



**Elizabeth Glaser
Pediatric AIDS Foundation**
Fighting for an AIDS-free generation

Risk & Eligibility Assessment

Ask the following questions. Confirm you are in a private area and ensure confidentiality of information.

<p align="center">Questions: In the last 6 months:</p> <p align="center"><i>If the answer to any of the following questions in YES – proceed with the eligibility assessment.</i></p>	<p align="center">Y/N</p>
Have you been sexually active?	
Have you had more than one sexual partner?	
Have you engaged in sexual relations with someone where neither you nor your sexual partner was wearing a condom?	
Have you engaged in sexual relations with someone you knew was HIV positive or weren't sure of their status?	
In the case you engaged in sex with HIV-positive partners or persons of unknown HIV status, was a condom used?	
Have you injected drugs that were not prescribed by healthcare provider?	
If yes, did you use syringes, needles or other equipment that had been used by someone else?	
Have you had sex while you or your partner was under the influence of alcohol or drugs?	
Have you had an STI?	
Have you come for PEP more than once?	
Have you experienced violence or sexual coercion by a sexual partner or any other person?	
Are you in a relationship with someone who was newly diagnosed with HIV?	
<p align="center">Additional Items</p> <p align="center"><i>*The individual does NOT need to meet ALL of the following criteria. Answers can inform content in counselling</i></p>	<p align="center">Y/N</p>
Has the individual been confirmed as HIV negative (rapid antibody testing following HTS algorithm on the day of PrEP initiation discussion)	
<p>The individual is free from other illness within the past month consistent with acute HIV infection in combination with preceding high-risk exposure of HIV, including:</p> <ul style="list-style-type: none"> • Sore throat • Fever • Muscle or joint pains • Swollen glands • Diarrhea • Headache <p>*Yes = the individual has NOT experience any of the symptoms in the previous month; No= the individual HAS experience one or more of the symptoms in the previous month</p>	

The individual has no contraindication to use of TDF +/- FTC (or 3TC) *Yes = the individual has no contraindication to use of TDF +/- FTC (or 3TC) No= the individual HAS contraindication to use of TDF +/- FTC (or 3TC)	
The individual is >35KG and >15 years	
The individual has healthy kidney function (creatinine clearance = < 90 ml/min or dipstick proteinuria > 1 for CrCl calculations)	



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Counseling & Readiness Assessment

This is the time to discuss more in-depth the details and important elements around PrEP the individual needs to know and understand before formally expressing willingness to initiate PrEP.

Counseling checklist	
Item to be discussed:	Check Box
<p>Explain more about PrEP:</p> <ul style="list-style-type: none"> • What it is • How it works • How to take PrEP • Potential side effects • Expectations when using it to ensure efficacy • That it can be stopped at any time or taken seasonally <p>Important things to discuss:</p> <ul style="list-style-type: none"> * Benefits, risks, and side effects of PrEP *Importance of strict medication adherence *Continued safer sex practices *Maintaining regular follow-up appointments 	
Allow time for questions and concerns (refer to FAQ sheet)	
<ul style="list-style-type: none"> • If the individual is <i>not willing</i> to commit – refer to risk reduction counseling and other prevention packages of care • If an individual <i>agrees to continue</i> in the initiation process. Ask the following questions to confirm their willingness 	
<p style="text-align: center;">Readiness assessment</p> <p>*If the individual responds YES to ALL items, move on to PrEP initiation</p> <p>If they respond NO to any items – clarify to address concerns or refer to another prevention package</p>	Y/N
Do you understand what has been explained to you on PrEP today?	
<p>Are you ready and willing to initiate PrEP today recognizing that:</p> <ul style="list-style-type: none"> • PrEP needs to be taken every day to be effective • PrEP does NOT protect against other STIs (aside from HIV) or pregnancy • You will need to come to the clinic quarterly to check in on how it is going and do an HIV test every three months • You can stop and restart at any time but it is recommended to talk to your provider 	
Allow time for additional questions and concerns	



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Criteria when to discontinue PrEP

- Tests HIV-positive
- Change in risk status (low risk)
- Renal dysfunction with creatinine clearance below 50 ml/min
- Client request to stop
- Sustained non-adherence
- The HIV positive partner in a discordant relationship achieves confirmed undetectable viral load [U=U]. But the couple should continue consistent condom use
- Risks outweigh benefits
- Request of user

Final Pre-Initiation Checklist

Review the checklist below to make sure all elements have been completed before initiating the individual on PrEP.

Item	Check Box
Taken an HIV rapid test on the same day with a confirmed HIV-negative result	
Confirmed the individual has NOT experienced any symptoms of acute viral infection in combination with preceding high-risk exposure of HIV in the last six weeks <ul style="list-style-type: none"> • Sore throat • Fever • Muscle or joint pains • Swollen glands • Diarrhea • Headache <i>*If the individual has any of these symptoms – need to complete an HIV RNA or p24 antigen test. The client may also be asked to come back for retesting after 6 weeks</i>	
Completed a behavior risk assessment	
Completed a substance and mental health screening	
Collected and documented partner information	
Confirmed readiness and willingness to initiate and commit to taking PrEP	
Completed STI screening and treatment	

Collected and documented medical history		
Discussed plans for accessing PrEP and ongoing check-in visits		
Confirmed serum creatine and creatinine clearance > 50 ml/min		
Checked for hepatitis B status by conducting HBsAg test ¹ <ul style="list-style-type: none"> • if HBsAg was negative, offer HBV vaccination • if HBsAg positive, can still initiate on PrEP and need to refer the patient for follow up with the specialist 		
Checked for hepatitis C status by conducting HCV serology		
For Women	Check Box	
Conduct a pregnancy test		
Discuss pregnancy and pregnancy intention ² <ul style="list-style-type: none"> • Is the client trying to conceive? • Is the client pregnant or breastfeeding? • Discuss safety around PrEP and pregnancy. Note: PrEP is not contraindicated in Pregnancy, therefore pregnant clients who're eligible for PrEP should be initiated on PrEP 		
Confirm whether the individual is using any contraception		
If not - discuss interest in using PrEP, long term hormonal contraception in addition to condoms		
For Pregnant Women – PrEP Screening Questions³	Yes	No
Has the client received a positive HIV test immediately prior to initiating PrEP?		
Does the client have any signs or symptoms of acute HIV infection? Acute HIV infection may include signs and symptoms of fever, sore throat, aches and pains, lymphadenopathy (swollen glands), mouth sores, headache, or rash. If the client has any of these signs or symptoms, the health provider should consider the possibility that acute HIV is present. In such circumstances, consider deferring PrEP start for 4 weeks and having the person tested for HIV again, which will allow time for possible HIV seroconversion to be detected		
Does client have any probable recent exposure to HIV? Possible HIV exposure in the previous 72 hours should not be offered PrEP but instead be offered PEP. Then, retest the client for HIV after 28 days. PrEP may be offered to clients who test negative at this point. However, PrEP does not need to be held while waiting for the 28-day test; there should be no gap in medication provision as individuals transition from PEP to PrEP.		
Does client have a confirmed allergy or contraindication to any medicine in the PrEP regimen?		
Does client have an estimated creatinine clearance of less than 60 ml/min (or a serum creatinine level of greater than 0.9 mg/dL, if pregnant) (where screening is feasible)?		

1 No contraindication between PrEP and being HBsAg-positive - However, will require monitoring of liver function and referral for management of liver disease

2 Pregnancy and breastfeeding are not contraindications to provision of PrEP. Pregnant or breastfeeding women whose sexual partners are HIV positive or are at high risk of HIV infection may benefit from PrEP as part of combination prevention of HIV infection. PrEP is also indicated for HIV-negative in discordant partnerships who wish to conceive. PrEP in these situations can be prescribed during the pre-conception period and throughout pregnancy to reduce risk of sexual HIV infection.

3 Appendix 1 - https://www.prepwatch.org/wp-content/uploads/2020/12/PrEP_for_PBFW_SampleClinicalPracticeGuidelines.pdf

<p>Does client have a current diagnosis of impaired liver dysfunction, kidney dysfunction, or pre-eclampsia?</p> <p>In the case of pre-eclampsia, it is generally safe to start or restart PrEP after delivery, provided the client has normal laboratory tests for kidney function (e.g., serum creatinine), as most cases of pre-eclampsia resolve shortly after birth.</p>		
<p>Does client have a positive test for hepatitis B virus (where screening is feasible)?</p>		

Pregnancy and PrEP

Women who are pregnant or breastfeeding are still eligible to start and take PrEP. Women who also become pregnant while on PrEP can continue taking it throughout their pregnancy and breastfeeding periods.

PrEP is safe and recommended to keep pregnant women and their babies HIV negative. Several studies have been conducted to assess the efficacy of PrEP in pregnant women and no findings have suggested a connection to risks of any birth defects or complications. Studies have also determined no impact on a mother’s milk supply during breastfeeding or the quality of milk. PrEP is also safe to use in combination with other family planning methods – like condoms – to also prevent other STIs.

Pregnancy women on PrEP will receive repeat HIV testing every three months during pregnancy and breastfeeding.

Additional guidance: https://www.prepwatch.org/wp-content/uploads/2020/12/PrEP_for_PBFW_SampleClinicalPracticeGuidelines.pdf

Couple desire to conceive with PrEP

HIV-negative women who would like to conceive with a male partner who is HIV positive can safely do so while on PrEP. Truvada (tenofovir disoproxil fumarate/emtricitabine) has been approved for this use and PrEP. Descovy (tenofovir alafenamide/emtricitabine) is also approved as PrEP, but not for cisgender women.

It is safe to take PrEP while trying conceive. No concerns of safety or efficacy have been shown in evaluations.