Annex 4 to the Standards
of Medical Care "HIV
Infection"
(paragraph 5 of Standard 1)

MEDICATED PRP FOR HIV INFECTION

Oral PrEP is prescribed for the prevention of HIV infection in people who are at increased risk of infection, people from key and vulnerable populations for HIV infection as part of combined measures to prevent HIV transmission. Information, counselling and prescribing of PrEP are carried out as part of combined prevention and as part of integrated HIV prevention services, such as condom provision, HIV testing, diagnosis and treatment of STIs, counselling on PrEP adherence, contraceptive use for women, and PTAO programmes.

PrEP involves the oral combination form of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC).

Daily oral PrEP can be given regardless of gender, sexual orientation, or sexual behavior.

PrEP-P is recommended for cisgender men, as well as transgender people and people with diverse gender self-identification, whose sex was determined to be male at birth, who do not take exogenous hormonal drugs based on estradiol and are at risk of HIV infection through sexual contact.

List of examinations before prescribing PrEP Mandatory:

- HIV testing: A negative HIV test result must be documented before starting PrEP.
- Determination of serum creatinine and calculation of creatinine clearance*.
- HBV screening: HBsAg**. People who test positive for HBsAg are recommended to take PrEP on a daily regimen.

Coveted:

- STI screening according to industry standards. People with STIs are prescribed PrEP and referred for appropriate treatment.
- HCV screening according to industry standards. If HCV is detected, the person is referred for appropriate treatment.
- If HBV** is detected, the person is referred for appropriate treatment. In the absence of HBV markers, vaccination is offered.

Note. *Must be carried out within the first three months from the start of PrEP. Waiting for the result should not be a barrier to prescribing PrEP.

**Must be done within the first three months of starting PrEP. Waiting for the HBsAg test result should not be a barrier to prescribing PrEP.

Waiting for the result should not be a barrier to prescribing PrEP.

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HCV screening is recommended every 12 months, especially for MSM, for people who inject drugs and people in prisons and other closed institutions.

Contraindications to PrEP

- Laboratory-confirmed positive HIV status of the person.
- Estimated creatinine clearance <60 ml/min.
- Signs/symptoms of acute HIV infection, likely recent risk of HIV infection.
- Contraindications to any component of PrEP.

Counselling of people who are prescribed PrEP

Counseling people before prescribing PrEP consists of informing and examining to identify contraindications:

a) assessment of the risks of HIV sexually transmitted infection (Annex 2);

b) discussion about the willingness and readiness to take PrEP;

c) development of a plan for effective prophylactic use of medicines, and choosing a PrEP scheme;

d) informing that PrEP provides protection against HIV infection after:

- 7 doses according to the daily regimen;
- 2 doses according to the PrEP-P regimen;

e) informing about possible PRs and necessary actions in case of their occurrence;

f) discussing the need for additional prophylaxis, as PrEP does not protect against STIs and unwanted pregnancies, as well as referrals for condoms and lubricants;

g) counselling on sexual and reproductive health, family planning, the use of means to prevent unwanted pregnancy and methods of safe conception;

h) assessment of the risk of intimate partner violence;

k) assessment of the use of surfactants and the presence of mental health problems Health.

PrEP schemes

PrEP with daily intake

Anyone at increased risk of HIV infection is given a combined TDF/FTC formulation according to the scheme of one tablet once a day 7 days before a risky exposure to HIV infection, then continued daily during the period of risk of infection and an additional 7 days after a potentially risky exposure for HIV infection:

7 days + (X days) + 7 days,

where X is the number of days during which a person is at risk of infection.

PrEP-P according to the "2+1+1" scheme

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It is recommended for cisgender men, transgender people, and people with diverse gender self-identification, whose sex was determined to be male at birth, who are not taking exogenous estradiol-based hormonal drugs, are at risk of HIV sexually transmitted

infection, have sexual intercourse less than 2 times a week, and can schedule sexual intercourse at least 2 hours in advance, or may delay sexual intercourse for at least 2 hours.

For PrEP-P, the combined TDF/FTC dosage form is prescribed according to the scheme: two tablets in the period from 2 to 24 hours before sexual intercourse, 24 hours after taking the first two tablets - one tablet, 48 hours after taking the first two tablets - taking the fourth tablet.

The PrEP-P regimen is prescribed when it comes to separate sexual intercourse. If sexual intercourse also occurs in the following days, PrEP can continue to be taken one tablet daily as long as sexual activity continues, and then for another two days after the last sexual intercourse.

Advising on the effectiveness and importance of adherence to PrEP regimen and adherence

PrEP is a highly effective method of preventing HIV infection only if it is adhered to.

PrEP is taken with or without food.

If PrEP has been missed, the missed dose should be taken as soon as it is mentioned.

PrEP is effective and safe when taken with hormonal contraceptives.

PrEP has no undesirable interactions with alcohol and surfactants.

Pregnancy and breastfeeding are not contraindications for prescribing and taking PrEP.

Counseling on the termination of PrEP

PrEP is stopped after the end of the period of risky HIV practices.

PrEP-P can be stopped 48 hours after the last potentially risky exposure to HIV infection.

Daily PrEP can be discontinued 7 days after the last potentially risky exposure to HIV infection.

PrEP users are recommended to undergo systematic routine HIV testing after its cessation and return to PrEP in case of resumption of risky practices.

In the presence of chronic HBV, an assessment is made whether PrEP should be discontinued, as TDF is also active against HBV, and if discontinuation Continuation of Appendix 4

There is a risk of reactivation of HBV infection. People with established chronic HBV infection should be clinically monitored for HBV exacerbation after PrEP discontinuation.

Developing and adhering to clinical routes to ensure the implementation of all phases of PrEP

PrEP scheme	PrEP with daily intake	PrEP-P

Target group	All people who are at increased risk of HIV infection, regardless of gender, sexual orientation or sexual behavior.	Cisgender men, transgender people, and people with diverse gender self-identification, whose sex was determined to be male at birth and who do not take exogenous estradiol-based hormonal drugs.
Identifying the risk of HIV infection	• Belonging to key or vulnerable populations (Annex 1); • the presence of an HIV-positive sexual partner who is not receiving ART or is receiving HIV but has not achieved virologic suppression of HIV or the level of HIV in the partner is unknown; • if there are doubts about the effectiveness of HIV treatment in a sexual partner; • if the sexual partner with HIV skips ART or the couple does not openly discuss HIV treatment, adherence to treatment, and HIV test results; • prescribing PEP because of the risk of HIV infection within the last 6 months; • having vaginal or anal sex without condoms with more than one partner in the last 6 months; • having a sexual partner with risky HIV behaviour; • the presence or recent treatment of an STI diagnosed by laboratory or anamnesis (within the last 6 months).	

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Evaluation of clinical criteria	• Documented negative HIV testing before PrEP; • absence of signs/symptoms of acute HIV infection; • no contraindications to TDF/FTC.

Assignment Scheme	TDF/FTC daily, 1 tablet per day	TDF/FTC in the period from 2 to 24 hours before sexual intercourse - two tablets, then 24 hours after taking the first two tablets - one tablet, 48 hours after taking the first two tablets - taking the fourth tablet.
Observations and other activities	Follow-up visits are scheduled at least every 3 months to receive medications, counseling on adherence, assessment of PR, support for the formation of safe behaviors to prevent HIV infection, and assessment of symptoms of STIs. HIV testing is carried out one month after the start of PrEP. In the future, HIV testing should be carried out quarterly throughout the entire period of taking any PrEP regimen. In the event of emergencies caused, in particular (but not limited to) by an epidemic or other dangerous event that has led (or may lead) to a threat to the life or health of the population, the imposition of martial law on the territory of Ukraine or in some of its areas, etc., it is possible for the patient to self-test for HIV if it is impossible to get to the HIV testing point and issue PrEP for a longer period. People starting PrEP with either regimen should have their serum creatinine measured once for the first three months after initiation of PrEP. People with a history of comorbidities, including diabetes mellitus or hypertension, people over 50 years of age, and those with a history of creatinine clearance <90 mL/min, should be screened for creatinine clearance every 6 to 12 months after initial determination.	

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	Screening for STIs should be done every three months. HCV screening every 12 months.

Cessation of PrEP	7 days after the last risky exposure, if the patient is no longer at risk of HIV infection.	48 hours after the last risky exposure, if the patient is no longer at risk of HIV infection.