AETC AIDS Education & Training Center Program Mountain West

U.S. Public Health Service PrEP for Prevention of HIV in the U.S. – 2021 Update

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Disclosures

- I attended Gilead's 2018 U.S. Latinx/Hispanic PrEP Advisory Program.
- Only FTC/TDF and FTC/TAF are approved by the U.S. FDA and only for use as daily PrEP in some, but not all, populations. This talk will include discussion of other options for PrEP.

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Resources

CDC/HHS

- https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
- https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf

IAS-USA

- https://www.iasusa.org/resources/guidelines/

Clinicians Consultation Center PrEPLine (855-448-7737)

- For questions or ambiguous test results

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Summary of guidance for daily oral PrEP

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications	
Dosage	• Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤90-day supply	
Follow-up care	**Follow-up visits at least every 3 months to provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men[3] – oral, rectal, urine, blood • Access to clean needles/syringes and drug treatment services for PWID **Follow-up visits every 6 months to provide the following:** • Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients[3] – [vaginal, oral, rectal, urine- as indicated], blood **Follow-up visits every 12 months to provide the following:** • Assess renal function for all patients • Chlamydia screening for heterosexually active women and men – vaginal, urine • For patients on F/TAF, assess weight, triglyceride and cholesterol levels	

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Summary of guidance for Cabotegravir

	Sexually-Active Adults	Persons Who Inject Drugs[1]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[2] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection • No signs/symptoms of acute HIV infection • No contraindicated medications or conditions	
Dosage	• 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle o Initial dose o Second dose 4 weeks after first dose (month 1 follow-up visit) o Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)	

p48: "Because of the long duration of drug exposure following injection, exclusion of acute HIV infection is necessary with the most sensitive test available, an HIV-1 RNA assay."

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Summary of guidance for Cabotegravir

Follow-up care	**At follow-up visit 1 month after first injection** • HIV Ag/Ab test and HIV-1 RNA assay **At follow-up visits every 2 months (beginning with the third injection – month 3) provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay • Access to clean needles/syringes and drug treatment services for PWID **At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following:** • Bacterial STI screening[2] for MSM and transgender women who have sex with men[2] – oral, rectal, urine, blood **At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following:** • Bacterial STI screening[1] for all heterosexually-active women and men – [vaginal, rectal, urine - as indicated], blood **At follow-up visits at least every 12 months (after the first injection) provide the following:** • Assess desire to continue injections for PrEP • Chlamydia screening for heterosexually active women and men – vaginal, urine **At follow-up visits when discontinuing cabotegravir injections provide the following:**

- Re-educate patients about the "tail" and the risks during declining CAB levels
- Assess ongoing HIV risk and prevention plans
- If PrEP is indicated, prescribe daily oral F/TDF or F/TAF beginning within 8 weeks after last injection
- Continue follow-up visits with HIV testing quarterly for 12 months

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Who should be prescribed PrEP?

- All sexually active adult and adolescent patients should receive information about PrEP **(IIIB)**
- For both men and women, PrEP with daily F/TDF is recommended for sexually-active adults and adolescents (>35 kg) who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition **(IA)**
- For both men and women, PrEP with daily F/TDF is recommended for persons who inject drugs (PWID) and report injection practices that place them at substantial ongoing risk of HIV exposure and acquisition **(IA**)
- PrEP should be prescribed in discordant couples
  - If the sexual partner with HIV has been inconsistently virally suppressed
  - If their VL is unknown
  - If the HIV-negative partner has other sexual partners
  - If the HIV-negative partner wants the additional reassurance of protection

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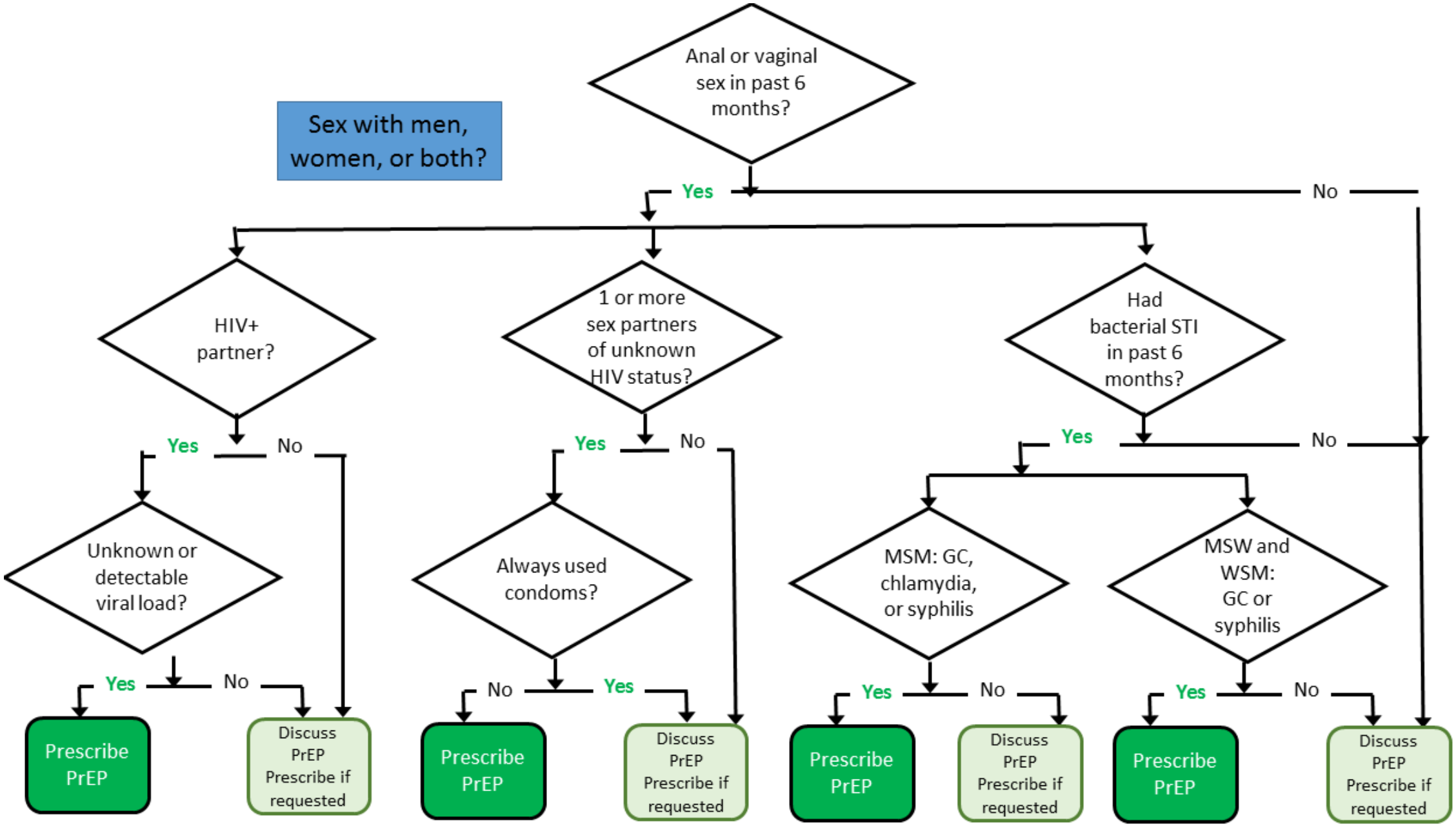
Assessing Indications for PrEP in Sexually Active Persons



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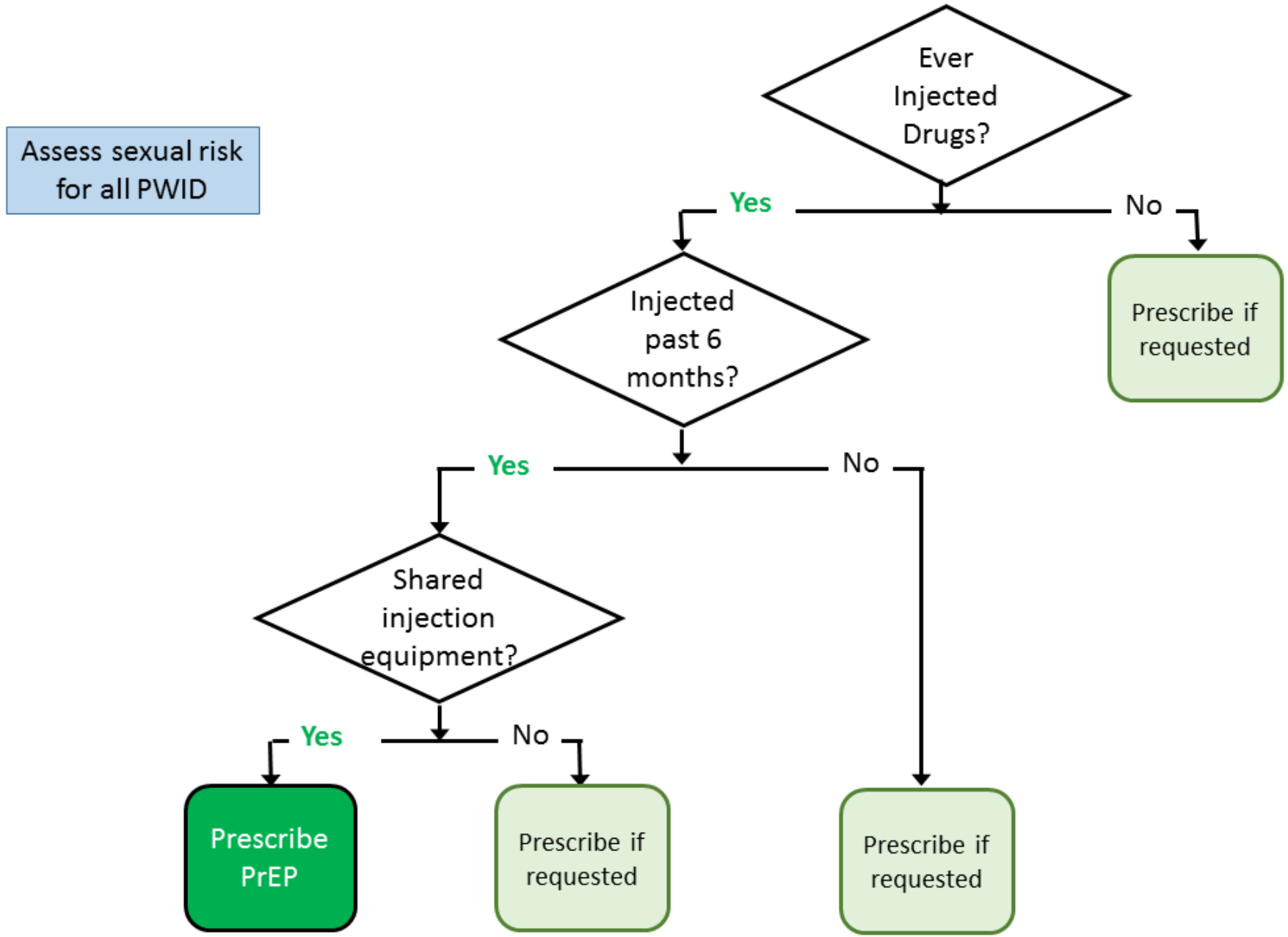
Assessing Indications for PrEP in Persons Who Inject Drugs



What to prescribe as PrEP?
F/TDF v F/TAF

- For most patients, there is no need to switch from F/TDF to F/TAF.
- F/TAF is indicated for patients with eCrCl 30-60.
- Clinicians may prefer F/TAF for patients with previously documented osteoporosis or related bone disease.

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What to prescribe as PrEP?

- For men only, daily oral PrEP with F/TAF is a recommended option for HIV prevention. PrEP with F/TAF has not yet been studied in women and so F/TAF is not recommended for HIV prevention for women or other persons at risk through receptive vaginal sex. **(IA)**
- For transgender women who have sex with men, daily oral PrEP with F/TAF is a recommended option for HIV prevention **(IIB)**
- The efficacy and safety of other daily oral antiretroviral medications for PrEP, either in place of, or in addition to, F/TDF or F/TAF, have not been studied extensively and are not recommended. **(IIIA)**
- Conditioned on a PrEP indication approved by FDA, PrEP with intramuscular cabotegravir (CAB) injections is recommended for HIV prevention in adults and adolescents who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition. **(IA)**

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How to prescribe PrEP?

- Same day PrEP

Same-day PrEP initiation **is not appropriate** for:

- Patients who express ambivalence about starting PrEP (e.g., need more time to think)
- Patients for whom blood cannot be drawn for laboratory testing
- Patients with signs/symptoms and sexual history indicating possible acute HIV infection
- Patients with history of renal disease or associated conditions (e.g., hypertension, diabetes)
- Patients without insurance or a means to pay when picking up the prescribed medication that day
- Patients who do not have a **confirmed** means of contact should laboratory test indicate a need to discontinue PrEP (e.g., HIV infection, unanticipated renal dysfunction)

Same-day PrEP initiation **may not be appropriate** for:

- Patients with a very recent possible HIV exposure but no signs and symptoms of acute infection (should be evaluated for nPEP before PrEP)
- Patients who may not be easily contacted for return appointments
- Patients with mental health conditions that are severe enough to interfere with understanding of PrEP requirements (adherence, follow-up visits)

- 2-1-1 dosing – clinicians may choose to prescribe F/TDF off label using 2-1-1 dosing for adult MSM who have sex less than once/week and can anticipate sex

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Baseline HIV testing

- Document an HIV test within one week before PrEP
- Ideally lab-based Ag/Ab test
- Point-of-care Ag/Ab testing is acceptable when clinicians prescribe PrEP based solely on the results of point-of-care rapid tests, a laboratory antigen/antibody test should always be ordered at the time baseline labs are drawn
- Oral fluid tests should not be used

Monitoring

- HIV infection should be assessed at least every 3 months for patients taking daily oral PrEP, and every 2 months for patients receiving CAB injections for PrEP. **(IA)**
- Estimated creatinine clearance (eCrCl) should be assessed every 6 months for patients over age 50 or those who have an eCrCl <90 ml/min at initiation. **(IIA)**
- For all other daily oral PrEP patients, eCrCl should be assessed at least every 12 months. **(IIA)**
- Triglycerides and cholesterol levels should be checked annually for all persons on F/TAF.
- For CAB – only HIV/STI testing is required.

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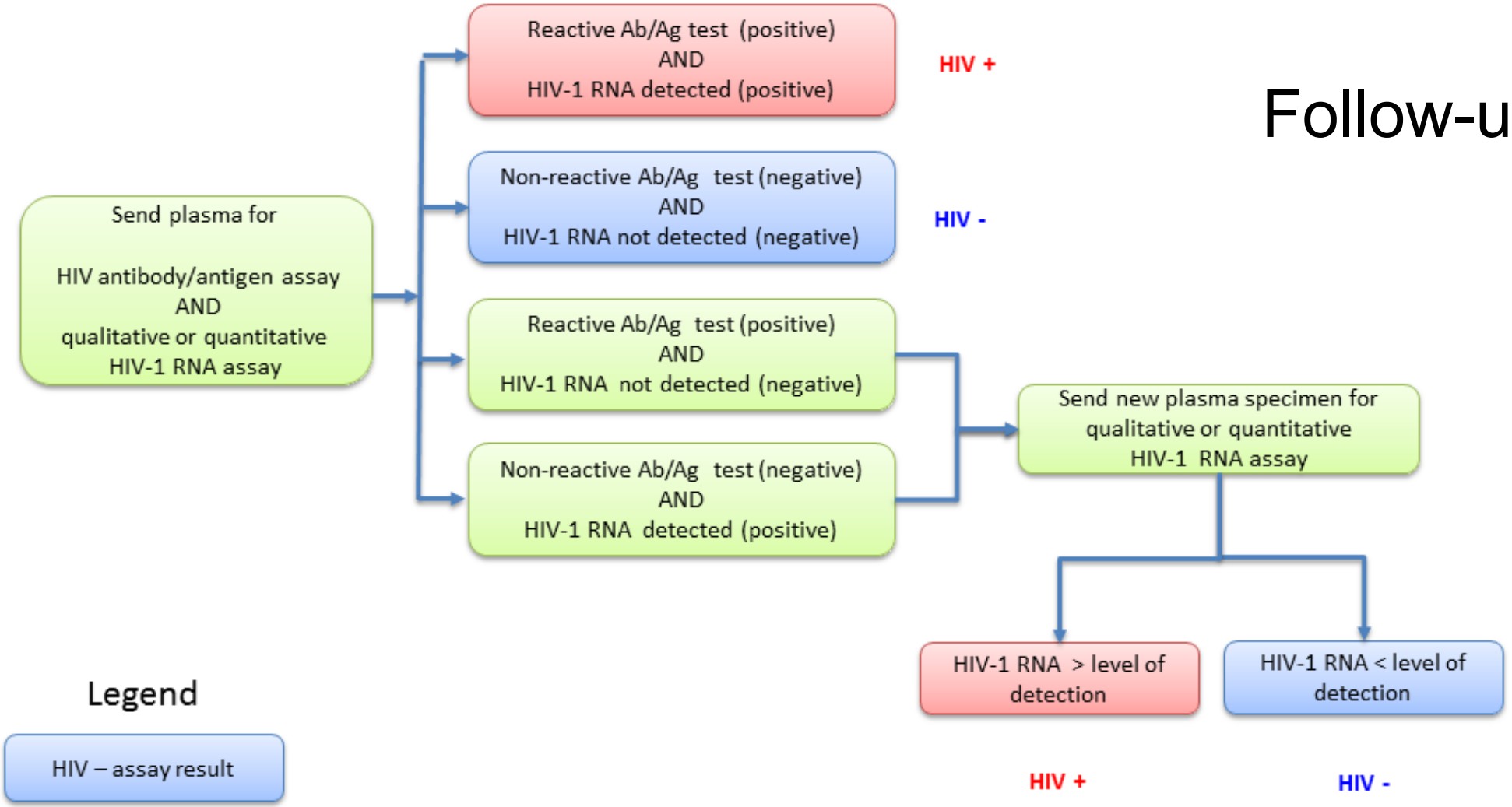
Follow-up HIV testing

If the patient has taken oral PrEP or PEP medication in the past 3 months
OR
has received a cabotegravir injection in the past 12 months



Legend

- HIV – assay result
- HIV + assay result
- HIV Status Unclear

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How feasible will HIV RNA screening be for you?

- No problem at all
- No problem for insured patients, not feasible for uninsured patients
- Not feasible currently because no access to a diagnostic NAT
- Not ever likely to be feasible

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Adherence support

Box B: Key Components of Oral Medication Adherence Counseling

Establish trust and bidirectional communication

Provide simple explanations and education

- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

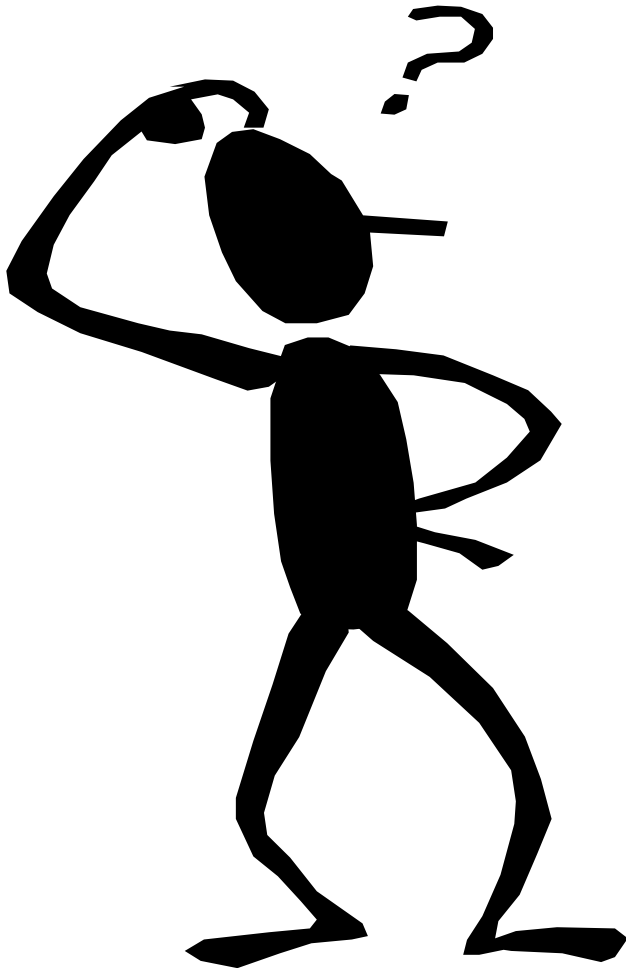
Support adherence

- Tailor daily dose to patient's daily routine
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence
- Reinforce benefit relative to uncommon harms

Monitor medication adherence in a non-judgmental manner

- Normalize occasional missed doses, while ensuring patient understands importance of daily dosing for optimal protection
- Reinforce success
- Identify factors interfering with adherence and plan with patient to address them
- Assess side effects and plan how to manage them

Questions?



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