude).

The doctor asks you what would be the best plan to transition the patient to cabotegravir (Apretude) for PrEP?

a) The patient is not eligible for cabotegravir therapy. Instead, discontinue Truvada and start Descovy today.
    a) Our patient IS eligible for cabotegravir (Apretude)
    b) Our patient is NOT eligible for TAF-FTC (Descovy)
        a) Hepatitis B screen >1 year ago
        b) At risk for HIV through vaginal receptive sex
        c) Nonadherent to oral mediations
b) Give the first injection of cabotegravir (Apretude) today and continue Truvada for 7 days.
c) **Give the first injection of cabotegravir (Apretude) and discontinue oral PrEP therapy today.**
d) Discontinue Truvada and start cabotegravir (Vocabria) 30mg oral daily today. The day after oral lead-in is completed, give the first injection of cabotegravir (Apretude).

The doctor asks you what would be the best plan to transition the patient to cabotegravir (Apretude) for PrEP?

a) The patient is not eligible for cabotegravir therapy. Instead, discontinue Truvada and start Descovy today.

b) Give the first injection of cabotegravir (Apretude) today and continue oral PrEP therapy for 7 days.

   a) This treatment regimen is not currently recommended in clinical practice guidelines

   b) Poor oral medication adherence

c) Give the first injection of cabotegravir (Apretude) and oral PrEP therapy today

d) Discontinue Truvada and start cabotegravir (Vocabria) 30mg oral daily today. The day after oral lead-in is completed, give the first injection of cabotegravir (Apretude).

The doctor asks you what would be the best plan to transition the patient to cabotegravir (Apretude) for PrEP?

a) The patient is not eligible for cabotegravir therapy. Discontinue tenofovir disoproxil-emtricitabine (Truvada) and start tenofovir alafenamide-emtricitabine (Descovy) today.

b) Give first injection of cabotegravir (Apretude) today and continue tenofovir disoproxil-emtricitabine (Truvada) for x7 days.

c) Give first injection of cabotegravir (Apretude) and discontinue tenofovir disoproxil-emtricitabine (Truvada) today.

d) Discontinue tenofovir disoproxil-emtricitabine (Truvada) and start cabotegravir (Vocabria) 30mg oral daily today. The day after oral lead-in is completed, give the first injection of cabotegravir (Apretude).

   a) Poor oral medication adherence

   b) Patient prepared to start injection today

The doctor asks you what would be the best plan to transition the patient to cabotegravir (Apretude) for PrEP?

a) The patient is not eligible for cabotegravir therapy. Discontinue tenofovir disoproxil-emtricitabine (Truvada) and start tenofovir alafenamide-emtricitabine (Descovy) today.

b) Give first injection of cabotegravir (Apretude) today and continue tenofovir disoproxil-emtricitabine (Truvada) for x7 days.

c) Give first injection of cabotegravir (Apretude) and discontinue tenofovir disoproxil-emtricitabine (Truvada) today.

d) Discontinue tenofovir disoproxil-emtricitabine (Truvada) and start cabotegravir (Vocabria) 30mg oral daily today. The day after oral lead-in completed, give first injection of cabotegravir (Apretude).

Summary

FDA approved pharmacologic options for PrEP therapy: TDF-FTC (Truvada), TAF-FTC (Descovy), and Cabotegravir (Arpetude)

Cabotegravir (Apretude) might be the better option over oral PrEP therapy in some patients

Pharmacokinetic considerations must be taken into account when starting or stopping PrEP therapy with cabotegravir (Apretude)

More research should be done regarding the transition from oral PrEP to cabotegravir (Apretude) to provide some definitive answers and guidance for therapy initiation

Thank You

Julena Maurer, PharmD

PGY-1 Pharmacy Resident | UPMC Shadyside Hospital

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