**Guideline Addendum for Oral Pre-Exposure Prophylaxis: TEMPLATE LANGUAGE**

**January 2022**

|  |
| --- |
| The intent of this document is to provide an adaptable template for an addendum to align national oral pre-exposure prophylaxis (PrEP) guidelines with the World Health Organization’s (WHO’s) updated and clarified recommendations on oral PrEP. This addendum may be used to update and clarify existing national guidelines to ensure wider access to oral PrEP. Areas requiring national updates are indicated in red.  The content of the document was sourced largely from [*Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach*](https://www.who.int/publications/i/item/9789240031593), which was formally released by WHO in July 2021, with further updates outlined in a [presentation](https://unaids-my.sharepoint.com/personal/zembel_unaids_org/_layouts/15/onedrive.aspx?id=%2Fpersonal%2Fzembel%5Funaids%5Forg%2FDocuments%2FDocuments%2FGPC%20Monitoring%2F2021%2FPrEP%2FPrEP%20webinar%2FPrEP%20Webinar%2027%20October%202021%2FGPCwebinar%5FWHOupdatesPrEP%2Epdf&parent=%2Fpersonal%2Fzembel%5Funaids%5Forg%2FDocuments%2FDocuments%2FGPC%20Monitoring%2F2021%2FPrEP%2FPrEP%20webinar%2FPrEP%20Webinar%2027%20October%202021) from WHO during a public webinar in October 2021. Additional guidance on differentiated service delivery and the use of HIV self-testing for PrEP are expected in 2022.  This document was developed by the Collaboration for HIV Options to Control the Epidemic (CHOICE) in close collaboration with the U.S. Agency for International Development (USAID). CHOICE is a collaboration between the USAID-funded Meeting Targets and Maintaining Epidemic Control (EpiC) and Reaching Impact, Saturation and Epidemic Control (RISE) projects. Countries should use this document as appropriate, depending on their needs and settings; CHOICE branding or acknowledgement is optional. |

This guideline addendum serves as an update to previous national guidance on oral pre-exposure prophylaxis (PrEP) in [country]. The content below about the necessity and frequency of diagnostics for oral PrEP service delivery, event-driven PrEP (ED-PrEP), and starting and stopping oral PrEP overrides previous requirements and recommendations.

**Assessing and Monitoring Renal Function**

|  |  |  |
| --- | --- | --- |
| **Population(s)** | **Initiation Screening** | **Follow-up Screening** |
| Individuals 29 years and younger with no kidney-related comorbidities | Optional | If not conducted or if baseline test is normal, follow-up is optional until 30 years of age or if kidney-related comorbidities develop.  If conducted, and baseline test result is <90 mL/min, conduct follow-up screening every six to 12 months, if available. |
| Individuals 30–49 years with no kidney-related comorbidities | Conduct once within one to three months of oral PrEP initiation, if available. | If baseline test is normal, further screening is optional until 50 years of age or if kidney-related comorbidities develop.  If baseline test result is <90 mL/min, conduct follow-up screening every six to 12 months, if available. |
| Individuals 50 years and older  Individuals of any age with kidney-related comorbidities  Individuals with previous creatinine screening of <90 mL/min | Conduct once within one to three months of oral PrEP initiation, if available. | Conduct follow-up screening every six to 12 months, if available. |

When screening is conducted, any individual with a result ≥60 mL/min can safely be prescribed oral PrEP. Since results can be reviewed at a follow-up visit, a wait for results should not delay oral PrEP initiation. If the results are <60 mL/min, the test should be repeated on a separate day before stopping oral PrEP, and oral PrEP should be stopped if the result of the repeat test is also abnormal. Creatinine clearance usually returns to normal levels after stopping PrEP. Oral PrEP can be restarted if results are confirmed to be ≥60 mL/min within one to three months after stopping oral PrEP.

**Hepatitis B**

Testing for hepatitis B surface antigen (HBsAg), once at initiation or within three months of initiation, is strongly encouraged but not required for oral PrEP use. Hepatitis B infection is not a contraindication for oral PrEP (daily or ED) use, and oral PrEP can safely be offered to a person with hepatitis B infection. Individuals with detectable HBsAg should be considered for treatment. Individuals with non-reactive HBsAg test may be considered for hepatitis B vaccination.

**Hepatitis C**

Testing for hepatitis C antibodies at initiation or within the first three months of initiation and every 12 months thereafter is strongly encouraged based on local epidemiological context but not required for oral PrEP use. Hepatitis C infection is not a contraindication for oral PrEP (daily or ED) use, and oral PrEP can safely be offered to a person with hepatitis C infection. Individuals with reactive serology should be assessed for treatment for hepatitis C.

**ED-PrEP**

ED-PrEP can be used to prevent HIV acquisition during sex by all people assigned male at birth (AMAB) who are not using estradiol-based exogenous hormones, such as gender-affirming hormones. This will include all cisgender men, transgender women, and nonbinary people who are not taking estradiol-based exogenous hormones. Chronic hepatitis B infection is not a contraindication for ED-PrEP; therefore, testing for hepatitis B before initiating ED-PrEP is not required (but strongly encouraged, see above). To start ED-PrEP, a double dose should be taken two to 24 hours before potential sexual exposure. Clients should be encouraged to take the loading dose as close to 24 hours before exposure as possible.

**Starting and Stopping Oral PrEP Safely**

|  |  |  |
| --- | --- | --- |
| **Population (s)** | **Starting Oral PrEP** | **Stopping Oral PrEP** |
| People assigned male at birth using PrEP to prevent HIV acquisition during sex who are not using estradiol-based exogenous hormones | Take a double dose two to 24 hours before potential sexual exposure, regardless of whether the intention is to use daily PrEP or ED-PrEP. Ideally, this loading dose should be taken closer to 24 hours before potential exposure. | Take a single dose daily for two days after the last potential exposure, regardless of whether the individual is using daily or ED-PrEP. |
| People using oral PrEP to prevent HIV acquisition from nonsexual exposures  People assigned female at birth  People assigned male at birth who are using estradiol-based exogenous hormones | Take a single dose daily for seven days before potential exposure. | Take a single dose daily for seven days after last potential exposure. |