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DECREE OF THE MINISTRY OF HEALTH
OF THE REPUBLIC OF BELARUS
July 25, 2022 No. 73

On approval of the clinical protocol

On the basis of the ninth paragraph of the first part of Article 1 of the Law of the Republic of Belarus of June 18 1993. № 2435-XII "Oh health care", Subparagraph 8.3 paragraph 8, subparagraph 9.1 Paragraph 9 Position about Ministry Health of the Republic of Belarus approved by the resolution of Council of Ministers of the Republic of Belarus of October 28, 2011 No. 1446, the Ministry of Health of the Republic of Belarus DECIDES:

1. Approve the clinical protocol "Provision of medical care to patients with HIV infection" (attached).

2. To declare invalid the resolution of the Ministry of Health of the Republic of Belarus of June 1, 2017 No. 41 "On approval of the clinical protocol "Diagnosis and treatment of patients with HIV infection".

3. This resolution shall enter into force after its official publication.

Minister **D.L.Pinevich**

AGREED
Brest Regional Executive Committee

Vitebsk Regional Executive Committee

Gomel Regional Executive Committee

Grodno Regional Executive Committee

Mogilev Regional Executive Committee

Minsk Regional Executive Committee

Minsk City Executive Committee

Ministry of Internal Affairs of the Republic of Belarus

Office of the President of the Republic of Belarus

State Border Committee of the Republic of Belarus

Ministry of Defense of the Republic of Belarus APPROVED

Decree of the Ministry of Health
of the Republic of Belarus
25.07.2022 № 73

CLINICAL PROTOCOL "Provision of medical care to patients with HIV infection"

CHAPTER 1

GENERAL PROVISIONS

1. This clinical protocol establishes general requirements for the scope of medical care for patients with infection caused by the human immunodeficiency virus (hereinafter referred to

as HIV) (code according to the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (hereinafter referred to as ICD-10) - B20-B24 Disease caused by the human immunodeficiency virus [HIV]; Z01.8 Other specified special examination; Z04.2 Inspection and observation after an accident at work; Z04.3 Examination and observation after another accident; Z09.8 Follow-up examination after another treatment for other conditions; Z11.4 Special screening for human immunodeficiency virus [HIV] infection; Z20.6 Contact with the patient and the possibility of infection with the human immunodeficiency virus [HIV]; Z21 Asymptomatic infection status caused by human immunodeficiency virus [HIV]; Z51.8 Other specified type of medical care; Z71.7 Counselling on issues related to human immunodeficiency virus [HIV]; Z72.2 Drug use; Z72.5 High-risk sexual behavior; Z91.8 Personal history of other specified risk factors not elsewhere classified).

2. The requirements of this clinical protocol are mandatory for legal entities and individual entrepreneurs engaged in medical activities in accordance with the procedure established by the legislation on health care.

3. For the purposes of this clinical protocol, terms and their definitions are used in the meanings established by the Law of the Republic of Belarus "On Health Care", the Law of the Republic of Belarus of November 19, 1993 No. 2570-XII "On the Rights of the Child", as well as the following terms and their definitions:

antiretroviral therapy (hereinafter referred to as ART) - treatment with the use of antiretroviral drugs (hereinafter referred to as ARV-drugs) of at least two different classes, which allows to suppress HIV replication;

ARV-LS is a drug (hereinafter referred to as a drug) that inhibits HIV replication. The following main classes of ARV-drugs are distinguished: nucleoside reverse transcriptase inhibitors (hereinafter referred to as NRTIs), non-nucleoside reverse transcriptase inhibitors (hereinafter referred to as NNRTIs), protease inhibitors (hereinafter referred to as PIs) with a pharmacological amplifier
(booster) (hereinafter referred to as IP/b) and integrase inhibitors (hereinafter referred to as AI);
viral suppression - suppression of HIV replication as a result of ART, in which the concentration of HIV ribonucleic acid (hereinafter referred to as RNA) in the blood plasma (viral load (hereinafter referred to as VN)) falls below the level of 50 copies of HIV in 1 ml of the test plasma sample; in the vast majority of patients, viral suppression is achieved within 6 months of effective ART; virological failure of treatment – inability to achieve and maintain
viral suppression, defined as a continuously detectable HIV VN greater than 200 copies/mL in two consecutive studies 3 months or more apart in a patient receiving a current ART regimen for at least 6 months;

HIV-positive status of the patient - the status of the patient, determined by the fact of obtaining positive results of laboratory tests during diagnostic testing for HIV infection;

HIV-service non-governmental non-profit organizations (hereinafter referred to as HIV-service NPOs) are non-governmental non-profit organizations that provide HIV prevention, care and support services; diagnostics HIV-Infection– complex Medical Services aimed at establishing a diagnosis of HIV infection, including, among other things, screening and diagnostic testing for HIV infection; diagnostic testing for HIV infection - the use of laboratory methods for the study of biological samples with the determination of HIV RNA, antibodies, antigen or antigens to HIV, antibodies to HIV antigens; Key Group Population– Group Population with Greatest risk of HIV infection: people who inject drugs; men who have sex with men; transgender people; sex workers; persons in places of deprivation of liberty; people living with HIV (hereinafter, unless otherwise indicated, PLHIV) are patients who have
positive results of diagnostic testing for HIV infection were obtained; undetectable VN - suppression of HIV replication as a result of ART, in which the concentration of HIV RNA in the blood plasma falls below the sensitivity threshold of the test system used (which should not exceed 50 copies of HIV in 1 ml); opportunistic diseases - opportunistic infections (hereinafter referred to as OI), neoplasms and HIV-related dysfunction of individual organs resulting from a deficiency in

the activity of helper T-lymphocytes (CD4 + lymphocytes) and (or) the direct cytopathic action of HIV; separation from treatment – discontinuation of ART for more than one month, including on the initiative of PLWH; primary HIV infection is a condition characterized by the risk of HIV infection in the last 6 weeks, detection of p24 antigen or HIV RNA in the blood and (or) seroconversion - the dynamics of antibodies to HIV from negative to positive, including changes in the reactivity of immune blotting (hereinafter referred to as IB); primary HIV infection can be manifested by acute retroviral syndrome or be asymptomatic; post-exposure (post-exposure) prophylaxis of HIV infection (hereinafter referred to as AEDs) is a method of medical prophylaxis using a short course of ART after exposure that can lead to HIV infection; pre-exposure (pre-contact) prophylaxis of HIV infection (hereinafter referred to as PrEP) is a method of medical prevention of HIV infection using ARV-drugs in persons at high risk of HIV infection; adherence to ART is the patient's behavior, manifested by strict adherence to the recommendations of a specialist doctor for taking ARVs. It is approximately estimated on the basis of the ratio of the number of doses taken to those prescribed for a certain period of time, expressed as a percentage. Adherence to ART above 90% is considered high; advanced HIV infection is a condition characterized by a decrease in CD4+ lymphocytes less than 200 cells / μL before the start of ART or on ART with detectable VN, or the development of any of the conditions and diseases characteristic of stages 3 and 4 of HIV infection; however, all children aged 2–5 years living with HIV are classified as patients with advanced HIV infection if they are not receiving effective ART, and all children under 2 years of age, regardless of treatment and laboratory parameters, are classified as patients with advanced HIV infection; screening testing for HIV infection - the primary stage of testing for HIV infection, including the determination of HIV antibodies or antibodies, HIV antigen or antigens using rapid tests or serological research methods; upon receipt of a reactive result of HIV screening testing, diagnostic testing for HIV infection is performed; therapeutic remission is a patient's condition that meets the following criteria: stable viral suppression (confirmed by two measurements of HIV VN with an interval of 6 months or more); restoration of immunity sufficient to protect against the emergence of new and the progression of existing opportunistic diseases; HIV resistance test – molecular genetic test for the presence of mutations in the HIV-1 genome that determine resistance to ARVs; Transgender people are persons who have declared the need to change their gender or have undergone correction (hormonal and (or) surgical) of their gender: from male at birth to female (hereinafter referred to as transgender women) or from female at birth to male (hereinafter referred to as transgender men).

4. Diagnosis of HIV infection is carried out according to the algorithm according to Appendix 1.

Mandatory referral for screening testing for HIV infection for epidemic and clinical indications is subject to contingents of the population in the presence of clinical indications specified in paragraph 9 of Appendix 1, as well as contingents of the population specified in paragraph 5 of Appendix 2 to the Decree of the Ministry of Health of the Republic of Belarus dated July 12, 2012 No. 97 "On the establishment of clinical indications and categories of persons subject to mandatory medical examination".

Each HIV screening is accompanied by pre-test and post-test counseling with psychological assistance.

Before screening and diagnostic testing for HIV infection, a referral for a blood test for viral infections and syphilis is filled out in the form established by the Ministry of Health. In the case of anonymous screening testing for HIV infection, instead of personal data, a code is indicated in the referral, which is communicated to the patient. Anonymous diagnostic testing for HIV infection is not allowed.

5. In case of confirmation of HIV-positive status based on the results of diagnostic testing for HIV infection, post-test counseling of the patient and epidemiological investigation of the case of HIV infection are carried out by an epidemiologist of the state institution "Republican Center for Hygiene, Epidemiology and Public Health", the state institution "Republican Center for Hygiene and Epidemiology of the Department of Finance and Logistics of the Ministry of Internal Affairs of the Republic of Belarus", Regional Center for Hygiene, Epidemiology and Public Health, State Institution "Minsk City Center for Hygiene and Epidemiology", City, District, Zonal Center for Hygiene and Epidemiology.

6. The diagnosis of HIV infection is established by an infectious disease doctor on the basis of epidemiological, clinical and laboratory data.

The diagnosis indicates: the stage of the disease, as well as the disease and (or) the condition characterizing the stage, which are established in accordance with the classification of HIV infection in patients aged 15 years and older and the classification of HIV infection in children under the age of 15 years in accordance with Annexes 2 and 3, respectively, as well as in accordance with the classification of HIV-associated immunodeficiency in accordance with Appendix 4; the number of CD4+ lymphocytes and HIV VN with the date of their last determination; therapeutic remission or virologic failure of treatment, and indication on separation from treatment (in the presence of these conditions).

Examples of HIV diagnoses include:

HIV infection, stage 1 (CD4 678 cells/μl, HIV VN <300 copies/ml 03.04.2022), therapeutic remission;

HIV infection, 2 Clinical stage Moderate reduction Mass Body (CD4 237 cells/μl, HIV VN 10,000 copies/ml on 31.03.2022), separation from treatment;

HIV infection, stage 3, thrombocytopenia, (CD4 178 cells/μl, HIV VN 2589 copies/ml on 03/28/2022), virological treatment failure;

HIV infection, stage 4, cryptococcal meningitis, immune system repair syndrome (CD4 8 cells/μL (1.2%), HIV VN 258,000 copies/ml 01.03.2022);

HIV infection, stage 4 (Pneumocystis pneumonia, 2014), (CD4 388 cells/μl, HIV VN <50 copies/ml 03.03.2022), therapeutic remission.

For the purposes of statistical accounting, the ICD-10 diagnosis code is used (B.20-B.24).

7. Patients with HIV-positive status belonging to key populations, if possible, are referred to the nearest HIV prevention room among injecting drug users or anonymous counseling centers based on HIV service NGOs to receive counseling, information, psychological, legal assistance, take measures to maintain high adherence to medical supervision and treatment, referral and (or) support to specialized organizations to solve medical and social problems that worsen the quality of life and adversely affect the state of health.

8. The provision of medical care to persons infected with HIV is carried out in accordance with the Instruction on the procedure for organizing the provision of medical care to persons infected with the human immunodeficiency virus, approved by the Decree of the Ministry of Health of the Republic of Belarus dated November 8, 2017 No. 93.

The algorithm for clinical and laboratory monitoring of the health status of patients with HIV infection is given in Appendix 5.

9. ART and other antimicrobial treatment are prescribed to patients with HIV infection, taking into account individual characteristics, severity of the disease, the presence of concomitant pathology, allergic history, clinical and pharmacological characteristics of drugs and potential drug interactions.

10. ARVs-drugs for medical prophylaxis are used to prevent mother-to-child transmission of HIV infection and, according to epidemic indications, to persons who are at high risk of HIV infection (PrEP is used) or who are at risk of HIV infection (AEDs are used). Medical prevention of mother-to-child transmission of HIV infection is carried out in accordance with the clinical protocol "Prevention of mother-to-child transmission of HIV", approved by the Decree of the Ministry of Health of the Republic of Belarus dated June 28, 2018 No. 59.

CHAPTER 2 DIAGNOSIS OF HIV INFECTION

11. Screening testing for HIV infection with the use of rapid tests is carried out by medical workers in healthcare organizations, employees of HIV service NGOs, as well as by self-testing of the population with rapid tests for HIV infection.

Screening testing for HIV infection using laboratory methods (hereinafter referred to as laboratory screening testing for HIV infection) is carried out by medical workers in healthcare

organizations and is based on the detection of antibodies to HIV 1, 2 or antibodies, antigen and (or) antigens of HIV 1, 2

enzyme-linked immunosorbent assay (hereinafter referred to as ELISA) or immunochemiluminescence analysis (hereinafter referred to as IHA), including the use of rapid blood tests.

12. For screening testing for HIV infection, rapid tests for HIV infection are used, the medical use of which is allowed in the territory of the Republic of Belarus. Testing with the use of rapid tests is carried out in accordance with the instructions for medical use (leaflet).

13. Upon receipt of a non-reactive (negative) result of screening testing for HIV infection and in the absence of data on primary HIV infection, the result of screening testing for HIV infection is recorded as negative, further studies are not conducted.

Suspected primary HIV infection with a non-reactive (negative) screening test result arises in the presence of epidemiological data in the form of contact with a high risk of infection for less than 6 weeks ago and (or) in the presence of clinical manifestations of acute retroviral syndrome.

Upon receipt of a reactive (positive) result of laboratory screening testing for HIV infection, the last name, first name, patronymic (if any), date of birth of the patient (with the exception of anonymous samples) are checked against the database of the Republican Register of Patients with HIV Infection (hereinafter referred to as the Register). If there is information about the patient in the Register, the result of the study is marked "statistically registered", further diagnostic testing for HIV infection is not prescribed and is not carried out.

Positive results of laboratory screening testing for HIV infection within 24 hours are sent to the health care organization that sent the biological sample for research, information about the positive result is transferred to the state institution "Republican Center for Hygiene and Epidemiology of the Department of Finance and Logistics of the Ministry of Internal Affairs of the Republic of Belarus", the state institution "Minsk City Center for Hygiene and Epidemiology", city, district, or zonal centers of hygiene and epidemiology at the place of residence (place of stay) of the patient.

14. In case of receiving a reactive (positive) result of screening testing for HIV infection, the medical worker who initiated the testing prescribes diagnostic testing for HIV infection to the patient (an employee of an HIV service NGO offers the client of an HIV service NGO to undergo diagnostic testing).

15. Diagnostic testing for HIV infection is carried out by medical workers in the laboratories of state health organizations using laboratory methods for studying blood samples. Delivery of samples for laboratory research is carried out no later than 48 hours from the moment of collection. A biological blood sample is taken in test tubes with ethylenediaminetetraacetic acid (hereinafter referred to as EDTA).

Diagnostic testing for HIV infection is prescribed by an infectious disease doctor, other specialist doctor based on the results of screening testing for HIV infection or in the presence of clinical indications (probable primary HIV infection with or without manifestations of acute retroviral syndrome, the presence of clinical manifestations similar to the 3rd or 4th clinical stage of HIV infection). The collected blood sample is sent to the laboratory for retesting.

Blood sampling for diagnostic testing for HIV infection can be carried out by a medical worker on the basis of HIV service NGOs with subsequent delivery to the laboratory of a state health organization.

16. Diagnostic testing for HIV infection is carried out in two stages.

At the first stage, biological material is tested for the detection of antibodies to HIV 1, 2 or antibodies, antigen and (or) antigens of HIV 1, 2 by ELISA or IHA, including using two rapid blood tests with a different set of antigenic, antioxidant determinants and high sensitivity (at least 99%) and specificity (at least 99%).

If a non-reactive (negative) result is obtained at the first stage of diagnostic testing for HIV infection (negative ELISA or ICA or two negative rapid tests), the result is recorded as negative, no further study is carried out. Within 24 hours, the result of the study is sent to the health care organization that sent the biological sample for research, and to the state institution "Republican Center for Hygiene and Epidemiology of the Department of Finance and Logistics of the Ministry

of Internal Affairs of the Republic of Belarus", regional centers of hygiene, epidemiology and public health, state institution "Minsk City Center for Hygiene and Epidemiology", city, district or zonal hygiene centers and epidemiology at the place of residence (place of stay) of the patient.

In case of obtaining a reactive (positive) result at the first stage of diagnostic testing for HIV infection (positive ELISA or ICA or positive one of two or both performed rapid tests), the patient's last name, first name, patronymic (if any), date of birth are checked against the Register database:

if there is information about the patient in the Register, further diagnostic testing for HIV infection is not carried out, the result of the study is marked "is statistically registered", within 24 hours the research result is sent to the health care organization that sent the biological sample for research, and to the state institution "Republican Center for Hygiene and Epidemiology of the Department of Finance and Logistics of the Ministry of Internal Affairs of the Republic of Belarus", regional centers of hygiene, epidemiology and public health, the state institution "Minsk City Center for Hygiene and Epidemiology", city, district or zonal centers of hygiene and epidemiology at the place of residence (place of stay) of the patient; in the absence of information about the patient in the Register, the sample of biological material from which a positive result was obtained at the first stage is sent to the second stage of diagnostic testing for HIV infection.

At the second stage, biological material is tested for the detection of HIV RNA.

A reactive (positive) result of a test for the detection of HIV RNA is considered to be a result that exceeds the sensitivity threshold of the test system used. In the case of a reactive (positive) result of laboratory tests at the second stage of diagnostic testing for HIV infection, the patient's HIV-positive status is recorded, within 24 hours the result is sent to the health care organization that sent the biological sample for research, and to the state institution "Republican Center for Hygiene and Epidemiology of the Department of Finance and Logistics of the Ministry of Internal Affairs of the Republic of Belarus", regional hygiene centers, epidemiology and public health, the state institution "Minsk City Center for Hygiene and Epidemiology", city, district or zonal centers of hygiene and epidemiology at the place of residence (place of stay) of the patient.

In the case of a non-reactive (negative) result for the detection of HIV RNA (below the sensitivity threshold of the test system used) at the second stage of diagnostic testing for HIV infection, a biological blood sample is re-taken in EDTA tubes and a repeated laboratory test using the IB method to determine the presence of antibodies to HIV antigens 1, 2 (if possible, the IB study is carried out using the same sample).

In case of obtaining a reactive (positive) result of IB, the HIV-positive status of the patient is recorded, within 24 hours the result is sent to the health care organization that sent the biological sample for research, and to the state institution "Republican Center for Hygiene and Epidemiology of the Department of Finance and Logistics of the Ministry of Internal Affairs of the Republic of Belarus", regional centers for hygiene, epidemiology and public health, the state institution "Minsk city center of hygiene and epidemiology", city, district or zonal centers of hygiene and epidemiology at the place of residence (place of stay) of the patient.

In case of obtaining a non-reactive (negative) result of the study conducted by the IS method, the patient's status is registered as negative, within 24 hours the result is sent to the health care organization that sent the biological sample for research, and to the state institution "Republican Center for Hygiene and Epidemiology of the Department of Finance and Logistics of the Ministry of Internal Affairs of the Republic of Belarus", regional centers of hygiene, epidemiology and public health, state institution "Minsk City Center for Hygiene and Epidemiology", city, district or zonal centers of hygiene and epidemiology at the place of residence (place of stay) of the patient.

17. Patients with uncertain results of diagnostic testing for HIV infection conducted using the IB method are referred for repeated diagnostic testing for HIV infection after 3 months in order to finally determine HIV status. If, 3 months after the first testing, the IB results are uncertain, the patient does not have risk factors for infection and clinical symptoms of HIV infection, the test result is regarded as a false positive. If, 3 months after the first testing, the results of IB are uncertain, the patient has risk factors for infection and (or) clinical symptoms of HIV infection, the decision on the patient's HIV status is made by a medical consultation.

18. Upon receipt of reactive (positive) results of laboratory tests at all stages of diagnostic testing for HIV infection, information on the results of the patient's examination is entered into the Register.

19. The algorithm for diagnosing HIV infection has features in the following groups: HIV-exposed children under the age of 18 months; Pregnant;

patients with probable primary HIV infection with or without acute manifestations retroviral syndrome.

Diagnosis of HIV infection in HIV-exposed children under the age of 18 months is carried out taking into account the following features:

detection and confirmation of HIV infection in exposed children under the age of 18 months is carried out using qualitative genetic molecular tests: polymerase chain reaction - deoxyribonucleic acid - HIV (hereinafter - PCR-DNA-HIV); for exposed children, the first qualitative genetic PCR-DNA-HIV molecular test is performed at 2 to 5 days of age. In case of a reactive (positive) result, a second blood sample is taken for confirmation, testing is carried out using qualitative genetic molecular tests PCR-DNA-HIV. If the retest is positive, the child's HIV-positive status is confirmed. In the case of a non-reactive (negative) result, retesting is carried out at the age of 8-10 weeks and 4 months. If a reactive (positive) test result is obtained during testing at the age of 8-10 weeks and (or) 4 months, a second blood sample is taken for confirmation, testing is carried out using qualitative genetic molecular tests PCR-DNA-HIV. If the repeated test gives a positive result, then the HIV-positive status of the child is confirmed. When the exposed child reaches the age of 18 months, laboratory tests are carried out according to the algorithm for diagnosing HIV infection in accordance with Appendix 1; in the presence of medical and epidemiological indications in children under the age of 18 months who are unexposed, their examination is carried out according to the algorithm for diagnosing HIV infection in accordance with Appendix 1.

Diagnosis of HIV infection in pregnant women is carried out taking into account the following features:

when registering for pregnancy up to 20 weeks, pregnant women are necessarily sent for laboratory screening testing for HIV infection for the detection of antibodies, antigen and (or) antigens of HIV 1, 2 by ELISA or IHA. Repeated laboratory screening for HIV infection of pregnant women with a negative result at the first test is carried out in cases determined by the Ministry of Health; in cases of registration for pregnancy in a period of more than 20 weeks, as well as a pregnant woman with an unknown HIV status during childbirth, additional screening testing for HIV infection is carried out using rapid tests until the results of testing for the detection of antibodies, antigen and (or) antigens of HIV 1, 2 by ELISA or IHA are obtained.

Suspected probable primary HIV infection may occur if there is epidemiological evidence (high-risk exposure for less than 6 weeks) or clinical manifestations of acute retroviral syndrome. In this case, in case of a negative or doubtful result of the detection of antibodies to HIV during screening testing for HIV infection, a test for the detection of HIV RNA or antibodies, antigen and (or) antigens of HIV 1, 2 by ELISA or IHA is also performed.

CHAPTER 3 ART

20. ART is indicated for PLHIV from the moment of diagnosis of HIV infection.

21. ART is carried out using schemes that combine several ARVs.

The main characteristics and dosage regimens of ARV-drugs, dosing regimens of liquid oral forms of ARV-drugs in children under the age of 4 weeks, simplified dosing regimens of solid oral forms of ARV-drugs for administration once a day in children aged 4 weeks and older, simplified dosing regimens for solid and liquid oral forms of ARV-drugs for administration twice a day in children aged 4 weeks and older are established according to Appendices 6-9, respectively.

The ART scheme consists of a combination of the base of the scheme, represented by two NRTIs, and a third drug of one of three classes: NNRTI, PI or AI. Non-standard ART regimens are prescribed to patients with virological treatment failures based on the results of the HIV resistance test, as well as to patients with viral suppression and inability to use certain drugs in the regimen (individual intolerance, interactions with other drugs).

22. First- and second-line ART regimens are prescribed according to Annexes 10 and 11, respectively, by a specialist physician trained in ART.

Third-line ART schemes are prescribed in accordance with Appendix 12. Third-line ART, non-standard ART regimens are appointed by a medical council with the involvement of heads of consultative and dispensary departments for HIV infection of healthcare organizations of the regional level and (or) specialists of specialized departments of educational institutions engaged in training, advanced training and (or) retraining of specialists with higher medical and pharmaceutical education.

23. The following factors are taken into account when initiating ART: immediate (on the day of the first visit after establishing HIV-positive status) or rapid (within 7 days after the first treatment) initiation of ART is optimal, which contributes to the effectiveness of treatment in most patients;

patients without signs of advanced HIV infection, ART begins as soon as possible after evaluating the results of laboratory tests necessary for the safe prescription of selected ARVs, if necessary, the ART regimen can be modified after receiving some examination results; patients with advanced HIV infection, ART begins after exclusion of tuberculous meningitis, toxoplasmosis of the brain and cryptococcal meningitis; in the presence of the listed OI, ARV-LS are prescribed after the initiation of etiotropic treatment of these OIs;

patients with primary HIV infection with manifestations of meningitis (meningoencephalitis) ART is started for emergency medical indications when a positive result of the screening stage of the examination is obtained before the result of the diagnostic stage is obtained; in this case, class AI drugs are included in the ART scheme; girls and women of childbearing age, as well as pregnant women, when prescribing dolutegravir (hereinafter referred to as DTG), are informed about the benefits and potential risks associated with taking DTG; Pregnant women start ART as soon as possible, taking into account the benefits and potential
risks to the fetus associated with taking certain ARVs.

24. Before starting ART, a conversation is held with the patient or one of the parents, adoptive parents of the minor, guardians, trustees in order to inform about the upcoming treatment and assess readiness to start it. In patients who are ready to start ART and have no medical contraindications to immediate or rapid initiation, treatment is started immediately, optimally within the first 7 days after establishing HIV-positive status. Patients with advanced HIV infection, pregnant women, and women with children under three years of age are prioritized for primary medical screening, ART and adherence to them.

At the beginning of ART, the patient receives from the medical professional the necessary information about the regimen of taking drugs, possible adverse reactions to them and subsequent medical supervision. If the patient refuses to start ART, the patient is encouraged to start ART at each follow-up visit for medical observation or hospitalization.

25. ART begins with a first-row diagram. Choosing the right first-line regimen and ensuring high adherence to ART in PLHIV is the key to long-term effective ART with the least adverse effects. When choosing an ART regimen, preference is given to prescribing combined drugs in fixed dosages with a single dose during the day, which improves adherence to ART. For immediate or rapid initiation of ART, preferred first-line regimens are prescribed.

26. Healthcare professionals who provide care to PLHIV help the patient maintain high adherence to ART. At each request for medical consultation (medical examination) or receipt of ARV-drugs, an analysis of adherence to ART is carried out, factors that determine insufficient adherence to ART are identified and recorded in medical documents. In the presence of dependence on alcohol or other psychoactive substances, signs of depression, cognitive problems, the patient is referred to a specialized specialist doctor, including the possibility of receiving anonymous treatment. If necessary, the patient is referred to an HIV prevention room for injecting drug users or anonymous counseling centers based on HIV service NGOs.

27. Modification of the ART regimen within the series is carried out in case of intolerance to a certain ARV-drug or the presence of medical contraindications to its use, including adverse drug interactions with one or more other vital drugs. The ART regimen is modified with the development of severe or long-lasting moderate adverse reactions to any of its components. Mild or moderate adverse reactions to drugs can be overcome or eventually go away on their own.

28. Modification of a satisfactorily tolerated ART regimen for the purpose of optimization is carried out to increase its effectiveness and safety: reducing the frequency of administration, the use of combined drugs or drugs with less metabolic consequences of long-term use.

Optimization of ART in the form of a transition to first-line DTG-containing regimens is carried out in accordance with the algorithm for switching to the tenofovir disoproxil (hereinafter referred to as TDF) + lamivudine (hereinafter referred to as 3TC) + DTG regimens in adults and children 10 years of age and older in accordance with Appendix 13.

An algorithm for optimizing ART regimens in children when they reach the appropriate body weight is given in Appendix 14.

Modifications of the circuit, leading to a decrease in its genetic threshold of resistance, are avoided.

It is allowed to maintain the current effective ART regimen, which is well tolerated by the patient, if there are no other reasons for changing this ART regimen, except for the appearance of new recommended ARVs. The exceptions are situations involving the cessation of production or supply of ARV-drugs and the use of schemes consisting of three NRTIs.

In the first six months after initiation or resumption of ART, modification of the regimen with the replacement of one or two components is permissible for detectable HIV VN. Subsequently, the modification of the treatment regimen is made only with undetectable VN HIV, according to the results of a study conducted within the last 3 months.

In patients without prior treatment failures, modification of the ART regimen usually does not lead to a decrease in its effectiveness.

29. Optimization of ART with the transition to DTG or bictegravir (hereinafter referred to as BIC) containing regimens is carried out taking into account the achievement of viral suppression and potential drug interactions.

The presence of potential drug interactions may require adjustment of the dose of DTG.

With undetectable HIV VN within the last three months in adults and children over 10 years of age, the transition is carried out without replacing the NRTI-based. When determining HIV VN in the range of 50-1000 copies / ml, work is carried out to optimize adherence to ART, the study is repeated after 3 months. If the HIV VN persists >200 copies/ml, the next line of ART is switched. Tenofovir is stored in the NRTI-based scheme using AI, in the presence of medical contraindications to the use of zidovudine (hereinafter referred to as AZT). Tenofovir is used in the form of TDF or tenofovir alafenamide (hereinafter referred to as TAF).

Testing for HIV VN in children younger than 10 years of age to switch to a DTG-containing regimen is desirable. It is mandatory to test for HIV VN in children under 10 years of age when switching from a scheme containing raltegravir (hereinafter referred to as RAL), where the transition is carried out only in the case of undetectable HIV VN.

30. The transition to the schemes of the second and subsequent series is carried out with the development of virological failure of treatment against the background of the treatment used. At the same time, at least two ARV-LS are replaced in the scheme. Replacement of one ARV-drug is permissible in the presence of the results of a molecular genetic test for HIV resistance with proven resistance only to this drug (excluding resistance to 3TC or emtricitabine (hereinafter referred to as FTC) due to an isolated M184V mutation, which does not require the replacement of these drugs in the scheme). In the new ART regimen, at least two fully active ARVs, one of which is AI or PI, is prescribed. In case of virologic failure of treatment before the appointment of a new regimen, a break in ART is not allowed. If it is impossible to achieve viral suppression due to HIV resistance and (or) medical contraindications to the use of existing ARVs, the patient is prescribed the most effective regimen available and continues to use it until new therapeutic options appear. At the same time, ART does not stop.

In the case of virological treatment failure, the probable causes of its occurrence (insufficient adherence to ART, drug interactions, primary resistance, etc.) are determined to prevent treatment failures in the future.

In patients with HIV VN 50–200 copies/mL, adherence to treatment and drug interactions are analyzed. In the absence of these problems, ART does not change. When re-determining with

an interval of 3 or more months, HIV VN more than 200 copies / ml is replaced with one of the recommended regimens of the next line, if necessary after the HIV resistance test.

31. Third-line regimens are selected based on the results of the HIV resistance test, the entire history of ART and the history of virological treatment failures, as well as previous HIV resistance tests. These schemes are prescribed by a medical consultation. In the case of the development of an opportunistic disease, the transition to the third-line scheme is made as soon as possible with its modification if necessary after obtaining the result of the study of HIV drug resistance.

In the third-line scheme, at least two active ARV-drugs are prescribed, one of which is represented by AI or PI / b. Boosters for PI are ritonavir (hereinafter referred to as RTV or / r) or cobicistat (hereinafter referred to as COB or / s). In the third-row IP/B scheme, preference is given to boosted darunavir (hereinafter referred to as DRV). Only in patients who have never taken PI before, it is permissible to prescribe boosted atazanavir (hereinafter referred to as ATV) or lopinavir / ritonavir (hereinafter referred to as LPV / r) in the third row. In all patients who have previously taken other PIs, DRV / RTV is prescribed at a dose of 600 mg / 100 mg 2 times a day.

If there is no choice in patients with a CD4 count of less than 100 cells/μL and a risk of significant deterioration, it is permissible to use an ART regimen with one fully active drug in order to improve immune status due to a decrease in HIV VN.

In patients with multiple virological treatment failures, it is most likely that the NRTI-base regimen does not contain any fully active ARV-drugs. In this case, a scheme of 4-5 ARV-LS, which includes AI, is considered. If the patient has a history of virological treatment failure during the period of taking the DTG regimen, he is prescribed 50 mg 2 times a day, if the results of the HIV resistance test do not determine another tactic (usual dose or complete refusal to use).

32. When ART is resumed after separation from treatment, the reason why treatment was discontinued is determined. If the separation occurred in the patient for reasons related to intolerance to ARV-drugs in the scheme, then this drug is replaced by another in accordance with the recommended components among the schemes of the corresponding series. Most often, it is replaced with ARV-LS of the same class, if it is not possible, of another class without lowering the genetic threshold of resistance. If the separation from ART occurred for reasons not related to the tolerability of ARV-drugs, then the last regimen that the patient took is prescribed, if it is not possible, a scheme of ARV-drugs of the same classes, taking into account the virological efficacy and tolerability of the previous ART. Further treatment tactics are determined after evaluating the effectiveness of ART.

33. Suspension of ART for medical reasons occurs in the following cases:

severe adverse reactions to drugs (severe hepatotoxicity, severe hypersensitivity reactions); acute psychotic disorder in a patient that is not associated with an opportunistic disease of the central nervous system (hereinafter referred to as the central nervous system), before the development of joint treatment tactics by specialist doctors (psychiatrist-narcologist, children's psychiatrist and infectious disease doctor); in the perioperative period (for 1-2 days);

with the development of acute insufficiency of organs and systems not caused by HIV infection.

If the patient suspends ART for medical reasons or refuses it for regimens containing NNRTIs (EFVs), nevirapine (NVPs)), if possible, the NRTI-base is extended by 7-14 days. In the case of using schemes containing PI or AI, the reception of all ARV-drugs in the scheme is stopped simultaneously.

34. An algorithm for laboratory monitoring of HIV infection and the effectiveness of ART in patients with HIV infection is given in Appendix 15.

Laboratory monitoring of the effectiveness of ART is carried out by determining the VN of HIV. After 3 months of effective ART, most patients have HIV VN
<500 copies/ml, after 6 months – <50 copies/ml. With an initial HIV VN of more than 10-6 copies/ml, the described response to therapy may be delayed by several weeks. The lack of response to therapy on the dynamics of HIV VN on ART requires an analysis of adherence and measures to restore it, and the persistence of HIV VN after 3 months of more than 200 copies/ml

leads to a statement of virologic failure of treatment and a rapid transition to the next series of ART.

The results of determining the number of CD4+ lymphocytes are necessary to establish the degree of HIV-associated immunodeficiency, prescribing or stopping prophylactic treatment of OI.

35. The HIV resistance test is performed for the following medical indications:

virological failure of first-line ART treatment when not possible use the recommended second-line schemes; virological failure of treatment with a second- or third-line regimen; initiation of ART if there is evidence of the possibility of infection as a result of contact with PLHIV with ineffective ART; initiation of ART if infection occurred while taking PrEP;

virological failure of treatment on the ART regimen of any series in a patient with hepatitis B virus co-infection (hereinafter referred to as HBV) receiving tenofovir; pregnancy with newly diagnosed HIV infection; perinatal HIV infection in children.

The prerequisites for performing an HIV resistance test are: the presence of HIV VN at least 1000 copies / ml;

continued use of ARV-drugs or no later than 4 weeks after withdrawal the entire ART scheme or its components.

A test for HIV resistance, as a rule, includes the determination of mutations to ARVLS of the NRTI, NNRTI and PI classes. If it is necessary to determine mutations of resistance to AI in the event of a virological failure of treatment against the background of the use of drugs of this class, a corresponding mark is made in the direction.

It is not allowed to postpone the start of ART while waiting for the results of a test for HIV resistance in patients with advanced HIV infection, tuberculosis (hereinafter referred to as TB), pregnant women, children under the age of 1 year. Treatment begins with an empirically selected or recommended regimen by this clinical protocol, followed by modification after receiving the result of the study. When choosing a regimen, preference is given to ARVs with a high genetic barrier of resistance (AI or PI).

Until the results of the HIV resistance test are obtained, the patient continues to be treated with the previous regimen or a new ART regimen is prescribed, which is then modified if necessary based on the results of the study.

CHAPTER 4 ART IN PREGNANT WOMEN

36. When a woman receiving effective ART becomes pregnant, therapy continues, unless there is insufficient data on efficacy during pregnancy (BIC, doravirin (hereinafter referred to as DOR), regimens of two ARVs) used in the ARV-drug regimen. In this case, the history of ART is analyzed and the potential risks and benefits of using the current regimen are discussed with the patient.

If the regimen uses ARV-drugs, the concentration of which during pregnancy does not reach the therapeutic level (DRV / s, rilpivirine (hereinafter referred to as RPV), DRV / r 800 mg / 100 mg 1 time per day), the ART regimen is replaced with the recommended one for the duration of pregnancy.

The use of EFV in pregnant women does not increase the risk of fetal abnormalities and adverse pregnancy outcomes.

DTG may be given to women of childbearing potential if they have been informed of a possible but not proven increase in the risk of neural tube defects (at conception and before the end of the first trimester at 0.19%, which is not statistically significant). If a woman becomes pregnant after the first trimester, DTG should be started or continued throughout pregnancy.

37. In women who have not received ART by the time of pregnancy, ART is started as soon as possible using one of the recommended regimens.

The ART regimens recommended for use in pregnant women are set out in Annex 16.

If ART is started in the second or third trimester, DTG is included in the regimen.

When receiving HIV VN more than 200 copies/ml during the prenatal examination, DTG joins the regimen if it is not already included in it. At the same time, blood is taken for the subsequent study of the HIV resistance test.

38. If, by the time of onset or during pregnancy, a virological failure of treatment is recorded, the transition to the scheme of the next series from among those recommended during pregnancy is made as soon as possible.

39. Medical supervision and laboratory examination of pregnant women with HIV infection, as well as therapeutic and preventive measures during childbirth and the postpartum period are carried out in accordance with the clinical protocol "Prevention of mother-to-child transmission of HIV infection".

CHAPTER 5 ART IN CHILDREN

40. ART is indicated for all HIV-positive children, regardless of age, clinical and immunological stage of HIV infection.

Children born to HIV-positive mothers are screened, and if HIV-positive status is detected, ART is started as soon as possible.

41. The preferred first-line ART regimen for children aged >4 weeks with a body weight of >3 kg is a regimen that includes DTG. An alternative AI for children aged >6 years and a body weight of >25 kg is BIC (in the form of a fixed combination of TAF/FTC/BIC).

In newborns, regimens are used to initiate ART, including: RAL (infants

aged <4 weeks with a body weight of ≥2 kg), or

LPV/r (infants aged ≥14 days <4 weeks), or

NVP (children aged ≤14 days).

Before starting ART, the child is drawn blood to perform a test for HIV resistance to ARV-drugs. ART begins before the results of the HIV resistance test are received, the choice of ART regimen takes into account the possibility of transmitted resistance (history of treatment of the person from whom the infection occurred) and resistance associated with the failure of prevention of mother-to-child transmission of HIV. If EFV or NVP was used during pregnancy, a non-NNRTI-based regimen is used in the event of vertical transmission: RAL, LPV/r or DTG is used.

42. When children reach the appropriate age and (or) body weight, ART regimens are modified with the transition to more effective, safe and convenient drugs to take.

43. High adherence to ART is critical in the treatment of children. To support adherence to ART, medical care is provided by multidisciplinary teams, including a pediatrician, a psychologist, a speech pathologist, and a social worker. For sexually active children, the motivation to take ART may be to ensure the safety of the sexual partner (H = H, the presence of undetectable VN <200 copies / ml for >6 months is associated with no risk of sexual transmission of HIV).

44. When managing HIV-positive children, the pediatrician should consult with a specialist in infectious diseases in children.

CHAPTER 6 OPPORTUNISTIC DISEASES. CO-INFECTION WITH HEPATITIS VIRUSES

45. Opportunistic diseases are manifestations of the progression of HIV infection, leading to a decrease in immunity, as a result of the absence of ART or its ineffectiveness.

46. To prevent the development of opportunistic diseases, antimicrobial prophylactic treatment is prescribed. Primary prophylactic treatment of opportunistic diseases is prescribed to prevent it, before the onset of an episode of the disease (based on the results of a study of the number of CD4 + lymphocytes). Secondary prophylactic treatment is prescribed after the completion of the main course of treatment to prevent the recurrence of opportunistic diseases.

Algorithms for prophylactic treatment of OI in patients with HIV infection over 18 years of age and prophylactic treatment of OI in patients with HIV infection under 18 years of age and in HIV-exposed children are given in Appendices 17 and 18, respectively.

47. With the development of opportunistic diseases, diagnostic examinations are carried out and treatment is prescribed.

The volume of medical care provided to patients with HIV infection in opportunistic diseases (adult population) in inpatient conditions is established in accordance with Appendix 19.

The volume of medical care provided to patients with HIV infection in opportunistic diseases (children's population) in stationary conditions is established in accordance with Appendix 20.

In the development of opportunistic diseases in a patient receiving ART, its effectiveness is assessed and in case of virologic failure of treatment, the following series of regimens are used.

In the case of drug allergy to sulfamethoxazole / trimethoprim, alternative drugs are prescribed or desensitization is performed. Desensitization schemes for sulfamethoxazole/trimethoprim shall be established in accordance with Annex 21.

48. Some patients with opportunistic diseases have difficulty swallowing tablets or capsules due to the severity of the condition or damage to the mucous membrane of the oropharynx and (or) esophagus. In such a situation, dosage forms for children (oral solutions, dispersible tablets) or some solid dosage forms for adults can be used. It is allowed to crush tablets or open capsules of the following ARV-drugs: abacavir (hereinafter referred to as ABC), 3TC (but not the combined form of ABC / 3TC), TDF and TAF (including in combination with FTC), AZT, EFV, NVP, DRV (but not RTV), DRV / c, DTG, RAL. It is allowed to crush tablets of the following drugs for the treatment and medical prevention of opportunistic diseases: sulfamethoxazole / trimethoprim (crushed with great effort), fluconazole, all drugs for the treatment of drug-sensitive TB.

49. TB is one of the most important opportunistic diseases in HIV infection. Timely diagnosis of TB improves the outcome of the disease in PLHIV and prevents the further spread of TB among the population.

At each medical examination or treatment of PLHIV for medical help, clinical and anamnestic screening for active TB in PLHIV is carried out in accordance with the algorithm in accordance with Appendix 22. In case of a positive screening result, a sputum examination using the GeneXpert MBT RIF method and a chest X-ray examination are performed as a matter of priority. If there are results indicative of active TB, ART is prescribed no later than 7 days after the start of the examination.

In patients with advanced HIV infection, the determination of Mycobacterium TB lipoarabinomannan antigen in urine using rapid ICA tests can be used to diagnose TB. The study is indicated for patients with a CD4+ lymphocyte count of less than 100 cells/μL before the start of ART on an outpatient basis, patients with a CD4+ lymphocyte count of 101-200 cells/μL in an inpatient setting in the presence of symptoms (fever, sweating, weight loss, headache, etc.). A positive test result requires further examination of the patient to confirm the diagnosis of TB.

50. In adults and children with active TB, ART begins as soon as possible within the first 2 weeks of anti-TB treatment, regardless of the CD4+ lymphocyte count and sensitivity profile of Mycobacterium TB. In case of poor tolerability of anti-TB drugs, especially in the treatment of drug-resistant TB, the initiation of ART can be delayed until the elimination of adverse events from taking these drugs, up to a maximum of 8 weeks.

In patients with tuberculous meningitis, ART begins after 4 weeks of anti-TB treatment, but no later than 8 weeks from the time of its initiation.

ART regimens in patients receiving TB treatment with rifampicin, as well as in patients receiving treatment with drug-resistant TB, are set out in Annexes 23 and 24, respectively.

In ART regimens in patients receiving prophylactic TB treatment using the rifapentine 1,900 mg + isoniazid 900 mg regimen once a week, ARV-drugs are used according to Appendix 25.

If TB is detected in a patient taking ART, anti-TB treatment is started as soon as possible within 7 days of confirmation of the diagnosis.

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[1] It is appointed at the expense of its own funds, funds of legal entities and other sources not prohibited by law, in the presence of medical indications (for health reasons, taking into account individual intolerance) by decision of the medical consultation, and if it is impossible to carry it out, by the attending physician or a person replacing him, with an entry in medical documents.

51. In patients with cryptococcal antigenemia in the absence of signs of meningitis, ART begins 2 weeks after initiation of primary prophylactic treatment with fluconazole. If cryptococcal meningitis is excluded by lumbar puncture, ART begins immediately.

In patients with cryptococcal meningitis, the transition to the second- and post-line regimen is made after 4-6 weeks, depending on the antifungal treatment regimen (not earlier than 2 weeks after the completion of the induction phase of treatment). In patients with tuberculous meningitis, the transition to the scheme of the second and subsequent rows is made after 8 weeks of anti-tuberculosis treatment.

52. Initiation of ART in patients with low CD4 counts may be accompanied by the development of inflammatory immune reconstitution syndrome (hereinafter referred to as IVS). In paradoxical IVS, the symptoms of opportunistic diseases, viral hepatitis or some other diseases (for example, psoriasis) are intensified, despite the treatment. Unmasking VES after initiation of ART suggests the appearance of symptoms of opportunistic diseases that were not diagnosed before the start of ART.

The development of HFI worsens the general condition of the patient and, in some opportunistic diseases, can be fatal (cryptococcal and tuberculous meningitis, progressive multifocal leukoencephalopathy, etc.). The timing of the onset of VSVI is from 2 weeks to 12 months after the start of ART, more often the first 3 months. Medical prevention of unmasking VSVI is a thorough medical examination of a patient with advanced HIV infection. With moderate severity of paradoxical VSVI, nonsteroidal anti-inflammatory drugs are used (taking into account the high probability of concomitant kidney damage, including HIV-associated, and the need to use TDF). In severe paradoxical VSVI, it is allowed to use a short course of glucocorticoid hormones (up to 1 month).

The exceptions are cryptococcal meningitis and Kaposi's sarcoma, in the treatment of which the use of glucocorticoid hormones is undesirable.

53. Co-infection with HIV and hepatitis C virus (hereinafter referred to as HCV) is an indication for the treatment of chronic infection caused by HCV with direct antiviral drugs (hereinafter referred to as PPD), regardless of the severity of liver fibrosis.

Treatment begins after HIV suppression is achieved or at any time if the activity of HCV infection, including manifestations of cirrhosis of the liver, prevents the use of vital drugs, for example, for the treatment of mycobacteriosis.

Medical examination and antiviral treatment of adult patients with HIV and HCV co-infection are carried out in accordance with the clinical protocol "Diagnosis and treatment of patients (adult population) with chronic viral hepatitis B and C", approved by the Decree of the Ministry of Health of the Republic of Belarus dated March 19, 2019 No. 19.

Taking into account the drug interactions of drugs PPD for the treatment of HCV infection and ARV-drugs in accordance with Appendix 26, a modification of the ART regimen is made.

54. For HIV and HBV co-infection, patients receive an ART regimen that includes tenofovir (except in cases of tenofovir intolerance). Discontinuation of tenofovir in the ART regimen may result in severe exacerbation of hepatitis. In patients with cirrhosis of the liver, more frequent monitoring of liver function is carried out within six months after the initiation, resumption or transition to the next line of ART due to the possible development of liver failure as a result of IVS.

If a patient co-infected with HIV and HBV needs to cancel TDF or TAF, its reception can be discontinued when seroconversion occurs, that is, when antibodies to the HBV surface antigen (hereinafter referred to as anti-HBs) appear. In patients with serocliren, that is, with the disappearance of the HBV surface antigen (hereinafter referred to as HBsAg) without the appearance of anti-HBs, determined for at least 3 years, the use of tenofovir can be discontinued, but under careful biochemical control of liver function. In patients with cirrhosis of the liver, antiviral treatment for HBV is not discontinued; If absolutely necessary, tenofovir can be replaced with entecavir.

55. All HBsAg-positive patients are screened for hepatitis D virus infection (IOP).

56. All PLHIV with a negative test result for anti-HBs are vaccinated against hepatitis B. The exception is patients with an isolated positive result of the determination of antibodies to HBV core antigen (HBcAg) with a negative test result for other HBV markers (HBsAg, anti-HBs).

Vaccination should be given in patients with achieved viral suppression on ART with a CD4+ lymphocyte count greater than 200 cells/μL (or with a lower number in patients who do not demonstrate an immunological response to ART).

CHAPTER 7 PRIMARY MEDICAL PROPHYLAXIS OF VACCINE-PREVENTABLE INFECTIONS IN PATIENTS WITH HIV INFECTION UNDER 18 YEARS OF AGE

57. Vaccination of HIV-exposed children, as well as HIV-positive children with mild or moderate immunodeficiency, is carried out in accordance with the Decree of the Ministry of Health of the Republic of Belarus dated May 17, 2018 No. 42 "On preventive vaccinations".

58. HIV-exposed children are given a TB vaccine for 3–5 days of life without prior determination of CD4+ lymphocyte counts.

59. Features Vaccination HIV-Positive Children with severe immunodeficiency (by the number of CD4 + lymphocytes in children aged 1-6 years <15%, over the age of 6 years - <15% or <200 cells / μl) are:

administration of live vaccines (measles, mumps, rubella, chickenpox smallpox, yellow fever, live flu vaccines) is contraindicated; in the primary series of vaccination against COVID-19, an additional dose of vaccine is used, since the immune response to the standard primary series may be suboptimal.

60. HIV-positive children who are not vaccinated within the calendar time (including pneumococcal and hemophilic infections) are vaccinated at any age according to the scheme recommended by the instructions for medical use (leaflet) of the corresponding vaccine.

61. Additionally, the following vaccines are recommended for use in HIV-positive children:

chickenpox vaccine at the age of 1 year and 6 years (possibly co-administered with measles, mumps and rubella vaccine). Previously unvaccinated children over 6 years of age are given the vaccine twice with an interval of ≥1 month. For the purpose of post-exposure prophylaxis, the vaccine is administered to children older than 12 months who are not immune to chickenpox, once no later than 5 days after contact with a patient with chickenpox; conjugate vaccine against meningococcal serogroup infection ACWY is administered at the age of 2 years and older according to a 2-dose regimen with an interval of ≥8 weeks, but not earlier than 4 weeks after the completion of the pneumococcal conjugate vaccine vaccination series. Children with immunodeficiency can be given boosters every 5 years; The human papillomavirus vaccine is administered at the age of 9 years and older in a three-dose regimen, regardless of the age of the child and the degree of immunodeficiency.

CHAPTER 8 CONCOMITANT SOMATIC DISEASES AND CONDITIONS IN PLHIV

62. The risks of developing concomitant somatic diseases and conditions (atherosclerosis, osteoporosis, some types of cancer, type II diabetes mellitus, steatosis and steatohepatitis, kidney disease, anxiety, depression) in PLHIV remain higher than the general population, despite the timely initiation of effective ART. The doctor provides recommendations on the effects on modifiable risk factors: weight correction (including diet and motor regimen), smoking cessation, reduction of alcohol consumption.

63. Drug therapy of concomitant diseases in PLHIV is accompanied by an analysis of potential drug interactions with ARV-drugs.

64. Corrections of doses of ARV-drugs in patients with impaired liver function and impaired renal function are carried out in accordance with Appendices 27 and 28, respectively.

65. Anxiety disorders, depression, and alcohol use disorders have a negative impact on ART outcomes. The primary diagnosis of these conditions is carried out for medical reasons by a specialist doctor providing ART when the patient seeks medical help.

Testing for the detection of alcohol use disorders (AUDIT) is carried out on the basis of a questionnaire in the form according to Appendix 29.

Testing for the detection of generalized anxiety disorder (hereinafter referred to as GAD) is carried out on the basis of a questionnaire in the form according to Appendix 30. Risk factors for

anxiety disorders include heredity, alcohol and other substance use, cognitive impairment, and social distress. In patients with possible GAD, a suicidal risk assessment is performed.

Testing to detect depression and determine its severity is carried out on the basis of the patient's health questionnaire PHQ-2, PHQ-9 for detecting depression in the form according to Appendix 31.

66. Patients with probable GAD are referred to a specialist doctor for further diagnosis and assistance, including medical care. Prior to this, other causes associated with exposure to drugs or other substances (excessive caffeine intake, use of psychostimulants), as well as concomitant diseases and conditions (hyperthyroidism, hypoglycemia and hyperadrenocorticism) are excluded.

In the presence of moderately severe, severe depressive disorder, as well as in identifying a suicidal risk, patients are referred to a psychiatrist-narcologist or a child psychiatrist.

CHAPTER 9 PREEP HIV INFECTION WITH ARV-DRUGS

67. PrEP is prescribed for epidemic indications to persons at high risk of HIV infection (in the absence of medical contraindications) from among the following populations: people who use drugs; men who have sex with men; sex workers; transgender people; sexual partners of PLHIV who have not achieved viral suppression (undetectable VN).

During the pre-PrEP consultation, it is clarified that PLHIV with undetectable VN as a result of effective ART are not sources of HIV infection in sexual relations without the use of a condom.

68. Medical contraindications for prescribing PrEP include: HIV-positive status of the applicant (according to the Register); hypersensitivity reaction to TDF/FTC or TAF/FTC, or any component
this drug in the anamnesis; impaired renal function (according to medical documents or according to the results of a medical examination), confirmed by the calculated creatinine clearance (hereinafter referred to as QC) <60 ml / min. (according to the Cockcroft-Gault formula) with the planned use of TDF and <30 ml / min. with the planned use of TAF.

69. PrEP can be provided on an outpatient basis with strict adherence to drug administration recommendations and with laboratory monitoring, including periodic testing for HIV infection.

70. PrEP is used during periods of significant risk of HIV infection and may be discontinued during periods of low risk or no risk.

71. For PrEP, TDF/FTC 300/200 mg film-coated tablets or TAF/FTC 25 g/200 mg tablets are prescribed.

72. For the use of TDF/FTC for PrEP purposes, one of two modes can be used - constant or intermittent (on demand). The choice of regimen is determined by gender, frequency and type of sexual contact, as well as personal preferences of the patient. Taking PrEP daily is more effective because it makes it easier to build high adherence to ART without developing more significant toxic and metabolic effects. At the same time, when taken correctly, the intermittent regimen (on-demand regimen) has comparable efficacy, but has gender and behavioral limitations of use and does not protect against parenteral HIV infection.

73. When using TAF/FTC for the purpose of PrEP, only a continuous drug regimen can be used.

74. Determination of medical indications for the use of PrEP is carried out by interviewing on the basis of the presence of any of the factors at high risk of HIV infection over the past 6 months:

or vaginal sex without a condom with a partner with unknown or HIV-positive status;

a new episode of sexually transmitted infection (hereinafter referred to as STIs) (syphilis, gonorrhea, chlamydia); obtaining

AEDs of HIV infection.

75. Before prescribing PrEP, the following diagnostic measures are carried out: examination by a specialist doctor;

HIV testing by determination of HIV antibodies or antibodies, antigen or

HIV antigens no more than 7 days before the start of administration; determination of HBsAg. A positive determination result is not a medical contraindication to PrEP, but requires additional medical examination to decide on the need for antiviral therapy for HBV infection; determination of blood creatinine;

in the absence of the possibility of rapid determination of blood creatinine: in persons under 30 years of age without a history of kidney disease, concomitant hypertension and (or) diabetes mellitus, PrEP can be prescribed until the result of the determination of blood creatinine is obtained and then canceled if medical contraindications are detected; in persons aged 30-50 years without concomitant arterial hypertension and (or) diabetes mellitus, the definition of proteinuria can be used; in the absence of protein in the urine, creatinine in the blood is routinely determined 3 months after the start of TDF / FTC.

76. Restrictions on the immediate appointment of PrEP are:

incomplete HIV testing (positive HIV screening test) until HIV negative status is confirmed; probable acute HIV infection (negative HIV test result in
Available Symptoms Acute retroviral syndrome) – Prior to confirmation HIV-negative status; unprotected sexual contact with known HIV-positive status
in the last 72 hours (in this case, the probe is proposed); parenteral use of psychoactive substances using generic
Devices (syringe needle other) jointly with Face with Unknown or HIV-positive status in the last 72 hours (in this case, AEDs are offered); taking ARV-drugs for the purpose of AEDs at the time of applying for PrEP (PrEP can be
assigned immediately after the completion of the PEP).

77. A continuous PrEP regimen consists of taking 1 TDF/FTC or TAF/FTC tablet daily at approximately the same time (±2 hours) once a day. A permanent TDF/FTC regimen can be used in all at-risk groups, including cisgender and transgender people who have sex with men or women. TAF/FTC can only be used on men and transgender women.

To start a permanent regimen of PrEP in transgender women who are not receiving sex hormone treatment, 2 TDF/FTC tablets are taken 2-24 hours before sexual contact (as in the intermittent regimen). All other categories of persons in the first 7 days after the start of a permanent PrEP regimen are recommended to practice sex using a condom and (or) use other methods of prevention.

Upon termination of the permanent PrEP regimen, TDF/FTC is continued for 7 days: after the last risky sexual contact - transgender men or transgender women receiving hormone therapy, after the last parenteral contact - all persons, regardless of gender and identity.

PrEP using daily TDF/FTC is effective and safe in women who are planning a pregnancy, pregnant and lactating, who have sexual partners from among PLHIV with unknown VN or with unachieved viral suppression.

78. An intermittent PrEP regimen (on-demand regimen) consists of taking 2 TDF/FTC tablets 2 to 24 hours before sexual contact, then one TDF/FTC tablet 24 hours after the first two, and then 1 additional TDF/FTC tablet 24 hours after the second dose (or 48 hours after the first two tablets). Thus, the regimen is described as 2 + 1 + 1 and takes 48 hours.

An intermittent PrEP regimen can be used to prevent sexual transmission of HIV in transgender women who are not receiving sex hormone treatment. The intermittent PrEP regimen is prescribed after informing about the availability of the use of a continuous PrEP regimen, if the patient considers it more acceptable to use the intermittent regimen. The efficacy of intermittent PrEP for other key populations has not yet been proven, but can be used when evidence-based recommendations emerge.

79. If a patient receiving PrEP decides to switch from an intermittent to a permanent regimen, they will continue taking one TDF/FTC tablet daily at approximately the same time of day.

If the patient decides to switch from a permanent to an intermittent regimen, he can stop daily use of TDF/FTC by taking the last pill 48 hours after the last sexual contact.

80. During the passage of PrEP, mandatory monitoring of safety and efficacy is carried out, including:

examination by a specialist doctor 1 month after the start and thereafter every Three months; testing for HIV infection by determining HIV antibodies or antibodies,
HIV antigen and/or antigens 1 month after initiation and then every 3 months; testing for HIV infection for medical reasons (signs of acute retroviral syndrome, breaks in PrEP for more than 7 days with a constant regimen); determination of blood creatinine and calculation of QC every 6-12 months in persons aged 50 years and older or in the presence of chronic kidney disease, as well as in patients with QC<90 ml / min., determined in the first 3 months of PrEP or before its initiation; when determining QC <60 ml / min, the analysis is repeated, in case of a repeated result of QC <60 ml / min, PrEP is stopped until the cause of renal dysfunction is clarified; if necessary, for medical reasons, the determination of anti-HBs is carried out,
determination of antibodies to HCV (hereinafter referred to as anti-HCV), examination for STIs.

81. Upon receipt of a reactive result of a rapid HIV test before prescribing or during monitoring of the effectiveness of PrEP, venous blood is collected for diagnostic testing for HIV infection.

82. If anti-HCV is detected or if the test results for STI pathogens are positive, PrEP can be prescribed, and recommendations are given for further medical examination by a specialized doctor, until the completion of which it is necessary to avoid unprotected sexual intercourse.

CHAPTER 10 HIV PEPS WITH ARV-DRUGS

83. AEDs shall be prescribed for epidemic indications to persons at risk of HIV infection (exposed) in the following cases:

injury with a sharp instrument when performing manipulations in the provision of medical care to a patient with positive HIV status or a patient with unknown HIV status, but belonging to a key population group (subcutaneous or intramuscular injection with a hollow needle, placement of an intravascular catheter, skin damage with a scalpel, hollow or suture needle during surgery); contact lasting more than 15 minutes of mucous membranes or damaged skin with blood
HIV-positive patient;

sexual contact (vaginal or sex, receptive oral sex with ejaculation) of an exposed person who is not receiving or adhering to PrEP, with an HIV-positive partner without viral suppression, or with a partner with unknown HIV status but belonging to a key population; parenteral use of psychoactive substances using generic
devices (syringe, needle, etc.) together with a person with HIV-positive status;

contact with other body fluids containing HIV (cerebrospinal, pleural, synovial, peritoneal, amniotic), taking into account the circumstances of skin damage, the duration of exposure and the presence of visible blood impurities.

84. Before initiating AEDs or within the first 48 hours, exposed individuals are screened for HIV, HCV, and HBV. If it is impossible to use rapid tests within these periods, blood is taken for subsequent serological studies in the laboratory. In case of sexual contact, a medical examination for STIs is offered, women of childbearing age are offered a pregnancy test if necessary. The same set of examinations is assigned to the person with whom the contact occurred, if it can be established. If HIV-positive status is known, a medical examination for HIV is performed. With a detectable HIV VN, an HIV resistance test is prescribed.

85. AEDs begin as soon as possible, preferably in the first 4 hours after exposure, but no later than 72 hours.

86. PEP is prescribed by a specialist doctor if there are medical indications. The patient can receive the first dose of ARV-LS in the emergency departments of infectious diseases hospitals with round-the-clock treatment. Subsequently, the patient goes to the nearest HIV consultation department (office) or to the infectious diseases office that dispenses ART, where the specialist prescribing ART determines the appropriateness of continuing the PEP and, if necessary, modifies the scheme based on the results of a medical examination of the exposed person and the person with whom the contact occurred. During working hours, the patient can apply directly to the consultative and dispensary department (office) for HIV infection or to the office of infectious

diseases that dispenses ART. The tolerability of ARV-drugs, drug interactions with other drugs is monitored by an infectious disease doctor or a specialist who has been trained in ART.

87. Medical contraindications to AEDs are: HIV infection in the exposed person;

negative result of HIV screening testing of the person with whom the contact occurred, in the absence of signs of acute HIV infection and information about belonging to a key population group; contact with body fluids without blood content that do not pose a threat of HIV infection (tears, urine, sweat, saliva), or not accompanied by a significant violation of the integrity of the skin and mucous membranes.

88. The exposed person to whom the AEDs are assigned is informed about the AED procedure, the mode of use of the ARV-drugs, the potential risks and benefits of taking some ARV-drugs, and laboratory monitoring after completion. Also, all exposed persons are encouraged to practice protected sex until confirmation of HIV-negative status after completion of AEDs.

89. The ARV-LS regimens used for HIV AEDs are given in Appendix 32 and consist of an NRTI-base and a third ARV-LS.

90. Tenofovir-containing AEDs are prescribed to individuals regardless of HBV co-infection. In individuals with HBV co-infection, liver function is monitored after completion of AEDs, and a biochemical blood test is performed 1 and 4 months after completion of AEDs. In persons with unknown status in relation to HBV infection, when prescribing AEDs, a test is performed for the presence of HBsAg in the blood and then, if a positive result is obtained, a set of additional medical examinations is performed.

91. The duration of the PEP is 28 days. Upon receipt of a negative result of HIV screening testing of a person with whom contact has occurred, PEP may be terminated prematurely if there is no information about the person's belonging to a key risk group. AEDs may also be discontinued if there has been sexual contact with an HIV-positive person who has an HIV VN test result of less than 200 copies/ml.

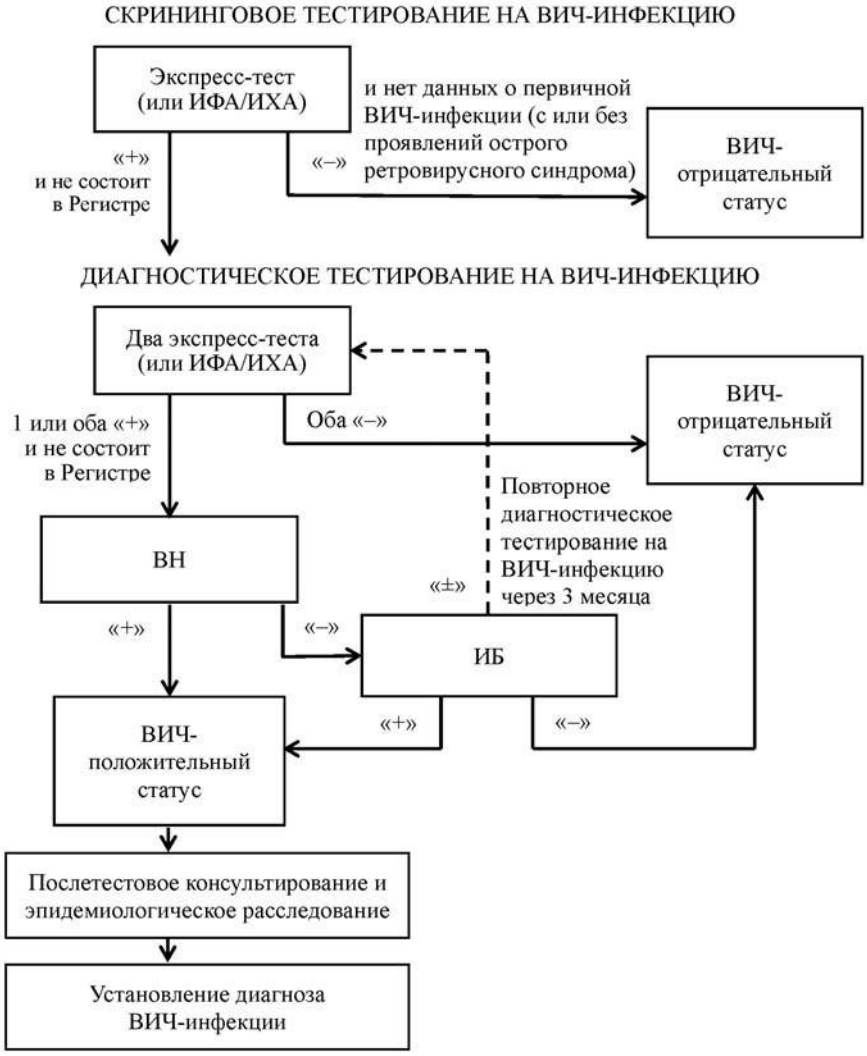
92. After completion of the AEDs, after 3 and 6 months, HIV testing is performed using laboratory ELISA methods on fourth-generation test systems.

93. If the person in contact had HCV infection, the exposed person is further screened for anti-HCV 3 and 6 months after exposure.

94. If the risk of HIV infection remains high after completion of the AED, PrEP is offered to the exposed person.

Annex 1
to the clinical protocol "Providing medical care to patients with HIV infection"

Algorithm for diagnosing HIV infection[2]



[2] Except for HIV-exposed children under 18 months of age, pregnant women, patients with probable primary HIV infection with or without manifestations of acute retroviral syndrome.

Notes:
"+" Positive (reactive) test result.
"–" Negative (non-reactive) test result.
"±" Doubtful (uncertain) test result.

to the clinical protocol "Provision of medical care"
Annex 2

patients with HIV infection"

Classification of HIV infection in patients aged 15 years and older

№ p / n	Stage	Diseases and conditions characterizing the stage
1	Acute infection	Asymptomatic course. Acute retroviral syndrome
2	1	Asymptomatic course. Persistent generalized lymphadenopathy
3	2	Unexplained moderate weight loss (loss of 5-10% of weight). Recurrent respiratory tract infections – (two or more cases of sinusitis, otitis media, bronchitis, pharyngitis, or tracheitis in any 6 months). Shingles (Herpes Zoster). Angular cheilitis. Recurrent mouth ulcers (two or more episodes in the last 6 months). Papular itchy rash. Fungal infections of the nails. Seborrheic dermatitis
4	3	Unexplained marked weight loss (loss of more than 10% of weight). Unexplained diarrhea (more than 1 month). Persistent unexplained fever, persistent or intermittent (more than 1 month). Candidiasis of the oral mucosa and (or) pharynx, recurrent (two or more times in the last 6 months) or prolonged (more than 1 month). Hairy leukoplakia of the mouth. TB of the lungs. Severe bacterial infections (e.g., pneumonia, bacteremia, bone and joint infections, pleural empyema, meningitis, severe inflammation of the uterus and appendages, pyomyositis).[1] Acute ulcerative-necrotic stomatitis, gingivitis or periodontitis. Hematologic disorders - unexplained anemia (hemoglobin less than 80 g / l), neutropenia (neutrophil count <0.5 x 10 9 / l), thrombocytopenia (platelet count <50 x 10^9 / l)

[1] Local or systemic bacterial infection (abscess, phlegmon, pyomyositis, sepsis, bacterial endocarditis) cannot be the only criterion for establishing stage 3 if any of the listed infectious complications is associated with intravenous drug administration.

to the clinical protocol "Provision of medical care"

5	4	HIV cachexia. Pneumocystis pneumonia (pneumonia caused by Pneumocystis jirovecii). Recurrent severe pneumonia, presumably bacterial (two or more cases in the last 12 months). Chronic infection caused by the herpes simplex virus (hereinafter referred to as HSV) with ulceration of the mucous membranes lasting more than 1 month or with damage to internal organs. Candidiasis of the esophagus or candidiasis of the trachea, bronchi, lungs. Extrapulmonary TB. Kaposi's sarcoma. Cytomegalovirus infection (retinitis, colitis or esophagitis). Toxoplasmosis (toxoplasmosis of the central nervous system, toxoplasmosis retinitis). HIV encephalopathy. Extrapulmonary cryptococcosis, including cryptococcal meningitis. Disseminated infection caused by atypical (non-tuberculous) mycobacteria. Progressive multifocal (multifocal) leukoencephalopathy. Chronic cryptosporidiosis (diarrhea lasting more than 1 month). Chronic isosporiasis (fever lasting more than 1 month). Disseminated (endemic) mycoses (coccidioidosis, histoplasmosis). Primary CNS lymphoma or B-cell non-Hodgkin lymphoma. HIV nephropathy with clinical and laboratory manifestations. HIV cardiomyopathy with clinical manifestations. Recurrent septicemia, including those caused by non-typhoid salmonella. Invasive cervical cancer. Atypical disseminated leishmaniasis

Annex 3

patients with HIV infection"

Classification of HIV infection in children under 15 years of age

No p/n	Stage	Diseases and conditions characterizing the stage
1	Acute infection	Asymptomatic course. Acute retroviral syndrome
2	1	Asymptomatic course. Persistent generalized lymphadenopathy
3	2	Unexplained persistent hepatosplenomegaly. Recurrent or chronic upper respiratory tract infections (otitis media, exudative otitis, sinusitis, tonsillitis). Zona. Linear erythema of the gums. Recurrent oral ulcers. Itchy papular rash. Fungal infections of the nails. Common (multiple) warts. Common molluscum contagiosum. Unexplained persistent enlargement of the parotid salivary glands

to the clinical protocol "Provision of medical care"

4	3	Unexplained moderate malnutrition that does not respond well to standard therapy[2] Unexplained long-term diarrhea (14 days or more). Unexplained persistent fever (above 37.5 °C, persistent or intermittent, more than 1 month). Persistent candidal stomatitis (in children older than 6 weeks). Hairy leukoplakia of the mouth. Tuberculous lymphadenitis, pulmonary TB. Severe recurrent bacterial pneumonia. Acute ulcerative-necrotic gingivitis or periodontitis. Hematological disorders - unexplained anemia (hemoglobin less than 80 g / l), neutropenia (neutrophil count less than $0.5^{\text{x } 10\,9\,/\,l}$), thrombocytopenia (platelet count less than 50 x 10^9 / l). Clinically significant lymphoid interstitial pneumonia. Chronic lung damage associated with HIV infection, including bronchiectasis
5	4	Unexplained severe protein-energy deficiency, growth retardation, or severe malnutrition that does not respond to standard therapy[3]. Pneumocystis pneumonia (causative agent of Pneumocystis jirovecii). Recurrent severe bacterial infections with the exception of pneumonia (e.g., pleural empyema, pyomyositis, bone and joint infections, meningitis). Chronic infection caused by HSV (cutaneous or mucocutaneous herpes lasting more than 1 month or visceral of any localization). Candidal esophagitis (or candidiasis of the trachea, bronchi, lungs). Extrapulmonary TB. Kaposi's sarcoma. Cytomegalovirus infection (retinitis or damage to other organs) that has developed in a child older than 1 month. Toxoplasmosis encephalitis (except newborns). HIV encephalopathy. Extrapulmonary cryptococcosis, including cryptococcal meningitis. Disseminated infection caused by atypical (non-tuberculous) mycobacteria. Progressive multifocal (multifocal) leukoencephalopathy. Chronic cryptosporidiosis (accompanied by diarrhea). Chronic isosporosis. Disseminated endemic mycosis (histoplasmosis, coccidioidomycosis, penicilliosis). CNS lymphoma or B-cell non-Hodgkin lymphoma. HIV-associated nephropathy. HIV-associated cardiomyopathy

Annex 4

patients with HIV infection"

Classification of HIV-associated immunodeficiency

No p/n	Classification of HIV-associated immunodeficiency	CD4+ lymphocyte count depending on age			
		up to 11 months. (in %)	12–35 months (in %)	36–59 months (in %)	over 5 years of age (cells/μL)
1	Negligible	more than 35	more than 30	more than 25	more than 500
2	Temperate	30–35	25–30	20–25	350–499
3	Expressed	25–29	20–24	15–19	200–349

[2] Moderate malnutrition **in** children under the age of 5 years is established with a ratio of body weight and height on a scale of Z <2 and (or) with a mid-shoulder circumference of 115 mm to 125 mm.

[3] Severe protein-energy deficiency in children under the age of 5 years is established with a ratio of body weight and height on a scale of Z <3 and (or) with a mid-shoulder circumference of <115 mm, and (or) in the presence of swelling. The assessment is carried out using the Anthro program, the assessment of the deficit of growth and body weight is also possible according to centile tables.

to the clinical protocol "Provision of medical care"

4	Heavy	less than 25	less than 20	less than 15	less than 200 (or less than 15%)

Annex 5
to the clinical protocol "Provision of medical care to patients with HIV infection"

Algorithm for clinical and laboratory monitoring of the health status of patients with HIV infection

№ p / n	Health services and interventions in the provision of medical care at the stage of medical supervision	Follow-up period		
		Initial examination when registering	Without ART	On ART
1	Dispensary reception (medical examination, consultation) of an infectious disease doctor. Collection of anamnesis and complaints in case of an infectious disease. Collection of anamnesis and complaints therapeutic	Once	1 time in 6 months	Before starting ART, then 1 time in 6 months
2	Determination of body mass index	Once	1 time in 12 months	1 time in 12 months
3	Analysis of drug interactions	–	–	At each medical examination by an infectious disease doctor
4	Clinical and anamnestic TB screening with assessment of clinical symptoms and contact with TB patient (not including lung X-ray and C-reactive protein determination)	Once	At the medical examination	At the medical examination
5	Skin tuberculin test or determination of interferon gamma secretion	Once	1 time in 2 years or after contact	1 time in 2 years or after contact
6	Determination of class G antibodies (IgG) to Toxoplasma (Toxoplasma gondii) in the blood	Once	In seronegative patients with a decrease in the number of CD4 + lymphocytes less than 200 cells / μl (in children with severe immunodeficiency) - once	In seronegative patients with a decrease in the number of CD4 + lymphocytes less than 200 cells / μl and the absence of viral suppression (in children with severe immunodeficiency) - once

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15	Determination of class G (IgG) HBsAg antibodies in the blood	Once; HBV vaccination is offered to seronegative people	–	–
16	Determination of antibodies to pale treponema (Treponema pallidum) in the blood	In adults - once, in children - For medical reasons	For medical reasons	For medical reasons
17	General (clinical) blood test	Once	1 time in 6 months	Before starting ART, then 1 time in 6 months until therapeutic remission, then 1 time in 12 months; when using the scheme with AZT - 1 time in 6 months
18	General urinalysis	Once		Before starting ART, then when using a scheme with TDF - through 3 months after start ART; then 1 time in 6 months when using a scheme with TDF, as well as in all patients with diabetes mellitus, arterial hypertension or glomerular filtration rate (hereinafter referred to as GFR) <60 ml / min.
19	Biochemical blood test	Once	1 time in 12 months	Before the start of ART, then 3 months after the start of ART, then 1 time in 12 months; when using ABC, EFV, ATV - 1 time in 6 months, determination of hepatic parameters 6 in HBsAg-positive patients every 3 months during the first year of ART, then 1 time in 12 months
20	Determination of glycated hemoglobin (HbA1)	If the fasting blood glucose concentration is 5.7–6.9 mmol/l		
21	Determination of lipid metabolism indicators: total cholesterol, triglycerides, high-density lipoproteins	–	With an increase in blood cholesterol levels 1 time in 12 months, 1 time in 12 months, all PLHIV over 40 years of age	With an increase in blood cholesterol levels 1 time in 12 months, 1 time in 12 months, all PLHIV over 40 years of age

22	Study of nephron function (Cockcroft-Gault clearance, or GFR assessment using the CKD-EPI formula)	Once	1 time in 12 months	Before starting ART and then 1 time in 12 months on ART without TDF. Before the start and then 1 time in 6 months when using TDF or with a decrease in clearance of less than 90 ml / min.
23	Study of the level of total calcium, inorganic phosphorus in the blood (in patients under the age of 18 years)	–	–	Before starting and then 1 time in 6 months when using TDF
24	Sign up electrocardiograms (hereinafter referred to as ECG)	–	–	Once before starting ART using IP/B
25	Fluorography of the lungs or X-ray of the lungs	1 time per year		
26	Ultrasound examination (hereinafter referred to as ultrasound) of the liver	1 time in 6 months in patients with cirrhosis of the liver, regardless of etiology, and in HBsAg-positive patients with any of the following concomitant risk factors: family history of hepatocellular carcinoma, age over 45 years, co-infection with IOP		
27	Preventive appointment with an obstetrician-gynecologist (for women)	1 time per year		
28	Preventive reception (medical examination, consultation), a neurologist, a pediatric neurologist	In patients with a CD4+ lymphocyte count of less than 200 cells / μL (in children with severe immunodeficiency) in the presence of complaints		
29	Preventive appointment (medical examination, consultation) of an ophthalmologist	In patients with a CD4+ lymphocyte count of less than 200 cells / μL (in children with severe immunodeficiency) in the presence of complaints		
30	Magnetic resonance imaging (hereinafter referred to as MRI) of the brain or computed tomography (hereinafter referred to as CT) of the head with contrast	Once in patients seropositive to toxoplasma with a CD4 + lymphocyte count of less than 100 cells / μL in the presence of clinical signs: fever, neurological symptoms of any severity, as well as in children with severe immunodeficiency		

[6] Determination of total and bound bilirubin, alanine aminotransferase (hereinafter referred to as ALT), aspartic aminotransferase (hereinafter referred to as AST), gammaglutamyl transpeptidase (hereinafter referred to as GGTP), alkaline phosphatase (hereinafter referred to as alkaline phosphatase), C-reactive protein.

Annex 6
to the clinical protocol "Provision of medical care to patients with HIV infection"

Main characteristics and dosage regimens of ARV-LS

№ p / n	International nonproprietary name ARV-LS, abbreviation	Forms of release and dosage	Dosage regimen in adults and children 10 years and older, recommended World Organization Health (hereinafter referred to as WHO)	Dosage regimens in children under 10 years of age recommended WHO, the European Network on HIV Infections in children (hereinafter referred to as PENTA) and the Office Health and Welfare U.S. security (hereinafter referred to as DHHS)	Restrictions on use, Caution
1	NRTI				
1.1	TDF	Tablets 300 mg; tablets 150 mg, 200 mg and 250 mg; powder with a measuring spoon (40 mg per spoon); also as part of fixed combinations	300 mg 1 time per day	Children ≥ 2 years old: powder at a dose of 8 mg / kg (rounded to a whole measuring spoon) 1 time per day. In children weighing 10-16 kg	It has a pronounced antiviral activity against HBV. It is not prescribed for GFR less than 50 ml / min., Not controlled by arterial

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		10 mg/ml; also as part of fixed combinations		Infants from 4 weeks to 3 months: 4 mg / kg solution 2 times a day orally. Children from 3 months to 3 years: 5 mg / kg 2 times a day orally. Children ≥3 years: 5 mg/kg (maximum 150 mg) 2 times a day, or 10 mg / kg (maximum 300 mg) 1 time per day orally. Tablets can be used in children weighing >14 kg, who know how to swallow them: children weighing 14-19 kg - 75 mg each 2 times a day or 150 mg 1 time per day, children weighing 20-24 kg - 75 mg in the morning and 150 mg in the evening or 225 mg 1 time per day, children weighing >25 kg - 150 mg 2 times a day or 300 mg 1 time per day	

1.5	AZT	Tablets 300 mg; capsules 100 mg; Dispersible tablets 60 mg; solution for oral administration 10 mg/ml; solution for infusion 10 mg / ml - 20 ml; also as part of fixed combinations	300 mg 2 times a day	Newborns >35 weeks Gestation: 4 mg / kg 2 times a day, over 4 weeks - 12 mg / kg 2 times a day orally. Newborns 30-34 weeks of gestation: 2 mg / kg 2 times a day in the first 2 weeks of life, 3 mg / kg 2 times a day until 6-8 weeks of life, then 12 mg / kg 2 times a day orally. Newborns <30 weeks Gestation: 2 mg / kg 2 times a day in the first 2 weeks of life, 3 mg / kg 2 times a day for up to 8-10 weeks of life, then 12 mg / kg 2 times a day orally.	It is not prescribed for anemia and neutropenia of moderate to severe degree; Be wary appoint with other drugs, leading to anemia, neutropenia. Other adverse reactions: lipodystrophy, dyslipidemia, hepatic steatosis, myopathy, rhabdomyolysis, hyperlactatemia, nail pigmentation, nausea. The contents of the capsules can be extracted and dispersed in water

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1.9	TAF/FTC	25 mg/200 mg tablets	1 tablet 1 time per day	Children >6 years old and weighing > 25 kg: 1 tablet 1 time per day. In combination with PI / b is prescribed for body weight >35 kg	It is not used for QC below 30 ml / min. Tablets should not be cut or crushed
1.10	ABC/3TC	Tablets 600 mg/300 mg; Dispersible tablets 60 mg/30 mg; Dispersible tablets 120 mg/60 mg	1 tablet 600 mg/300 mg 1 time per day	Adult dosage is prescribed for children weighing >25 kg	Tablets should not be cut or crushed
1.11	AZT/3TC	Tablets 300 mg/150 mg; Dispersible tablets 60 mg/30 mg	1 tablet 300 mg/150 mg 2 times a day	Adult dosage is prescribed for children weighing >25 kg	Similar with restrictions on use, cautions to AZT and 3TC
2	AI				

2.1	DTG	Tablets (film-coated) 50 mg; Pills (dispersible) 5 mg and 10 mg; also as part of fixed combinations	50 mg 1 time per day	Children ≥ 4 weeks: dispersible tablets with a body weight of 3-5 kg - 5 mg, 6-9 kg - 15 mg, 10-13 kg – 20 mg, 14–20 kg - 25 mg, 20 - 25 kg - 30 mg 1 time per day. Children weighing > 20 kg: use an adult tablet 50 mg 1 time per day	Frequent adverse reactions: overweight, sleep disturbances, headache; decrease in creatinine secretion without disturbing glomerular filtration. Rare dangerous adverse reaction: systemic hypersensitivity reaction. It is recommended to take DTG with food. It is taken 2 hours before or 6 hours after drugs containing polyvalent cations (magnesium or aluminum containing antacids, saline laxatives, sucralfate, iron and calcium preparations)
2.2	RAL	Tablets (film-coated) 400 mg; tablets (chewable) 25 mg and 100 mg; granules (100 mg in a sachet-dose)	400 mg 2 times a day	Children ≥4 weeks: chewable tablets or granules of 6 mg / kg 2 times a day. Children weighing >25 kg: An adult tablet of 400 mg is used 2 times a day	Decrease in creatinine secretion without disturbing glomerular filtration. Frequent adverse reaction: the appearance of overweight. Rare dangerous adverse reactions: rhabdomyolysis, systemic hypersensitivity reaction. 400 mg tablets are permissible to divide and grind. It is taken 2 hours before or 6 hours after drugs containing polyvalent cations (magnesium or aluminum containing antacids,
					saline laxatives, sucralfate, iron and calcium preparations)
2.3	BIC	As part of fixed combinations	–	–	Decrease in creatinine secretion without disturbing glomerular filtration. Frequent adverse reaction: the appearance of overweight
3	NNRTIs				

3.1	EFV	Tablets 600 mg; 400 mg tablets; tablets divided with a notch of 200 mg; also as part of fixed combinations	400 mg or 600 mg 1 time per day	Children ≥ 3 years of age: 367 $^{mg/m^2}$ or 15 mg / kg once a day orally, but not more than 600 mg / day (preferably use a simplified dosing regimen). Children with a body weight of >40 kg can be prescribed both a dosage of 400 mg and a dosage of 600 mg 1 time per day	Not used in patients with severe mental disorders, depression. Adverse reactions: depression, sleep disturbances, headache, dyslipidemia, decreased vitamin D in plasma, rash, hepatitis, gynecomastia. EFV is not routinely indicated in children of the first 3 years of life due to variability in pharmacokinetics, requiring genotyping of CYP2B6 to determine the appropriate dosage regimen
3.2	NVP	Dispersible tablets 50 mg; syrup 10 mg/ml	–	It is used in schemes for the prevention of mother-to-child transmission of HIV: full-term newborns 16 mg / day once; premature babies weighing 1500-2000 g - 8 mg / day once. Not recommended for use in ART regimens in children, a modification of the scheme with the transition to other ARVs-drugs is shown	–
3.3	DOR	Tablets 100 mg; also as part of fixed combinations	1 tablet 1 time per day	Children under 18 years of age are not prescribed	Infrequent adverse reactions: sleep disturbances, headache

3.4	RPV	Tablets 25 mg; also as part of fixed combinations	1 tablet 1 time per day	Children >12 years with a ~~b~~body weight of >35 kg: 1 tablet 1 time per day	Taken with food (a serving of at least 500 kcal), when administered with antacids, the latter are taken 2 hours before or 4 hours after taking the RPV. Infrequent adverse reactions: depression, sleep disturbances, headache, rash, hepatitis, decreased creatinine secretion without impaired glomerular filtration
4	Pharmacological enhancers (boosters)				
4.1	RTV	Tablets 100 mg; suspension 80 mg/ml	100 mg 1-2 times a day (depending on the method of administration, amplified IE)	Children's dosages are given below in the lines relating to the individual reinforceable UIs	It is prescribed with caution in violation of intracardiac conduction. Frequent adverse reactions: nausea, diarrhea, dyslipidemia. The tablets should not be cut or crushed. It is recommended to take with food
4.2	COB	As part of fixed combinations	150 mg once daily	–	Decrease in creatinine secretion without disturbing glomerular filtration. They are not used in pregnant women due to their lower efficacy. The tablets should not be cut or crushed. It is recommended to take with food
5	UI				

5.1	LPV/r	Tablets 200 mg/50 mg; 100 mg/25 mg tablets; solution for oral administration 80/20 mg/ml; granules for the preparation of a solution for oral administration 40 mg / 10 mg	400 mg/100 mg 2 times a day	Children from 2 weeks to 6 months: 300 mg / 75 mg / m 2 2 times a day, which is approximately 16 mg / 4 mg / kg 2 times a day in the form of a solution or granules. Children > 6 months: 300 mg / 75 mg / m 2 2 times a day (but not more than 400 mg / 100 mg 2 times a day), which for children weighing < 15 kg is approximately	It is prescribed with caution in violation of intracardiac conduction. LPV/r enhances the nephrotoxicity of TDF With a joint Applying. Frequent adverse reactions: nausea, diarrhea, dyslipidemia. It is not recommended for patients with coronary artery disease. The LPV/r solution requires refrigeration (shelf life 42 days after opening), contains 42% alcohol and 15%

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				together with RTV capsule 100 mg once a day. Children weighing ≥25 kg: ATV adult capsule 300 mg together with RTV capsule 100 mg once daily (including in combination ATV/r)	ranitidine at 12-hour intervals with ATV)
5.3	ATV/r	Tablets 300 mg/100 mg	1 tablet 1 time per day	Children >12 years with a ~~b~~body weight of >35 kg: 1 tablet 1 time per day	The tablets should not be cut or crushed. It is recommended to take with food
5.4	ATV/sec	Tablets 300 mg/150 mg	1 tablet 1 time per day	Children >12 years with a ~~b~~body weight of >35 kg: 1 tablet 1 time per day	The tablets should not be cut or crushed. It is recommended to take with food

5.5	.DRV	Tablets 600 mg; Pills 800 mg; "children's" tablets 75 mg and 150 mg; syrup 100 mg/ml	DRV 600 mg + RTV 100 mg 2 times a day. Earlier those who did not receive PI or did not have mutations of resistance to DRV: DRV 800 mg + RTV 100 mg 1 time per day.	Children >3 years of age weighing ≥10 kg: DRV syrup 20 mg/kg together with RTV syrup 3.2 mg / kg 2 times a day. The syrup is usually used in children weighing 10-19 kg, with a mass of 14-24 kg, you can use children's DRV tablets in a total single dosage of 375 mg together with RTV tablets of 50 mg 2 times a day. Children weighing ≥25 kg: DRV adult tablet 600 mg together with RTV tablet 100 mg 2 times a day. Children with a body weight of > 14 kg who have not previously received PI or do not have mutations of resistance to DRV, a single daily dosage regimen is possible: DRV 800 mg + RTV 100 mg 1 time per day	Appointed with caution in violation of intracardiac conduction. Frequent adverse reactions: nausea, diarrhea. It is recommended to avoid the appointment of patients with coronary artery disease. DRV / r is not indicated for children of the first 3 years due to the risk of seizures. The tablets can be cut and crushed. Recommended to be taken with food

5.6	DRV/r	Tablets 800 mg/100 mg	Earlier those who did not receive PI or did not have mutations of resistance to DRV: 1 tablet 1 time per day	Children with a body weight of >14 kg, who have not previously received PI or do not have mutations of resistance to DRV, a single daily dosage regimen is possible: DRV 800 mg + RTV 100 mg 1 time per day	The tablets should not be cut or crushed. It is recommended to take with food

5.7	DRV/c	Tablets 800 mg/150 mg	1 tablet 1 time per day with meals	Children with body weight ≥40 kg: 1 tablet 1 time per day with meals	With CC less than 70 ml / min. is not prescribed with TDF. Frequent adverse reactions: dyslipidemia, hyperbilirubinemia, lipodystrophy. The tablets should not be cut or crushed. It is recommended to take with food
6	Combined drugs with fixed dosages for a single dose per day				
6.1	TDF/3TC/DTG (TLD)	Pills 300 mg/300 mg/50 mg	1 tablet 1 time per day	Children >12 years old with a body weight of >35 kg, 1 tablet 1 time per day	–
6.2	ABC/3TC/DTG	Pills 600 mg/300 mg/50 mg	1 tablet 1 time per day	Children with body weight ≥25 kg: 1 tablet 1 time per day	–
6.3	3TC/DTG	Tablets 300 mg/50 mg	1 tablet 1 time per day	Children with body weight ≥25 kg: 1 tablet 1 time per day	The tablets can be cut and crushed
6.4	TAF/FTC/BIC	Pills 25 mg/200 mg/50 mg; Pills 15 mg/120 mg/30 mg	1 tablet 25 mg/200 mg/50 mg 1 time per day	Children with body weight 14-24 kg: 1 tablet 15 mg/120 mg/30 mg once daily. Children with body weight ≥25 kg: 1 tablet 25 mg/200 mg/50 mg 1 time per day	It is not used for QC below 30 ml / min. Tablets should not be cut or crushed
6.5	TDF/FTC/EFV	Pills 300 mg/200 mg/400 mg; Pills 300 mg/200 mg/600 mg	1 tablet 1 time per day	Assign patients aged 12 years and older, 1 tablet 1 time per day	–
6.6	TDF/3TC/EFV	Pills 300 mg/300 mg/400 mg; Pills 300 mg/300 mg/600 mg	1 tablet 1 time per day	Assign patients aged 12 years and older with a body weight of more than 40 kg, 1 tablet 1 time per day	–
6.7	TAF/FTC/RPV	Pills 25 mg/200 mg/25 mg	1 tablet 1 time per day	Children with body weight ≥35 kg: 1 tablet 1 time per day	It is not used when QC is below 30 ml / min. Tablets should not be cut or crushed.

6.8	TDF/FTC/RPV	Pills 300 mg/200 mg/25 mg	1 tablet 1 time per day	Children ≥12 years old with a body weight of ≥35 kg, 1 tablet 1 time per day	It is recommended to take with food (AUC RPV on an empty stomach is 40% less). It is not prescribed for VN >100,000 copies / ml. Rifampicin and proton pump inhibitors are contraindicated, since they significantly reduce the concentration of RPV
6.9	DTG/RPV	50 mg/25 mg tablets	1 tablet 1 time per day	Children ≥12 years old with a body weight of ≥35 kg, 1 tablet 1 time per day	The tablets can be cut and crushed. It is recommended to take with food (>533 kcal)
6.10	TDF/3TC/DOR	Pills 300 mg/300 mg/100 mg	1 tablet 1 time per day	Children are not shown	Tablets should not be cut or crushed
6.11	TAF/FTC/DRV/c	Pills 10 mg/200 mg/800 mg/150 mg	1 tablet 1 time per day	Children ≥12 years old with a body weight of ≥35 kg, 1 tablet 1 time per day	The tablets can be cut, but not crushed. It is recommended to take with food

Note. TAF, RAL, BIC, DOR, RPV, COB and (or) combinations with them are appointed at their own expense, funds of legal entities and other sources not prohibited by law, in the presence of medical indications (for vital indications, taking into account individual intolerance) by decision of the medical consultation, and if it is impossible to conduct it - the attending physician or a person replacing him, with an entry in medical documents.

Annex 7
to the clinical protocol "Provision of medical care to patients with HIV infection"

Dosing regimens of liquid oral forms of ARV-drugs in children under the age of 4 weeks[7]

№ p / n	ARV-LS	The content of the active ingredient in the children's dosage form		The number of milliliters depending on body weight in the morning and evening					
				2.0–2.9 kg		3.0–3.9 kg		4.0–4.9 kg	
				morning	Evening	morning	Evening	morning	Evening
1	AZT	10 mg/ml		1 ml	1 ml	1.5 ml	1.5 ml	2 ml	2 ml
2	ABC	20 mg/ml		0.4 ml	0.4 ml	0.5 ml	0.5 ml	0.6 ml	0.6 ml
3	NVP	10 mg/ml		1.5 ml	1.5 ml	2 ml	2 ml	3 ml	3 ml
4	3TS	10 mg/ml		0.5 ml	0.5 ml	0.8 ml	0.8 ml	1 ml	1 ml
5	LPV/r8	80/20 mg/ml		0.6 ml	0.6 ml	0.8 ml	0.8 ml	1 ml	1 ml
		Granules 40 mg/10 mg sachets		–	–	2	2	2	2
6	RAL9	10 mg/ml (granules for oral suspension: 100 mg sachet)	≤1 weeks	0.4 ml (once a day)		0.5 ml (once a day)		0.6 ml (once a day)	
			>1 weeks	0.8 ml	0.8 ml	1 ml	1 ml	1.5 ml	1.5 ml

[7] Data on the pharmacokinetics of most ARVs (except AZT) in newborns are limited; However, these standardized dosages for infants in the first month of life are used with a high degree of certainty, although some uncertainty persists in preterm infants and infants with low birth weight.

[8] LPV/r solution is not prescribed to newborns younger than 2 weeks, as well as premature infants before they reach the gestational age of 42 weeks because of the risk of metabolic and cardiac adverse reactions.

[9] Granules for the preparation of a suspension for oral administration of RAL are used in newborns weighing at least 2 kg, the regimen is once a day during the first week of life and twice a day after.

Annex 8
to the clinical protocol "Provision of medical care to patients with HIV infection"

Simplified dosing regimens for solid oral forms of ARV-LS for once-daily administration in children 4 weeks of age and older

№ p / n	ARV-LS	The content of the active ingredient in the children's dosage form	Number of tablets or capsules, depending on body weight, to be taken once a day					The content of the current Substances in a tablet (or capsule) for adults	Number of tablets (or capsules) for adults, depending on body weight, to be taken once a day
			3.0–5.9 kg[4]	6.0 - 9.9 kg	10.0 - 13.9 kg	14.0 - 19.9 kg	20.0 - 24.9 kg		25.0 - 34.9 kg
1	EFV[5]	Tablets (divisible with notch) 200 mg	–	–	1	1,5	1,5	200 mg	2
2	ABC/3TC	Tablets (dispersible) 60 mg/30 mg	2	3	4	5	6	600 mg/300 mg	1
		Tablets (dispersible) 120 mg/60 mg	1	1,5	2	2,5	3		
3	ABC	Tablets (dispersible) 60 mg	2	3	4	5	6	300 mg	2
4	TAF[6]/FTC	25 mg/200 mg tablets	–	–	–	–	–	25 mg/200 mg	1
5	ATV[7]	Capsules 100 mg	–	–	2	2	2	300 mg	1
		Capsules 200 mg	–	–	1	1	1		
6	.DRV[8]	Tablets 150 mg	–	–	–	4	4	600 mg	1
		Tablets 600 mg	–	–	–	1	1		
7	RTV15	Tablets 25 mg	–	–	–	4	4	100 mg	1
		Tablets 50 mg	–	–	–	2	2		
8	DTG16	Film-coated tablets, 50 mg	–	–	–	–	1	50 mg	1

[4] These dosages are used with a high degree of certainty in infants older than 4 weeks of life with a body weight of <3.0 kg, although some uncertainty persists in preterm infants and infants with low birth weight.

[5] EFV is not recommended for children under 3 years of age and weighing <10 kg.

[6] TAF can be used in children >6 years of age with a body weight of >25 kg as part of combinations with fixed doses of TAF / FTC 25 mg / 200 mg and TAF / FTC / DTG 25 mg / 200 mg / 50 mg. Children weighing >35 kg TAF can be prescribed as part of a combination of TAF / FTC / RPV and with a combination of TAF / FTC with boosted PI.

[7] ATV is used in children aged >3 months in powder form, >6 years in capsule form. ATV should be boosted by RTV: children weighing >5 kg receiving ATV in powder form - the dose of RTV is 80 mg (1 ml of solution) once a day, children weighing >10 kg receiving ATV in the form of capsules - the dose of RTV is a standard capsule of 100 mg.

[8] DRV, boosted by RTV, is used in children >3 years old; if PIs have not been used before, a once-in-a-day regimen is preferred.

		Tablets (dispersible) 5 mg	1	3	4	5	6		
		Tablets (dispersible, divisible with a notch) 10 mg	0,5	1,5	2	2,5	3		

[15] RTV is used as a booster for ATV or DRV or as an additional booster for LPV/r when used concomitantly with rifampicin.

[16] DTG dispersible tablets and film-coated DTG tablets are not bioequivalent: 30 mg of a dispersible DTG tablet corresponds to 50 mg of a film-coated tablet. DTG 50 mg film-coated tablets are preferred for children who have reached a mass of 20 kg (unless they are unable to swallow the tablets). For children weighing ≥30 kg can be used and is preferred combined drugs TLD (TDF/3TC/DTG in dosages of 300 mg/300 mg/50 mg). It is preferable to take DTG with food, antacids/mineral supplements containing polyvalent cations should be avoided 6 hours before and 2 hours after ingestion.

Annex 9
to the clinical protocol "Provision of medical care to patients with HIV infection"

Simplified dosing regimens for solid and liquid oral forms of ARV-drugs for twice daily administration in children 4 weeks of age and older

№ p / n	ARV-LS	The content of the active ingredient in the children's dosage form	Number of tablets or milliliters depending on body weight in the morning and evening										The content of the active ingredient in the tablet for adults	Number of tablets for adults depending on the weight Body	
			3.0 - 5.9 kg17		6.0 - 9.9 kg		10.0 - 13.9 kg		14.0 - 19.9 kg		20.0 - 24.9 kg			25.0 - 34.9 kg	
			morning	Evening	morning	Evening	morning	Evening	morning	Evening	morning	Evening		morning	Evening
1	Solid dosage forms														
1.1	AZT	Tablets (dispersible) 60 mg	1	1	1,5	1,5	2	2	2,5	2,5	3	3	300 mg	1	1
1.2	AZT/3TC	Tablets (dispersible) 60 mg/30 mg	1	1	1,5	1,5	2	2	2,5	2,5	3	3	300 mg/150 mg	1	1
1.3	ABC	Tablets (dispersible) 60 mg	1	1	1,5	1,5	2	2	2,5	2,5	3	3	300 mg	1	1
1.4	ABC/3TC18	Tablets (dispersible) 60 mg/30 mg	1	1	1,5	1,5	2	2	2,5	2,5	3	3	600 mg/300 mg	0,5	0,5
		Tablets (dispersible) 120 mg/60 mg	0,5	0,5	0,5	1	1	1	1	1,5	1,5	1,5			

1.5	LPV/r19	100 mg/25 mg tablets	–	–	–	–	2	1	2	2	2	2	100 mg/25 mg	3	3
		Granules 40 mg/10 mg	2	2	3	3	4	4	5	5	6	6			
1.6	DRV20	Tablets 75 mg	–	–	–	–	–	–	5	5	5	5	400 mg	1	1
1.7	RTV21	Tablets 25 mg	–	–	–	–	–	–	2	2	2	2	100 mg	1	1
		Tablets 50 mg	–	–	–	–	–	–	1	1	1	1			
1.8	RAL22	Chewable tablets 25 mg	1	1	2	2	3	3	4	4	6	6	400 mg	1	1
		Chewable tablets 100 mg	–	–	–	–	–	–	1	1	1,5	1,5			
		Granules 100 mg	0,25	0,25	0,5	0,5	–	–	–	–	–	–			
2[9][10]	Liquid dosage forms (solutions and suspensions for oral administration)														
2.1	AZT	10 mg/ml	6 ml	6 ml	9 ml	9 ml	12 ml	12 ml	–	–	–	–	–	–	-
2.2	ABC[11]	20 mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	–	–	–	–	–	–	-
2.3	3TS	10 mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	–	–	–	–	–	–	-
2.4	LPV/r[12]	80 mg/20 mg/ml	1 ml	1 ml	1.5 ml	1.5 ml	2 ml	2 ml	2.5 ml	2.5 ml	3 ml	3 ml	–	–	–
2.5	.DRV	100 mg/ml	–	–	–	–	2.5 ml	2.5 ml	3.5 ml	3.5 ml	–	–	–	–	–
2.6	RTV	80 mg/ml	–	–	–	–	0.5 ml	0.5 ml	0.6 ml	0.6 ml	–	–	–	–	–
2.7	RAL	10 mg/ml (granules for oral suspension: 100 mg sachet)	3 ml	3 ml	5 ml	5 ml	8 ml	8 ml	10 ml	10 ml	–	–	–	–	–
2.8	NVP[13]	10 mg/ml	5 ml	5 ml	8 ml	8 ml	10 ml	10 ml	13 ml	13 ml	15 ml	15 ml	–	–	–

[9] RTV is used only as a pharmacological booster (booster) in combination with ATV or DRV.

[10] In infants aged >4 weeks, RAL can be used in both granules and crushed chewable tablets: pharmacokinetics studies in infants show their bioequivalence.

[11] The recommended dosage of ABC solution for children older than 4 weeks is significantly higher than for newborns: this is done to ensure the comparability of the dose of the liquid dosage form and dispersible tablets, and does not lead to an increase in toxicity.

[12] The LPV/r solution requires compliance with the cold chain during transportation and storage. The LPV/r solution contains 42.4% alcohol and 15.3% propylene glycol, which may be significant when used in newborns and infants.

[13] NVP is not used in ART regimens in children; Previously, NVP was prescribed to children in single dosages in the first 2 weeks of administration once a day, then switched to maintenance 2 times a day; children >25 kg were given NVP in an adult single dose of 200 mg.

[17] These dosages are also used with a high degree of certainty in infants older than 4 weeks of life with a body weight of <3.0 kg, some uncertainty persists in premature infants and infants with low birth weight.

[18] The recommended dosage of ABC solution for children older than 4 weeks is significantly higher than for newborns to ensure comparability of the dose of the liquid dosage form and dispersible tablets, and does not lead to an increase in toxicity.

[19] Thermostable LPV/r tablets should be swallowed whole and should not be divided, crushed or chewed (although the 100 mg/25 mg tablet is large enough that some children may have difficulty swallowing it). In the case of normal swallowing of tablets by a child, an adult tablet of 200 mg / 50 mg can be prescribed to children 14-24 kg (1 tablet in the morning and evening), as well as children 25-34 kg (1 tablet in the morning and 2 in the evening).

[20] DRV is used in children ≥ 3 years old; prescribed together with RTV, the dosage of RTV for children weighing <15 kg is 0.5 ml of a suspension of 80 mg / ml, for children weighing 15-30 kg is 50 mg (tablets of 25 or 50 mg), or if they are not available, it is possible to use an adult dosage of 100 mg (such an excess of dosage is safe and well tolerated).

Annex 10
to the clinical protocol "Providing medical care to patients with HIV infection" First-line **ART regimens**

№ p/n	Category Patients	Preferred first-row schemes	Alternative first-row schemes	Valid first-row schemes
1	Adults and children ≥10 years old	TDF/XTC26+DTG27 TAF28/FTC+DTG27 TAF/FTC/BIC	TDF/XTC26+EFV400 mg TAF/FTC+EFV ABC/3TC+DTG27	TDF/XTC26+EFV600 mg TDF/XTC26+IP/B TAF28/FTC+IP/B AZT/3TC+EFV 600 mg TDF/XTC26+DOR (RPV29) TAF28/FTC+DOR (RPV29) 3TC+DTG27, 30
2	Children ≥4 weeks – <10 years	ABC+3TC+DTG	ABC+3TC+LPV/r (ATV/r, DRV/r31) TAF28/FTC+DTG (BIC32)	ABC+3TC+EFV (NVP) ABC+3TC+RAL33 AZT+3TC+EFV (NVP) AZT+3TC+LPV/r (RAL)
3	Newborns (<4 weeks)	AZT (ABC)+3TC +RAL34	AZT (ABC) +3TC +NVP	AZT (ABC) +3TC +LPV/r35

[26] 3TC or FTC.

[27] DTG may be prescribed to women of childbearing age who want to become pregnant or who do not use contraception if they have been informed of a possible but not proven increase in the risk of neural tube defects (at conception and before the end of the first trimester at 0.19%, which is not statistically significant). If a woman becomes pregnant after the first trimester, DTG should be started or continued throughout pregnancy.

[28] TAF is recommended for patients with established osteoporosis, osteopenia and (or) impaired renal function, as well as with the combined use of nephrotoxic drugs. In non-booster ART regimens, TDF and TAF have comparable negative effects on kidney function and bone density in the short term. The use of TAF in AI circuits is much more likely to lead to overweight gain compared to TDF.

[29] RPV can be used for CD4>200 cells/μL and HIV BH <100,000 copies/ml, contraindicated when used together with antacids, taken with high-calorie foods.

[30] The 3TC+DTG regimen can be used in HBsAg-negative patients, with HIV<500,000 copies/mL; cannot be prescribed after failure of PrEP unless a resistance test indicates that 3TC remains active.

[31] DRV/r can be given to a child ≥3 years old.

[32] BIC can be given to a child >6 years old and weighing ≥25 kg.

[33] RALs are used as part of an alternative regimen only if solid dosage forms of IP/b (LPV/r, ATV/r or DRV/r) are not available.

[34] Newborns starting ART on the RAL regimen are switched to DTG as soon as possible if an age-appropriate dosage form is available. For newborns weighing <2 kg, the preferred regimen includes NVP rather than RAL.

[35] LPV/r syrup or granules can be used from the age of ≥14 days.

Annex 11
to the clinical protocol "Provision of medical care to patients with HIV infection"

Second-line ART schemes

№ p/n	Categories of patients	ART components (NRTI-base or third ARV-LS)		
		In first-row schemes	In preferred second-row schemes	In alternative second-row schemes
1	Adults and children ≥10 years old	TDF (TAF)+XTC36	AZT37+3TC	AZT37+3TC circuits without NRTI[38]

		ABC+3TC	AZT37+3TC	AZT37+3TC circuits without NRTI[38]
		AZT+3TC	TDF (TAF)+XTC36	ABC+3TC
		DTG	ATV/r (LPV/r)	DRV/r 2 DTG39, 40
		EFV (NVP)	DTG40 BIC41	ATV/r (LPV/r, DRV/r)
		LPV/r (ATV/b)	DTG40 BIC41	DRV/b42
		DRV/b	DTG40 BIC41	ATV/r (LPV/r)[43]
2	Children under 10 years of age	ABC+3TC	AZT+3TC	AZT+3TC
		AZT+3TC	ABC+3TC	ABC+3TC
		DTG	LPV/r (ATV/r)	DRV/r
		LPV/r	DTG BIC41	RAL
		EFV(NVP)	DTG BIC41	LPV/r (ATV/r)[43]

[36] 3TC or FTC.

[37] If there are medical contraindications to the use of AZT and the use of second-row AI, it is possible to keep the TDF in the NRTI base or switch to ABC; with the use of NNRTI, IP/b, as well as with the duration of use of the regimen in conditions of virologic treatment failure of >6 months, an HIV resistance test is performed to justify the acceptability of refusing to use AZT.

[38] In patients treated with second-line NNRTIs in the first-line regimen, a regimen consisting of DTG and IP/B, or DTG+RPV, may be used.

[39] Double the daily dose of DTG: 50 mg tablet (with a body weight of <20 kg - in the appropriate single dose) 2 times a day can be prescribed according to the results of an HIV resistance test in patients who do not receive rifampicin or other drugs, when used together with which the daily dose of DTG is recommended to be doubled.

[40] DTG may be given to adult women of childbearing potential who want to become pregnant or who do not use contraception if they have been informed of a possible but not proven increase in the risk of neural tube defects (at conception and before the end of the first trimester at 0.19%, which is not statistically significant). If a woman becomes pregnant after the first trimester, DTG should be started or continued throughout pregnancy.

[41] Provided that other ARVs, included in the combined dosage form with BIC, meet the requirements for the replacement of NRTI-based. BIC-containing combination regimens are available for adults and for children weighing ≥14 kg.

[42] DRV / b is used only in the mode of twice a day (adults and children weighing ≥25 kg - at a dose of 600/100 mg 2 times a day).

[43] LPV/r or ATV/b may be used if they are still active on an HIV resistance test.

Annex 12
to the clinical protocol "Provision of medical care to patients with HIV infection"

Third-line ART schemes

№ p / n	Categories of patients	Scheme of the first row	Scheme of the second row	Diagram of the third row
1	Adults and children ≥10 years old	2 NRTI+ EFV(NVP)	2 NRTI+LPV/r	2 NIOT44+DTG (BIC45) DTG+DRV/r 2 NIOT44+DRV/r
			2 NRTI+DTG	1-2 NRTI+IP/b±2DTG46

		2 NRTI+LPV/r	2 NRTI+DTG	1-2 NRT+DRV/r±2DTG46
			2 NRTI+DRV/r	2 NIOT44+DTG (BIC45)
		2 NRTI+DRV/r	2 NRTI+ DTG	By HIV resistance test
		2 NRTI+DTG	2 NRTI+ ATV/b(LPV/r)	1-2 NRTI+DRV/b±2DTG46
			2 NRTI+DRV/b	By HIV resistance test
2	Children under 10 years of age	2 NRTI+ EFV(NVP)	2 NRTI+LPV/r	2 NIOT44+DTG (BIC45) DTG+DRV/r 2 NIOT44+DRV/r
			2 NRTI+DTG	2 NRTI+IP/b±DTG
		2 NRTI+LPV/r	2 NRTI+ DTG	1-2 NRT+DRV/r±2DTG46 HIV resistance test for children under 3 years of age
		2 NRTI+DRV/r	2 NRTI+ DTG	By HIV resistance test
		2 NRTI+DTG	2 NRTI+ ATV/b(LPV/r)	1-2 NRT+DRV/r±2DTG46 HIV resistance test for children under 3 years of age
			2 NRTI+DRV/b	By HIV resistance test

[44] Of the 2 NRTIs in the third-line regimens, one should have the maximum residual activity on the HIV resistance test (optimally, be fully active).

[45] Provided that other ARVs, included in the combined dosage form with BIC, meet the requirements for the replacement of NRTI-based. BIC-containing combination regimens are available for adults and for children weighing ≥14 kg.

[46] Double daily dose of DTG: 50 mg tablet (with a body weight of <20 kg - in the appropriate single dose) 2 times a day joins the third-line ART regimens in patients who previously received either DTG in standard dosage or LPV / r (ATV / r) in 1-2 rows in the absence of information about HIV resistance.

Annex 13
to the clinical protocol "Provision of medical care to patients with HIV infection"

Algorithm for switching to the TDF+3TC+DTG scheme in adults and children 10 years and older

№ p / n	Current clinical and laboratory picture	Preferred approach	Comments
1	Virologic treatment failure (HIV VN >200 copies/mL in two studies three months or more apart in a patient receiving ART for at least 6 months by the time of the first study)	Upgrade to 2 NRTI+DTG	There is no evidence to support the efficacy of DTG when used in combination with an inactive NRTI base. The TDF used in the first row can be stored in the NRT basis of the scheme for medical contraindications to the use of AZT

2	VN is suppressed	Replacement with TDF+3TC+DTG can be considered as planned	The transition should be considered in the context of drug availability and patient choice. Substitution may cause new side effects and interfere with adherence to treatment. DTG modes may be longer in the long run
3	Clinical and immunological stability and VN are unknown	Perform a VN test and consider medical indications for DTG-based ART replacement	There is no evidence to support the effectiveness of DTG when used in combination with an inactive main link NRTI

Annex 14
to the clinical protocol "Provision of medical care to patients with HIV infection"

Algorithm for optimizing ART regimens in children when they reach the appropriate body weight

№ p / n	Current drugs	Body weight	Preferred approach
1	AZT+3TC	<30 kg	ABC+3TC
2	AZT+3TC, ABC+3TC	>30 kg	TDF+XTC47
3	NVP, EFV	<20 kg	DTG (or LPV/r)[48]
4	NVP, EFV, LPV/r	>20 kg	DTG49

[47] 3TC or FTC.

[48] DTG can be used in children aged >4 weeks with a body weight of ≥3 kg; in case of unavailability of pediatric dosage forms of DTG, it is possible to switch to LPV / r.

[49] When a body weight of 20 kg is reached, it is possible to use an "adult" DTG 50 mg tablet once a day.

Annex 15
to the clinical protocol "Provision of medical care to patients with HIV infection"

Algorithm for laboratory monitoring of HIV infection and the effectiveness of ART in patients with HIV infection

No p/n	Period of medical observation	Molecular biological study of blood plasma on the concentration of HIV RNA (HV HIV)	Study of the number of CD4 + lymphocytes[50]
1	Before the start of ART	Once before starting ART	1 time in 12 months or for medical reasons in the presence of signs of stage 3 or 4 diseases

2	Before resuming ART	Be sure to do it once when resuming EFV-containing schemes, in other cases it is not necessary	
3	After initiating ART or switching to follow-up regimens until HIV viral suppression is achieved	1 time in three months	1 time in 6 months (with the amount of CD4+ lymphocytes more than 50 μl/μl); 1 time in 3 months (with the amount of CD4+ lymphocytes less than 50 cells/μl)[51] or in secondary prophylactic treatment of OI
4	After resumption of ART until HIV viral suppression is achieved	1 time in three months, except for EFV-containing schemes. 1, 3 and 6 months after renewal EFV-containing schemas	1 time in 6 months (with the amount of CD4+ lymphocytes more than 50 μl/μl); 1 time in 3 months (with the amount of CD4+ lymphocytes less than 50 cells/μl) or with secondary prophylactic treatment of OI
5	Against the background of ART after achieving HIV viral suppression	1 time in 12 months. When VN detectable HIV occurs, counseling on adherence to ART and assessment of possible drug interactions – VN control after 3 months. For medical reasons	1 time in 6 months (with the amount of CD4+ lymphocytes are less 200 cells/μl); 1 time in 12 months (with the number of CD4 + lymphocytes 200–500 cells/μl); with the number of CD4+
		when signs of disease appear 3 or 4 stages, or unsatisfactory adherence to treatment	lymphocytes greater than 500 cells/μL control can be discontinued

[50] Including that carried out in diagnostic testing for HIV infection.

[51] In patients with a persistent lack of immunological response with viral suppression for more than 12 months, it is permissible to monitor the number of CD4 + lymphocytes 1 time in 12 months.

Annex 16
to the clinical protocol "Providing medical care to patients with HIV infection"

ART regimens recommended for use in pregnant women

Preferred schemes	Alternative schemes in descending order of preference
TDF/XTC52+DTG53 TAF54/FTC+DTG53 TDF / XTC52 or TAF[54] / FTC + DRV / r 600/100 mg 2 times a day	TDF/XTC52+EFV55 TAF54/FTC+EFV55 ABC/3TC+DTG53 ABC / 3TC + DRV / r 600/100 mg 2 times a day ABC/3TC+EFV55

[52] 3TC or FTC.

[53] DTG may be given to adult women of childbearing potential who want to become pregnant or who do not use contraception if they have been informed of a possible but not proven increase in the risk of neural tube defects

(at conception and before the end of the first trimester at 0.19%, which is not statistically significant). If a woman becomes pregnant after the first trimester, DTG should be started or continued throughout pregnancy.

[54] TAF is not used in pregnant women up to 14 weeks of gestation due to insufficient safety and efficacy data.

[55] EFV can be used at a dose of 600 or 400 mg at any stage of pregnancy.

Annex 17
to the clinical protocol "Provision of medical care to patients with HIV infection"

Algorithm for prophylactic treatment of OI in patients with HIV infection over 18 years of age

№ p / n	OI	Primary preventive treatment	Secondary preventive treatment[56]
1	Pneumocystis pneumonia	Sulfamethoxazole/trimethoprim 800 mg/160 mg or 400 mg/80 mg per day, or 800 mg/160 mg 3 times a week with a CD4+ lymphocyte count <200 cells/μL or <15%. Prophylactic treatment is discontinued after reaching a CD4+ lymphocyte count of 100 cells/μL and HIV suppression, lasting at least 3 months	
		–	In severe hypersensitivity reaction to sulfamethoxazole / trimethoprim - dapsone 100 mg daily
2	Toxoplasmosis of the brain, toxoplasmosis chorioretinitis	Sulfamethoxazole/trimethoprim 800 mg/160 mg daily or 800 mg/160 mg 3 times a week with CD4+ lymphocyte count	Sulfamethoxazole / trimethoprim 800 mg / 160 mg 2 times a day. In severe hypersensitivity to sulfonamides and ineffectiveness
		<100 cells / μL and in the presence of IgG to toxoplasma in the blood. Prophylactic treatment is discontinued after reaching the number of CD4+ lymphocytes >100 cells / μL and HIV suppression for at least 3 months	desensitization - clindamycin 600 mg 3 times a day + azithromycin 500 mg per day. Prophylactic treatment is discontinued after reaching a CD4+ lymphocyte count of >200 cells / μL and HIV suppression, lasting at least 6 months
3	TB	In case of a positive test result for latent tuberculosis infection (skin tuberculin test or interferon-gamma release test) or close contact with a patient with TB - isoniazid 5 mg / kg per day (no more than 300 mg / day) 6 months or rifapentine[57] 900 mg 1 time per week + isoniazid 900 mg 1 time per week for 12 weeks	
4	Disseminated infection caused by atypical mycobacteria (Mycobacterium avium complex)	With the number of CD4+ lymphocytes <50 cells / μL - azithromycin 500 mg 3 times a week, or 250 mg 5 times a week, or clarithromycin 500 mg 2 times / day orally. Prophylactic treatment is discontinued after HIV suppression is achieved	One of the treatment regimens is at least 12 months before the symptoms disappear and the CD4+ lymphocyte count reaches >100 cells / μL and HIV suppression, lasting at least 6 months
5	Moniliasis	Not shown	

6	Cryptococcosis	In the presence of cryptococcal antigen in the blood and its absence in the cerebrospinal fluid Fluconazole 800 mg / day is prescribed for 2 weeks, then 400 mg / day for 8 weeks. ART is prescribed 2 weeks after the start of fluconazole use	Fluconazole 200 mg/day orally for at least 12 months, provided that the CD4+ lymphocyte count is >100 cells/μL and viral suppression for at least 3 months
7	CMV infection	Not shown	With CMV retinitis - valganciclovir 900 mg / day orally. Prophylactic treatment is discontinued after reaching the CD4+ lymphocyte count >100 cells / μL and HIV suppression, lasting at least 3 months after consulting an ophthalmologist
8	HSV infection	Not shown	With frequent (more than 6 episodes per year) or severe relapses - valacyclovir 500 mg / day orally indefinitely, regardless of the number of CD4 + lymphocytes

[56] A decrease in the number of CD4 + lymphocytes below the level indicated in the table is a medical indication for the resumption of prophylactic treatment in patients without viral suppression.

[57] It is appointed at its own expense, funds of legal entities and other sources not prohibited by law, in the presence of medical indications (for health reasons, taking into account individual intolerance) by decision of a medical consultation, and if it is impossible to conduct it, by the attending physician or a person replacing him, with an entry in medical documents.

Annex 18
to the clinical protocol "Provision of
medical care to patients with HIV infection"

Algorithm for prophylactic treatment of OI in patients with HIV infection under 18 years of age and in HIV-exposed children 58

o n	OI	Primary preventive treatment		Secondary preventive treatment	
		Treatment regimens	Medical indications for prescription and duration of preventive treatment	Treatment regimens	Medical indications for discontinuation of prophylactic Treatment
	Invasive bacterial infections (S. pneumoniae and others)	Normal human immunoglobulin for intravenous administration 0.2 to 0.4 g/kg each 4 weeks	HIV-positive children with severe immunosuppression of CD4+ lymphocyte counts (under the age of 6 years <15%, over 6 years <100 cells/μl) and hypogammaglobulinemia in terms of IgG <4 g / l	It is possible to consider normal human immunoglobulin for intravenous administration of 0.2-0.4 g/kg every 4 weeks	Restoration hypogammaglobulinemia (IgG level ≥4 g / l)
2	Pneumocystis pneumonia	Selection scheme: Sulfamethoxazole / trimethoprim 5-10 mg / kg / day for trimethoprim orally in 2 divided doses (not more than 320 mg of trimethoprim per day). Reception modes: 3 days a week in a row or every other day; 2 days a week in a row or every other day; daily with a daily dose once a day. Alternative schemes: 1. Dapsone (children older than 1 month) - 2 mg / kg (not more than 100 mg) once a day orally daily or 4 mg / kg (not more than 200 mg) in one oral dose 1 time per week. 2. Atovaquone inside children 1-3 months - 30-40 mg / kg, children 4-24 months - 45 mg / kg, children from 24 months to 12 years - 30-40 mg / kg, children ≥13 years old - 1500 mg 1 time per day orally with meals daily	1. HIV-exposed children from the moment of discontinuation of ARV prophylaxis or from the 5th day of life (if ARV prophylaxis is not started) until the age of 6 months or until three negative HIV DNA results (qualitative PCR) performed within the regulated time frame (the last of the three examinations - at the age of 4-6 months). 2. HIV-positive children aged 6–12 months with each episode of any respiratory infection for the duration of its acute manifestations, regardless of the number of CD4 + lymphocytes. 3. HIV-positive children aged 1-6 years with the number of CD4 + lymphocytes <500 cells / μL or <15%. 4. HIV-positive children over 6 years of age with CD4+ lymphocyte counts <200 μL or <15 %	Selection scheme: Sulfamethoxazole/trimethoprim 5-10 mg / kg / day for trimethoprim orally in 2 divided doses (not more than 320 mg of trimethoprim per day). Reception modes: 3 days a week in a row or every other day; 2 days a week in a row or every other day; daily with a daily dose once a day. Alternative schemes: 1. Dapsone (children older than 1 month) - 2 mg / kg (not more than 100 mg) once a day orally daily or 4 mg / kg (not more than 200 mg) in one oral dose 1 time per week. 2. Atovaquone inside children 1-3 months - 30-40 mg / kg, children 4-24 months - 45 mg / kg, children from 24 months to 12 years - 30-40 mg / kg, children ≥13 years -	Against the background of ART, the number of CD4+ lymphocytes (for >3 months): in the first year of life >25%, at the age of 1-6 years >15%, over the age of 6 years >200 cells / μL

				1500 mg 1 time per day orally with meals daily	
3	Toxoplasmosis of the brain, toxoplasmosis chorioretinitis	Selection scheme: Sulfamethoxazole/trimethoprim 5 mg / kg / day (or 150 mg / m^2 / day) for trimethoprim 1 time per day orally daily. Alternative schemes: 1. Dapsone (children older than 1 month) - 2 mg / kg (not more than 100 mg) orally 1 time per day plus Pyrimethamine 1 mg / kg (not more than 25 mg) orally 1 time per day plus calcium folinate 5 mg orally each 3 days; 2. Atovaquone inside children 1-3 months - 30-40 mg / kg, children 4-24 months - 45 mg / kg, children from 24 months to 12 years old - 30-40 mg / kg, children ≥13 years old - 1500 mg 1 time per day orally with or without pyrimethamine 1 mg / kg (not more than 25 mg) orally 1 time per day plus calcium folinate 5 mg orally every 3 days	HIV-positive children with detection of IgG to toxoplasma and severe immunosuppression by CD4+ lymphocyte count: under the age of 6 years <15%, over 6 years <100 cells / μL	Selection scheme: Sulfamethoxazole/trimethoprim 5 mg/kg/day (or 150 mg / m^2 / day) on trimethoprim 1 time per day orally daily. Alternative schemes: 1. Sulfadiazine 42.5-60 mg/kg 2 times a day (no more than 2-4 g / day) orally plus Pyrimethamine 1 mg / kg (not more than 25 mg) orally 1 time per day plus calcium folinate 5 mg orally every 3 days; 2. clindamycin 7-10 mg / kg orally 3 times a day plus pyrimethamine 1 mg / kg (not more than 25 mg) orally 1 time per day plus calcium folinate 5 mg orally every 3 days; 3. Atovaquone orally for children 1-3 months - 30-40 mg / kg, children 4-24 months - 45 mg / kg, children from 24 months to 12 years - 30-40 mg / kg, children ≥13 years old - 1500 mg 1 time per day orally with or without pyrimethamine 1 mg / kg (not more than 25 mg) orally 1 time per day plus calcium folinate 5 mg orally every 3 days	If all the criteria are met: 1. ART >6 months; 2. the treatment of toxoplasmosis encephalitis has been completed and there are no clinical manifestations; 3. CD4+ lymphocyte count (for ≥6 months): aged 1–6 years ≥15%, older 6 years ≥200 cells/μL

4	Disseminated infection caused by atypical mycobacteria (Mycobacterium avium complex)	Azithromycin 5 mg/kg (max 250 mg / day) 1 time per day orally or 20 mg / kg (not more than 1250 mg) 1 time per week orally, or clarithromycin 7.5 mg / kg (not more than 500 mg) 2 times a day orally	HIV-positive children with significantly reduced CD4 + lymphocyte count: under the age of 1 year <750 cells/μl, at the age of 1 to 2 years <500 cells/μl, at the age of 2-6 years <75 cells/μl, over the age of 6 years <50 cells/μl	Azithromycin 5 mg / kg (not more than 250 mg / day) 1 time per day orally or clarithromycin 7.5 mg / kg / (not more than 500 mg) 2 times a day inside plus ethambutol 15-25 mg / kg 1 time per day orally	If all the criteria are met: 1. ART >6 months. 2. The treatment of atypical mycobacteriosis has been completed and there are no clinical manifestations. 3. CD4+ lymphocyte count (for >6 months): at the age of 1-6 years >15%, over the age of 6 years >100 cells / μL

				herpes mucous: Acyclovir 20 mg / kg (not more than 800 mg) 2 times a day orally for a long time (1 year or more). 2. Virus-suppressive treatment after neonatal HSV infection: Acyclovir 300 mg / m^2 3 times a day orally for 6 months	

9	Chickenpox. Zona	1. Normal human immunoglobulin for intravenous administration of 0.4 g / kg (administration early, no later than 96 hours after exposure). 2. Acyclovir 20 mg / kg (not more than 800 mg) 2 times a day orally for 7 days (start of administration 7-10 days after contact)	Primary prevention is not routinely recommended, but may be considered after contact with the sick person for VZV-seronegative HIV-positive children with severe immunosuppression	Secondary medical prophylaxis is not recommended	–
10	Influenza	Oseltamivir is used for prophylactic purposes 1 time per day: children aged >13 years - 75 mg, aged 1-12 years - 2 mg / kg (with a body weight of <15 kg - 30 mg, 15-23 kg - 45 mg, 23-40 kg - 60 mg, >40 kg - 75 mg), aged 9-11 months - 3.5 mg / kg, at the age of 3-8 months - 3 mg / kg orally. Dose adjustment is required with a decrease in GFR. Oseltamivir is prescribed as soon as possible within the first 48 hours after the contact has occurred. The duration of the course in the event of an outbreak in a hospital or closed institution is at least 2 weeks, but not less than 7 days after the onset of the last case of the disease; in the case of home or other close contact in the community: for those previously vaccinated against influenza - 1 week after the last contact,	HIV-positive children after exposure to influenza or influenza-like illness: having severe immunosuppression regardless of vaccination status; having moderate or severe immunosuppression, if for some reason they are not vaccinated with seasonal influenza vaccine, or in the first 2 weeks after vaccination, or if low efficacy of the vaccine in the season is assumed (discrepancy between vaccine and actually circulating strains of the influenza virus)	Secondary medical prophylaxis is not recommended	–
		For those who are not vaccinated against influenza 2 weeks after the Vaccination			

[58] Treatment of TB of various localization in children, including preventive treatment, is prescribed by a TB doctor.

Note. Atovaquone, pyrimethamine, sulfadiazine, foscarnet, cidofovir, probenecid are prescribed at their own expense, funds of legal entities and other sources not prohibited by law, in the presence of medical indications (for health reasons, taking into account individual intolerance) by decision of the medical consultation, and if it is impossible to carry it out, the attending physician or the person replacing him, with the registration of an entry in medical documents.

Annex 19
to the clinical protocol "Provision of medical care to patients with HIV infection"

The volume of medical care provided to patients with HIV infection in opportunistic diseases (adult population) in inpatient settings

No p/n	Name of nosological forms of diseases	ICD-10	Diagnostics		Treatment
			Mandatory	Additional (for medical reasons)	
1	TB of the lungs	Q20.0 HIV-related disease with manifestations mycobacterial infection	X-ray of the lungs. Microscopic examination of sputum smears for Mycobacterium TB (Mycobacterium tuberculosis) twice. Bacteriological examination of sputum for Mycobacterium tuberculosis (Mycobacterium tuberculosis) twice. Determination of Mycobacterium TB DNA in sputum and mutations associated with rifampicin resistance (hereinafter referred to as Xpert MBT/RIF). Bacteriological examination of sputum for aerobic and facultative anaerobic microorganisms.	Bronchoscopy. CT scan of the chest organs (health care organizations of the republican and regional levels). Molecular biological study of blood plasma for the concentration of HIV RNA. Study of the parameters of the acid-base composition of the blood. Bacteriological examination of bronchoalveolar fluid for Mycobacterium tuberculosis twice in 1 to 3 days. Bacteriological examination of lavage fluid for aerobic and facultative anaerobic microorganisms	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment (after exclusion of cerebral toxoplasmosis and cryptococcal meningitis). Sulfamethoxazole/trimethoprim [59,800] mg/160 mg daily for the duration of TB treatment, regardless of CD4+ lymphocyte count. With paradoxical VSVI, prednisolone orally 40 mg per day for 2 weeks, followed by 20 mg per day for 2 weeks

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				Bacteriological examination of the bone marrow for Mycobacterium tuberculosis. Esophagogastroduodenoscopy (hereinafter referred to as EFGDS). Colonic endoscopy. Histological examination of the preparation of the mucous membrane of various parts of the colon. Histological examination of the preparation of the gastric mucosa. Histological examination of the tissues of the peritoneal preparation. Molecular biological study of blood plasma for HIV RNA concentration	With paradoxical VSVI, prednisolone orally 40 mg per day for 2 weeks, followed by 20 mg per day for 2 weeks

4	TB of peripheral lymph nodes	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as: puncture or biopsy of the lymph node. Bacteriological and microscopic examination of lymph node punctate for Mycobacterium tuberculosis. Xpert MBT/RIF lymph node aspirate. Consultation with a TB doctor	Histological examination of the preparation of lymph node tissues. Cytological examination of the preparation of fine-needle aspiration biopsy. Ultrasound of the lymph nodes. Molecular biological study of blood plasma for HIV RNA concentration	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment (after exclusion of cerebral toxoplasmosis and cryptococcal meningitis). Sulfamethoxazole/trimethoprim 800 mg/160 mg daily daily for the duration of TB treatment, regardless of CD4+ lymphocyte count. With paradoxical VSVI, prednisolone orally 40 mg per day for 2 weeks, followed by 20 mg per day for 2 weeks
5	Tuberculous pleurisy	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as: puncture of the pleural cavity. Bacteriological and microscopic examination of pleural fluid for Mycobacterium tuberculosis. Bacteriological examination of pleural fluid for aerobic and facultative anaerobic microorganisms.	Xpert MBT/RIF pleural fluid. CT scan of the chest organs (health care organizations of the regional and republican levels). Molecular biological study of blood plasma for the concentration of HIV RNA. Consultation with a thoracic surgeon	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment (after exclusion of cerebral toxoplasmosis and cryptococcal meningitis). Sulfamethoxazole/trimethoprim 800 mg/160 mg daily daily for the duration of TB treatment, regardless of CD4+ lymphocyte count.
			Microscopic examination of native and stained pleural fluid preparation. Study of the physical properties of pleural fluid. Biochemical study of pleural fluid. Consultation with a TB doctor		With paradoxical VSVI, prednisolone orally 40 mg per day for 2 weeks, followed by 20 mg per day for 2 weeks

6	TB of bones and joints	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as: radiography of the affected bones and joints. Diagnostic aspiration of the joint. Biopsy of joint tissue. Bacteriological and microscopic examination of the discharge for Mycobacterium tuberculosis. Bacteriological and microscopic examination of bone biopsy specimen for Mycobacterium tuberculosis. Bacteriological and microscopic examination of synovial fluid Mycobacterium tuberculosis	CT or MRI of the bones and joint(s) of the affected area. Molecular biological study of blood plasma for the concentration of HIV RNA. Consultation with an orthopedic traumatologist	Treatment together with a phthisiologist and an orthopedic traumatologist. ART begins within the first 2 weeks of anti-tuberculosis treatment (after exclusion of cerebral toxoplasmosis and cryptococcal meningitis). Sulfamethoxazole/trimethoprim 800 mg/160 mg daily daily for the duration of TB treatment, regardless of CD4+ lymphocyte count. With paradoxical VSVI, prednisolone orally 40 mg per day for 2 weeks, followed by 20 mg per day for 2 weeks
7	Tuberculous pericarditis	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as echocardiography. Pericardial puncture and pericardiocentesis (if fluid is available). Bacteriological examination of pericardial fluid for Mycobacterium tuberculosis. Bacteriological examination of pericardial fluid for aerobic and facultative anaerobic microorganisms. Consultation with a cardiologist	Consultation with a cardiac surgeon. CT scan of the chest organs (health care organizations of the regional and republican levels). Molecular biological study of blood plasma for HIV RNA concentration	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment (after exclusion of cerebral toxoplasmosis and cryptococcal meningitis). Sulfamethoxazole/trimethoprim 800 mg/160 mg daily daily for the duration of TB treatment, regardless of CD4+ lymphocyte count. Prednisolone 60 mg / day orally for a week, then with a dose reduction of 10 mg per week (total

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					ART is prescribed after alleviating the symptoms of dysphagia, excluding active TB, cerebral toxoplasmosis, and cryptococcal meningitis

12	Extrapulmonary cryptococcosis, including cryptococcal meningitis	Q20.5 Disease caused by HIV, with manifestations of other mycoses	General clinical examination of cerebrospinal fluid with the determination of the level of glucose, protein. Mycological (and microscopic) examination of cerebrospinal fluid for cryptococcus (Cryptococcus neoformans), determination of cryptococcal antigen in cerebrospinal fluid and blood before treatment, then after 2 weeks and further for medical reasons. General (clinical) blood test, detailed. Study of CD4+ lymphocytes. ELECTROCARDIOGRAM. X-ray of the lungs. Urinalysis is general. Biochemical blood test to determine the level of urea, creatinine, electrolytes (potassium, calcium, sodium, chlorine), glucose (control in the treatment of amphotericin B 1 time in 1-3 days). Biochemical blood test with determination of the level of bilirubin, total protein, albumin, AST, ALT, ALKALINE PHOSPHATASE, GGTP. Consultation with a neurologist, ophthalmologist	Microbiological blood test for mushrooms. MRI of the brain with contrast or CT of the head with contrast (health care organizations at the regional and national levels). Molecular biological study of blood plasma for the concentration of HIV RNA. CT scan of the chest organs (health care organizations of the regional and republican levels)	Etiotropic therapy using one of the following regimens (listed in order of decreasing effectiveness): 1. induction phase (at least 2 weeks, until the disappearance of changes in the cerebrospinal fluid): amphotericin B (lipid complex) 6 mg / kg / day intravenously or amphotericin B 0.7-1.0 mg / kg / day intravenously) + fluconazole 800 mg/day intravenously or orally; amphotericin B (lipid complex) 3 mg/kg/day intravenously or amphotericin B 0.7 mg/kg/day intravenously) + flucytosine 25 mg/kg 4 times a day inside; fluconazole 1200 mg / day intravenously or orally. Administration of amphotericin B is carried out by prolonged intravenous infusion for at least 6 hours. Before starting the administration of amphotericin B, metamizole is administered once to improve tolerability 500 mg intravenously or diclofenac 75 mg intravenously; 2. consolidating phase (8 weeks): fluconazole 800 mg on the first day, then fluconazole 400 mg / day intravenously or orally; 3. cerebrospinal puncture (therapeutic) in the presence of signs of increased intracranial pressure with the evacuation of cerebrospinal fluid (20-30 ml) to normalize intracranial pressure (up to 3 times a day);

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			total protein, albumin, AST, ALT, ALKALINE PHOSPHATASE, GGTP. Study of CD4+ lymphocytes. Determination of antibodies to toxoplasma (Toxoplasma gondii) in the blood. Consultation with a neurologist, ophthalmologist. Biochemical blood test with determination of the level of urea, creatinine, electrolytes (potassium, calcium, sodium, chlorine), glucose. ELECTROCARDIOGRAM. General urinalysis		desensitization clindamycin 600 mg 4 times a day + azithromycin 1000 mg/day
15	Cryptosporidiosis	B20.8 HIV disease with manifestations of other infectious and parasitic diseases	Microscopic examination of feces for cryptosporidium (Cryptosporidium parvum). General (clinical) blood test detailed. Study of CD4+ lymphocytes. Biochemical blood test with determination of the level of urea, creatinine, electrolytes (potassium, calcium, sodium, chlorine), glucose. ELECTROCARDIOGRAM. General urinalysis	Examination of feces for cryptosporidium (Cryptosporidium parvum) by IHA. Microscopic examination of tissues for cryptosporidium (Cryptosporidium parvum). Ultrasound of the abdominal cavity and kidneys. Molecular biological study of blood plasma for the concentration of HIV RNA. Biochemical blood test with determination of bilirubin levels, total protein, albumin, AST, ALT, Alkaline phosphatase, GGTP	ART is prescribed after the exclusion of active TB, cerebral toxoplasmosis, and cryptococcal meningitis. For the correction of water-electrolyte disorders, electrolyte solutions are used intravenously and solutions for oral rehydration. Loperamide 4 mg once, followed by 2 mg after each episode of diarrhea, but not more than 16 mg per day
16	Kaposi's sarcoma	Q21.0 HIV disease with manifestations of Kaposi's sarcoma	Skin biopsy. Morphological (histological) examination of the skin preparation	In the visceral form - radiographic (CT, MRI), endoscopic examinations, depending on the affected organ. Biopsy of the tissues of the affected organ. Histological examination of the drug	For the treatment of mild to moderate forms with isolated skin lesions, ART is prescribed. Treatment of severe cutaneous and visceral forms is prescribed in conjunction with an oncologist

17	Burkitt's lymphoma. Primary CNS lymphoma or B-cell non-Hodgkin lymphoma	Q21.1 HIV-related disease with manifestations of Burkitt's lymphoma. Q21.2 Disease caused by HIV,	Ultrasound of the lymph nodes. Ultrasound of the abdominal organs, kidneys, small pelvis. CT scan of the neck. CT scan of the chest organs. CT scan of the pelvic organs.	MRI of the brain. MRI of the spinal cord. Spinal puncture with the determination of the level of glucose and protein in the cerebrospinal fluid. Microscopic examination	Treatment is prescribed in conjunction with an oncologist. The timing of the initiation of ART is determined individually depending on the number of CD4+ lymphocytes and the planned chemotherapy
		with manifestations of other non-Hodgkin's lymphomas	CT scan of the abdominal cavity and retroperitoneal space with intravenous bolus contrast. Lymph node biopsy. Histological examination of the preparation of lymph node tissues in lymphoproliferative diseases. Obtaining a histological preparation of the bone marrow. Histological examination of the bone marrow preparation. General (clinical) blood test detailed. Urinalysis is general. Biochemical blood test with determination of the level of urea, creatinine, electrolytes (potassium, calcium, sodium, chlorine), glucose, bilirubin, total protein, albumin, AST, ALT, ALKALINE PHOSPHATASE, GGTP, LDH. ELECTROCARDIOGRAM. Study of CD4+ lymphocytes. Consultation with an otorhinolaryngologist, neurologist, ophthalmologist. With primary lymphoma of the central nervous system - consultation with a neurosurgeon	cerebrospinal fluid, counting cells in the counting chamber (determination of cytosis). Examination of CD4+ lymphocytes every 1-2 months during chemotherapy treatment. Immunocytochemical study of cerebrospinal fluid. Molecular biological study of blood plasma for HIV RNA concentration	Treatment. If the CD4+ count is less than 200 cells/μL, ART is started as soon as possible. At higher levels, ART can be delayed until completion Initial stage chemotherapy treatment

18	Progressive multifocal leukoencephalopathy	Q22.0 HIV disease with manifestations of encephalopathy	MRI of the brain with contrast, or CT of the head with contrast (health care organizations of the regional and republican levels). Spinal puncture with the determination of the level of glucose and protein in the cerebrospinal fluid. Microscopic examination of cerebrospinal fluid, counting cells in the counting chamber (determination of cytosis).	MRI of the brain with contrast, or CT of the head with contrast (health care organizations of the regional and republican levels), again after 3-6 months. Molecular biological study of blood plasma for the concentration of HIV RNA. Molecular biological study of cerebrospinal fluid for JC virus.	Immediate initiation of ART. With paradoxical VSVI methylprednisolone 1 g intravenously or dexamethasone 0.3 mg/kg/day intravenously for 3-5 days, followed by gradual dose reduction
			Study of CD4+ lymphocytes. Consultation with a neurologist, ophthalmologist	Molecular biological examination of cerebrospinal fluid for CMV, HSV, chickenpox virus (Varicella Zoster)	
19	HIV encephalopathy HIV encephalitis	Q22.0 HIV disease with manifestations of encephalopathy	Similar to the mandatory diagnosis of progressive multifocal leukoencephalopathy	Similar to additional diagnostics in progressive multifocal leukoencephalopathy, as well as: molecular biological examination of cerebrospinal fluid for HIV RNA concentration (in patients with disease progression on ART)	Immediate initiation of ART

[59] With the development of a mild to moderate hypersensitivity reaction to sulfamethoxazole / trimethoprim, desensitization is performed.

Note. Rifabutin, flucytosine, primaquine are prescribed at their own expense, funds of legal entities and other sources not prohibited by law, in the presence of medical indications (for health reasons, taking into account individual intolerance) by decision of the medical consultation, and if it is impossible to carry it out - the attending physician or the person replacing him, with the registration of an entry in medical documents.

Annex 20
to the clinical protocol "Provision of medical care to patients with HIV infection"

The volume of medical care provided to patients with HIV infection in opportunistic diseases (children's population) in inpatient settings

No p/n	Name of nosological forms of diseases	Compliance with the ICD-10 code	Diagnostics		Treatment
			Mandatory	Additional (for medical reasons)	
1	TB of the lungs	Q20.0 HIV-related disease with manifestations mycobacterial infection	X-ray of the lungs. Microscopic examination of sputum smears and gastric lavage for Mycobacterium TB (Mycobacterium tuberculosis) twice. Bacteriological examination of sputum and gastric lavage for Mycobacterium TB (Mycobacterium	Focal test with tuberculin. Performing a skin test Diaskintest. Bronchoscopy. CT scan of the chest organs. Molecular biological study of blood plasma for the concentration of HIV RNA. Investigation of the parameters of acid-	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment, in the case of tuberculous meningitis or poor tolerability of anti-tuberculosis drugs - after 4-8 weeks (after exclusion
			tuberculosis) twice. Determination of Mycobacterium TB DNA in sputum, gastric lavage and mutations associated with Xpert MBT/RIF. Bacteriological examination of sputum for aerobic and facultative anaerobic microorganisms. Biochemical blood test with determination of the level of urea, creatinine, electrolytes (potassium, calcium, sodium, chlorine), glucose, bilirubin, total protein, albumin, AST, ALT, ALKALINE PHOSPHATASE, GGTP. Study of CD4+ lymphocytes. General (clinical) blood test detailed. Urinalysis is general. ELECTROCARDIOGRAM. Consultation with a TB doctor	the main composition of the blood. Bacteriological examination of bronchoalveolar fluid for Mycobacterium tuberculosis twice. Bacteriological examination of lavage fluid for aerobic and facultative anaerobic microorganisms	toxoplasmosis of the brain and cryptococcal meningitis). Sulfamethoxazole/trimethoprim 5 mg/kg/day orally trimethoprim daily throughout the course of TB treatment, regardless of CD4+ lymphocyte count. Dexamethasone 0.3-0.4 mg/kg/day orally for 2-4 weeks, then the dose is reduced by 0.1 mg/kg every week to a dose of 0.1 mg/kg/day, then the dose is reduced by 4 mg/day per week, then by 1 mg per week with complete cancellation (the total duration of treatment with dexamethasone is about 12 weeks)

2	TB of the nervous system (including tuberculous meningitis)	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as: general clinical examination of cerebrospinal fluid with the determination of glucose and protein levels. microscopic examination of cerebrospinal fluid for Mycobacterium tuberculosis; bacteriological and microscopic examination of cerebrospinal fluid for Mycobacterium tuberculosis; Xpert MBT/RIF Spinal Liquid; MRI of the brain with contrast or CT scan of the head with contrast. Consultation with a pediatric neurologist, ophthalmologist, TB doctor	Focal test with tuberculin. Performing the Diaskintest skin test. Molecular biological study of blood plasma for HIV RNA concentration	Treatment together with a phthisiologist. ART begins after 4 to 8 weeks of treatment for tuberculous meningitis (after cerebral toxoplasmosis and cryptococcal meningitis have been ruled out). Sulfamethoxazole/trimethoprim 5 mg/kg/day orally trimethoprim daily throughout the course of TB treatment, regardless of CD4+ lymphocyte count. Dexamethasone 0.3-0.4 mg/kg/day orally for 2-4 weeks, followed by dose reduced by 0.1 mg / kg per week to a dose of 0.1 mg / kg / day, then the dose is reduced by 4 mg / day per week, then by 1 mg per week with complete cancellation (the total duration of treatment with dexamethasone is about 12 weeks)

3	TB of the intestines, peritoneum and mesenteric lymph nodes	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as: bacteriological examination of blood for Mycobacterium TB (Mycobacterium tuberculosis). Bacteriological examination of feces for Mycobacterium TB (Mycobacterium tuberculosis) three times. Ultrasound of the abdominal cavity and kidneys. Consultation with a TB doctor	Focal test with tuberculin. Performing the Diaskintest skin test. EFGDS. Colonic endoscopy. MRI of the abdominal organs or CT of the abdominal cavity and retroperitoneal space with intravenous bolus contrast. Laparoscopy. Biopsy of the lymph node using video endoscopic technologies (health care organizations of the regional and republican levels). Bacteriological examination of the bone marrow for Mycobacterium tuberculosis. Histological examination of the preparation of the mucous membrane of various parts of the colon. Histological examination of the preparation of the gastric mucosa. Histological examination of the tissues of the peritoneal preparation. Molecular biological study of blood plasma for HIV RNA concentration	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment, in the case of tuberculous meningitis or poor tolerability of anti-tuberculosis drugs - after 4-8 weeks (after exclusion of toxoplasmosis of the brain and cryptococcal meningitis). Sulfamethoxazole/trimethoprim 5 mg/kg/day orally trimethoprim daily throughout the course of TB treatment, regardless of CD4+ lymphocyte count. With paradoxical VSVI: prednisolone 2 mg/kg/day (not more than 60 mg/day) or methylprednisolone at an equivalent dose for 2 weeks, followed by staged withdrawal within 2-4 weeks

4	TB of peripheral lymph nodes	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as: ultrasound of the lymph nodes; puncture or biopsy of the lymph node; bacteriological and microscopic examination of lymph node punctate Mycobacterium tuberculosis; Xpert MBT/RIF lymph node aspirate. Consultation with a TB doctor	Focal test with tuberculin. Performing the Diaskintest skin test. Histological examination of the preparation of lymph node tissues. Cytological examination of the preparation of fine-needle aspiration biopsy. Molecular biological study of blood plasma for HIV RNA concentration	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment, in the case of tuberculous meningitis or poor tolerability of anti-tuberculosis drugs - after 4-8 weeks (after exclusion of toxoplasmosis of the brain and cryptococcal meningitis). Sulfamethoxazole / trimethoprim 5 mg / kg / day by mouth trimethoprim daily throughout the course

					TB treatment regardless of CD4+ lymphocyte count. With paradoxical VSVI: prednisolone 2 mg/kg/day (not more than 60 mg/day) or methylprednisolone at an equivalent dose for 2 weeks, followed by staged withdrawal within 2-4 weeks

5	Tuberculous pleurisy	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as: puncture of the pleural cavity; bacteriological and microscopic examination of pleural fluid for Mycobacterium tuberculosis; bacteriological examination of pleural fluid for aerobic and facultative anaerobic microorganisms; microscopic examination of native and stained pleural fluid preparation; study of the physical properties of pleural fluid; biochemical examination of pleural fluid; study of the level of protein in the pleural fluid. Consultation with a TB doctor	Focal test with tuberculin. Performing the Diaskintest skin test. Xpert MBT/RIF pleural fluid. CT scan of the chest organs. Molecular biological study of blood plasma for the concentration of HIV RNA. Consultation with a thoracic surgeon	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment, in the case of tuberculous meningitis or poor tolerability of anti-tuberculosis drugs - after 4-8 weeks (after exclusion of toxoplasmosis of the brain and cryptococcal meningitis). Sulfamethoxazole/trimethoprim 5 mg/kg/day orally trimethoprim daily throughout the course of TB treatment, regardless of CD4+ lymphocyte count. With paradoxical VSVI: prednisolone 2 mg/kg/day (not more than 60 mg/day) or methylprednisolone at an equivalent dose for 2 weeks, followed by staged withdrawal within 2-4 weeks
6	TB of bones and joints	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as: radiography of affected bones and joints; diagnostic aspiration of the joint; biopsy of joint tissues; bacteriological and microscopic examination of bone discharge for Mycobacterium TB (Mycobacterium tuberculosis); Bacteriological and microscopic examination	Focal test with tuberculin. Performing the Diaskintest skin test. CT or MRI of the bones and joint(s) of the affected area. Molecular biological study of blood plasma for HIV RNA concentration	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment, in the case of tuberculous meningitis or poor tolerability of anti-tuberculosis drugs - after 4-8 weeks (after exclusion of toxoplasmosis of the brain and cryptococcal meningitis). Sulfamethoxazole/trimethoprim 5 mg / kg / day by mouth trimethoprim

			bone biopsy for Mycobacterium tuberculosis; bacteriological and microscopic examination of synovial fluid for Mycobacterium tuberculosis; Consultation with an orthopedic traumatologist, TB doctor		daily throughout the course of TB treatment, regardless of the number of CD4+ lymphocytes. With paradoxical VSVI: prednisolone 2 mg/kg/day (not more than 60 mg/day) or methylprednisolone at an equivalent dose for 2 weeks, followed by staged withdrawal within 2-4 weeks
7	Tuberculous pericarditis	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to the mandatory diagnosis of pulmonary TB, as well as: echocardiography; pericardial puncture and pericardiocentesis (in the presence of liquid); bacteriological examination of pericardial fluid for Mycobacterium tuberculosis; bacteriological examination of pericardial fluid for aerobic and facultative anaerobic microorganisms; Consultation with a pediatric cardiorheumatologist, TB doctor	Focal test with tuberculin. Performing the Diaskintest skin test. Consultation with a cardiac surgeon. CT scan of the chest organs (health care organizations of the regional and republican levels). Molecular biological study of blood plasma for HIV RNA concentration	Treatment together with a phthisiologist. ART begins within the first 2 weeks of anti-tuberculosis treatment, in the case of tuberculous meningitis or poor tolerability of anti-tuberculosis drugs - after 4-8 weeks (after exclusion of toxoplasmosis of the brain and cryptococcal meningitis). Sulfamethoxazole/trimethoprim 5 mg/kg/day orally trimethoprim daily throughout the course of TB treatment, regardless of CD4+ lymphocyte count. With paradoxical VSVI: prednisolone 2 mg/kg/day (not more than 60 mg/day) or methylprednisolone at an equivalent dose for 2 weeks, followed by staged withdrawal within 2-4 weeks

8	Disseminated infection caused by atypical mycobacteria (Mycobacterium avium complex)	Q20.0 HIV-related disease with manifestations mycobacterial infection	Similar to mandatory diagnosis for pulmonary TB and extrapulmonary TB, as well as: bacteriological examination on atypical mycobacterium of blood, bone marrow, material obtained by aspiration of lymph nodes, abscesses of skin and soft tissues, bones and joints, any biological fluids. Ultrasound of the abdominal organs.	Molecular biological study of blood plasma for the concentration of HIV RNA. Consultations of specialist doctors depending on the affected area. Repeated bacteriological examination of blood for mycobacteria after 4-8 weeks in the absence of the effect of treatment	Etiotropic treatment includes ≥2 drugs: 1. selection scheme: clarithromycin 7.5-15 mg / kg (not more than 500 mg) 2 times a day orally plus ethambutol 15-25 mg / kg / day 1 time per day orally. In case of clarithromycin intolerance, azithromycin is an alternative 10-12 mg / kg (not more than 500 mg) once a day orally. Children receiving ethambutol have their visual acuity checked monthly

			X-ray examination, CT or MRI of the affected area. Consultation with a TB doctor		and preservation of color perception (when they reach a sufficient age for examination); 2. in severe cases, a third drug is added: rifampicin 10-20 mg / kg (not more than 600 mg) once a day orally or intravenously, or rifabutin 10-20 mg / kg (not more than 300 mg) once a day orally; 3. if it is impossible to add rifampicin or rifabutin or if it is necessary to add a fourth drug due to the severity of the course: ciprofloxacin 10-15 mg/kg 2 times a day orally (not more than 1.5 g/day), or levofloxacin 500 mg 1 time per day orally, or amikacin 15-30 mg/kg/day (no more than 1.5 g / day) intravenously or intramuscularly in 1 or 2 injections; 4. clofazimine is not used, since in adults it is associated with greater mortality; 5. The duration of treatment is at least 12 months, followed by a transition to supportive suppressive treatment (secondary prevention). ART begins 2 weeks after initiation of antimycobacterial therapy (after ruling out toxoplasmosis of the brain and cryptococcal meningitis). In the case of rifampicin, it is preferable to use AI (DTG, RAL) in a double dose in the ART regimen

9	Pneumocystis pneumonia	B20.6 HIV disease with Pneumocystis carinii pneumonia (Pneumocystis jirovecii)	X-ray of the lungs. General (clinical) blood test detailed. Pulse oximetry. Study of CD4+ lymphocytes.	Bronchoscopy. Microbiological examination of lavage fluid for cysts of pneumocysts (Pneumocystis carinii (Pneumocystis jirovecii)).	Etiotropic treatment (duration – 21 days): 1. Selection scheme: Sulfamethoxazole / trimethoprim 5 mg / kg on trimethoprim 4 times a day

					per day from 6 to 10 days, then 0.5 mg / kg (up to 20 mg) once a day from 11 to 21 days, or methylprednisolone intravenously 1 mg / kg 4 times a day for the first 7 days, then 1 mg / kg 2 times a day from 8 to 9 days, 0.5 mg / kg 2 times a day from 10 to 11 days; 1 mg / kg once a day from 12 to 16 days. Mechanical ventilation in case of respiratory failure with preservation of hypoxemia during oxygen respiration. ART begins on days 3-4 of etiotropic treatment, but no later than 14 days (after exclusion of active TB, toxoplasmosis of the brain and cryptococcal meningitis)

10	CMV infection with CNS involvement, generalized form, retinitis	Q20.2 Disease caused by HIV with manifestations of cytomegalovirus disease	Determination of antibodies of classes M, G (IgM, IgG) to CMV in the blood. Molecular biological blood test for CMV. General (clinical) blood test twice a week against the background of etiotropic therapy and once a week against the background of secondary preventive treatment. Study of CD4+ lymphocytes. ELECTROCARDIOGRAM. Urinalysis is general. Biochemical blood test with determination of the level of urea, creatinine, electrolytes (potassium, calcium, sodium, chlorine) twice a week against the background of etiotropic therapy and once a week against the background of secondary preventive treatment. Biochemical blood test with determination of the level of glucose, bilirubin, total protein, albumin, AST, ALT, ALKALINE PHOSPHATASE, GGTP, LDH. Next examinations	Molecular biological study of blood plasma for HIV RNA concentration	Etiotropic treatment: 1. Selection scheme: Ganciclovir 5 mg / kg (children of the first year of life - 6 mg / kg) intravenously every 12 hours, or Valganciclovir 16 mg / kg (not more than 900 mg) 2 times a day orally with food intake. The drug of choice for intact enteral assimilation is oral valganciclovir (a prodrug of ganciclovir). It is possible to switch from intravenous ganciclovir to oral valganciclovir. It is necessary to monitor the development of neutropenia and other cytopenias as frequent adverse reactions; 2. alternative regimens (used in the development of resistance to ganciclovir, which can be suspected in the absence of effect during treatment with ganciclovir): foscarnet 60 mg / kg 3 times a day intravenously (or 90 mg / kg 2 times a day intravenously), or

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					Children aged >12 years with a body weight of > 35 kg instead of oral acyclovir may be prescribed valacyclovir (a prodrug of acyclovir with better bioavailability) in appropriate doses for adult patients. With resistance to acyclovir, it is possible to use foscarnet 40 mg / kg 3 times a day or 60 mg / kg 2 times a day intravenously (in the form of an extended infusion no faster than 1 mg / kg / minute, usually within 2 hours). With frequent (>6 episodes per year) or severe recurrences of mucocutaneous herpes, virus-suppressive treatment is considered as secondary medical prevention

12	Chickenpox. Zona	Q20.3 HIV disease with manifestations of other viral infections	General (clinical) blood test. Study of CD4+ lymphocytes. ELECTROCARDIOGRAM. Urinalysis is general. A biochemical blood test with the determination of the level of urea, creatinine, electrolytes (potassium, calcium, sodium, chlorine) is performed twice a week with the appointment of acyclovir at a dose of 20-30 mg / kg / day or more. Biochemical blood test with determination of the level of glucose, bilirubin, total protein, albumin, AST, ALT, ALKALINE PHOSPHATASE, GGTP, LDH. The following examinations are performed in case of damage to the central nervous system: general clinical examination of cerebrospinal fluid with determination of glucose and protein levels. Consultation with a pediatric neurologist, ophthalmologist	Determination of antibodies to varicella virus (Varicella virus) in the blood. Molecular biological examination of cerebrospinal fluid for CMV, HSV, chickenpox virus (Varicella Zoster). EFGDS. Biopsy of the esophagus and stomach using endoscopy. MRI of the brain with contrast or CT scan of the head with contrast	Chickenpox: 1. Chickenpox with mild or moderate manifestations in children without severe immunodeficiency: acyclovir 20 mg / kg / dose (not more than 800 mg / dose) 4 times a day inside; 2. Chickenpox with severe manifestations or in children with severe immunodeficiency: acyclovir 10 mg / kg / dose (or 500 mg / m^2 / dose) 3 times a day intravenously; 3. The duration of treatment for chickenpox is 7-10 days (up to 48 hours after the last rash). Zona: 1. Uncomplicated shingles in children without severe immunodeficiency: acyclovir 20 mg / kg / dose (not more than 800 mg / dose) 4 times a day orally lasting 7–10 days; 2. Shingles in children with severe immunodeficiency, or with the involvement of trigeminal

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					with serum creatinine levels >1,2 mg/dL (or >106 μmol/L) in three Sequential dose measurements fluconazole 12 mg/kg administered every 48 hours before the level drops creatinine <1.2 mg/dL; 2. hemodynamically unstable Patients or high probability Candida resistance to azoles in the department of the hospital organization. Drugs of choice - echinocandins: Mycafungin newborns – 10-12 mg/kg, children older than 1 month with a body weight of ≤ 50 kg - 2 mg/kg, children 2–8 years with body weight ≤ 40 kg - 3-4 mg / kg, children 9–17 years old with body ≤ 40 kg – 2-3 mg/kg, children with body mass >40 kg – 100 mg 1 time per day intravenously, or caspofungin for children under 3 months of age 25 mg/m^2 1 time per day intravenously, children over 3 months to 18 years old – loading dose 70 mg/m^2/day (no more than 70 mg) once intravenously, then 50 mg/m^2 (no more than 70 mg) 1 time per day intravenously, or Anidulafungin for children ≥ 2 Years– loading dose of 3 mg/kg (not more than 200 mg) once intravenously, then 1.5 mg / kg (not more than 100 mg) 1 time per day intravenously. Alternative drugs: amphotericin B 0.7–1.0 g/kg/day (newborns 0.25 g/kg/day) or lipid forms of amphotericin B 5-6 g/kg/day (newborns 1–3 g/kg/day) intravenously daily (Development should be monitored neutropenia as a frequent HP amphotericin B). With uncomplicated candidemia, called C.albicans, initial treatment with amphotericin B can be

					continued with the use of fluconazole; 3. Duration of treatment of candidemia Is ≥14 days after the last one Positive p Sowing result blood, in the absence of clinical symptoms (stabilization hemodynamics, fever care) and secondary foci of infection (including endophthalmitis). You should make sure in reducing risk factors candidemia, including delete or rearrange the central venous catheter, cancel or reduce the dose immunosuppressive drugs, including glucocorticoids, hold antibacterial de-escalation Therapy. Voriconazole is widely used in mold mycoses (for example, with aspergillosis) and routinely It is not recommended for candidiasis due to with the presence of azole-resistant candida (especially C.krusei and C.glabrata), and due to unstable pharmacokinetics and a variety of medicines interactions at the level of inhibition CYP3A4. Voriconazole dosage: children 2–14 years with a body weight of <40 kg – loading dose of 9 mg / kg (not more than 350 mg) every 12 hours for days, then 8 mg / kg (not more than 350 mg) every 12 hours intravenously, In the future, you can go For oral administration mg/kg (not more than 200 mg) every 12 hours; Children ≥12 Years an≥40 kg – loading dose of 6 mg / kg every 12 hours during the day, then 3–4 mg/kg every 12 hours intravenously, In the future, you can go oral administration 200 mg each

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			Spinal puncture with definition in the spinal cord liquids, glucose levels, protein. Puncture is contraindicated in the presence of signs of dislocation syndrome. Microscopic examination cerebrospinal fluid, Counting cells in the counting chamber (determination of cytosis). General (clinical) blood test Deployed. Study of CD4+ lymphocytes. Determination of antibodies to toxoplasma (Toxoplasma gondii) in the blood. Consultation with a pediatrician neurologist, ophthalmologist. Biochemical blood test with the determination of urea levels, creatinine, electrolytes (potassium, calcium, sodium, chlorine), glucose. ELECT General urinalysis	on the concentration of HIV RNA. Biochemical blood test with the determination of the level of bilirubin, total protein, albumin, AST, ALT, Alkaline Consultation with an anesthesiologist- children's resuscitator	in a daily dose of 10 mg / kg / day trimethoprim in 2-3 injections intravenously or orally. In case development of severe local or systemic reactions Hypersensitivity is used desensitization. For the period of treatment sulfamethoxazole/trimethoprim – folic acid 0.5-1 mg 3 times per day inside; 2. Alternative scheme: pyrimethamine 2 mg/kg (no more than 50 mg) 1 once a day orally within 3 days, then 1 mg / kg (not more than 25 mg) 1 time per day inside, plus sulfadiazine 25-50 mg/kg (not more than 1-1.5 g / dose) 4 times a day orally, plus calcium folinate 10-25 mg 1 time per day inside (or folic acid 0.5- 1 mg 3 times a day orally). During pyrimethamine treatment is performed complete blood count weekly; 3. In case of intolerance sulfonamides clindamycin is prescribed at 5-7.5 mg / kg (no more than 600 mg / dose) 4 times a day orally or intravenously; 4. after completion of the etiotropic Secondary treatment is prescribed medical prophylaxis. Dexamethasone (in clinical and (or) neuroimaging signs cerebral edema) 0.5 mg / kg 4 times a day intravenously for 1-3 days with rapid Cancellation. Mechanical ventilation with a decrease in the le ≤8 points on the Glasgow Coma Scale. Relief of convulsive syndrome. ART starts after 2 weeks from the beginning of etiotropic treatment after Exclusions of active TB and cryptococcal meningitis

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Note. Rifabutin, pentamidine, atovaquone, primaquine, foscarnet, cidofovir, probenecid, flucytosine, pyrimethamine, sulfadiazine are prescribed at their own expense, funds of legal entities and other sources not prohibited by law, in the presence of medical indications (for health reasons, taking into account individual intolerance) by decision of the medical consultation, and if it is impossible to carry it out, the attending physician or the person replacing him, with an entry in medical documents.

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Annex 21

Desensitization regimens to sulfamethoxazole/trimethoprim[60]

№ p / n	It's time	Sulfamethoxazole/trimethoprim dose	Dosage of suspension [14] or tablets
1	Six-hour desensitization scheme[15]		
1.1	0	0.02 mg/0.004 mg	5 ml of 1:10,000 suspension
1.2	1 hour	0.2 mg/0.04 mg	5 ml of 1:1000 suspension
1.3	2 hours	2 mg/0.4 mg	5 ml of 1:100 suspension
1.4	3 hours	20 mg/4 mg	5 ml of 1:10 suspension
1.5	4 hours	200 mg/40 mg	5 ml of suspension
1.6	5 hours	800 mg/160 mg	2 tablets 400 mg/80 mg
2	Ten-day desensitization scheme[16]		
2.1	Day 1	2 mg/0.4 mg	1 ml of 1:20 suspension
2.2	Day 2	4 mg/0.8 mg	2 ml of 1:20 suspension
2.3	Day 3	8 mg/1.6 mg	4 ml of 1:20 suspension
2.4	Day 4	16 mg/3.2 mg	8 ml of 1:20 suspension
2.5	Day 5	40 mg/8 mg	1 ml of suspension
2.6	Day 6	80 mg/16 mg	2 ml of suspension
2.7	Day 7	160 mg/32 mg	4 ml of suspension
2.8	Day 8	320 mg/64 mg	8 ml of suspension
2.9	Day 9	400 mg/80 mg	1 tablet 400 mg/80 mg
2.10	Day 10	800 mg/160 mg	2 tablets 400 mg/80 mg
3	Six-day desensitization scheme[17]		
3.1	Day 1	80 mg/16 mg	2 ml of suspension
3.2	Day 2	160 mg/32 mg	4 ml of suspension
3.3	Day 3	240 mg/48 mg	6 ml of suspension
3.4	Day 4	320 mg/64 mg	8 ml of suspension
3.5	Day 5	400 mg/80 mg	1 tablet 400 mg/80 mg
3.6	Day 6	800 mg/160 mg	2 tablets 400 mg/80 mg

[60] Tactics Use sulfamethoxazole/trimethoprim at Development Hypersensitivity reactions depend on the severity of clinical manifestations:

with mild manifestations in the form of erythematous rash and itching, but without weeping and fever, sulfamethoxazole / trimethoprim is continued under the supervision of a specialist doctor, and antihistamines are prescribed; with the appearance of a vesicular rash, ulceration of the mucous membranes and (or) the addition of fever,

[14] Sulfamethoxazole / trimethoprim suspension contains 200 mg of sulfamethoxazole and 40 mg of trimethoprim in 5 ml. Dilution of the suspension is carried out by adding an appropriate amount of water.

[15] A rapid six-hour desensitization regimen is indicated for the development of hypersensitivity reactions during the main course of treatment for pneumocystis pneumonia or toxoplasmosis of the brain, or, if necessary, to start this course in patients with a history of sulfonamide allergy.

[16] A ten-day regimen is used at the stage of preventive treatment (primary or secondary).

[17] The six-day scheme is an abbreviated version of the ten-day scheme.

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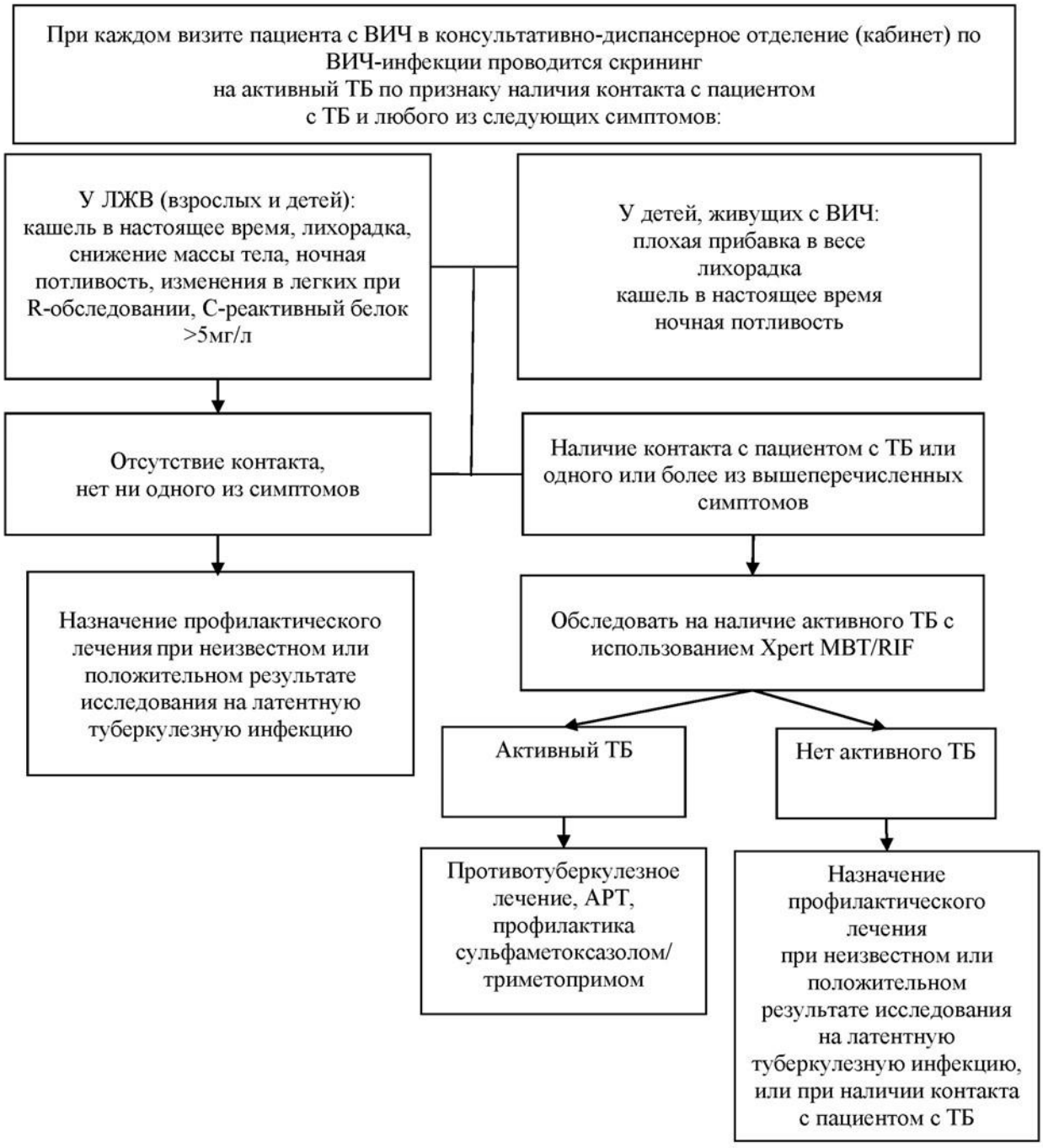
sulfamethoxazole / trimethoprim is stopped until all manifestations of the hypersensitivity reaction disappear (usually up to 2 weeks) and then resumed under the supervision of a specialist doctor, or desensitization to drugs is performed; with the development of exfoliative dermatitis, Stevens-Johnson syndrome, erythema multiforme exudative, sulfamethoxazole / trimethoprim is canceled without subsequent resumption of its intake.

The choice of the duration of the desensitization scheme is carried out depending on the severity of the clinical situation.

In all cases, desensitization is carried out by taking sulfamethoxazole / trimethoprim orally.

Annex 22

Algorithm for screening for active TB in PLHIV



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Annex 23

ART regimens in patients treated with TB with rifampicin

№ p / n	Categories of patients	Preferred schemes	Alternative schemes in descending order of preference
1	Adults and children ≥10 years old	TDF65+XTC66+DTG67 TDF+XTC66+EFV68	ABC+3TC+DTG67 ABC+3TC+EFV68 AZT+3TC+DTG67 AZT+3TC+ EFV68
2	Children ≥4 weeks – <10 years	ABC+3TC+DTG67	AZT+3TC+DTG67 ABC(AZT)+3TC+RAL69 ABC(AZT)+3TC+LPV/r70
3	Newborns (<4 weeks)	AZT(ABC)+3TC+LPV/r70 AZT+3TC+ABC	–

[65] TDF may be replaced by TAF in children 12 years of age and older.

[66] 3TC or FTC.

[67] Double the daily dose of DTG: 50 mg tablet (with a body weight of <20 kg - in the appropriate single dose) 2 times a day, the use of DTG in this dose continues for another two weeks after the abolition of rifampicin.

[68] EFV is used at a dose of 400 or 600 mg 1 time per day.

[69] RAL is used in a double dose - 12 mg / kg twice a day - in children aged 4 weeks to 12 years, the use of RAL at this dose continues for another two weeks after the withdrawal of rifampicin.

[70] LPV/r is used in a double dose. LPV/r can be selected as an alternative only in children who have failed treatment with DTG or as a preferred drug in children <4 weeks or weighing <3 kg.

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ART regimens in patients treated with drug-resistant TB

№ p / n	Categories of patients	Preferred schemes	Alternative schemes in descending order of preference

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1	Adults and children ≥10 years old	TDF+XTC71+DTG TAF+ XTC71+DTG TAF+FTC+BIC	ABC+3TC+DTG TDF[18]+XTC71+IP/B[19] ABC+3TC+IP/B73 AZT+3TC+DTG AZT74+3TC+IP/B73 [20] DTG+IP/B73, [21]
2	Children ≥4 weeks – <10 years	ABC+3TC+DTG	AZT74+3TC+DTG ABC(AZT[74])+3TC+RAL ABC+3TC+LPV/r DTG(RAL)+IP/B73
3	Newborns (<4 weeks)	ABC+3TC+LPV/r73 ABC+3TC+NVP	AZT74+3TC+NVP AZT74+3TC+LPV/r73

[71] 3TC or FTC.

Annex 25

ARVs used in ART regimens in patients receiving prophylactic TB treatment with rifapentine 900 mg + isoniazid 900 mg once weekly

№ p / n	Class or individual ARV-LS	Comments
1	All NRTIs, including TAF 25 mg/day	No dose adjustment is required
2	EFV76 400 or 600 mg	No dose adjustment is required
3	II77: DTG and RAL	No dose adjustment is required
4	LPV/r78	Doubling a single dose while maintaining the multiplicity

[76] Other NNRTIs (NVP, RPV, DOR, etravirine (hereinafter referred to as ETV)) are not used with rifapentine.

[77] BIC is not used with rifapentin, RAL can be used with prophylactic weekly rifapentin.

[78] Other IP/B are not used with rifapentine.

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[18] TDF may be replaced by TAF in children 12 years of age and older.

[19] All IP/b, including LPV/r, increase the concentrations of bedaquiline and delamanide, which may lead to a cumulative effect on prolongation of the QT interval on the ECG; patients receiving this combination of drugs should be under strict medical supervision.

[20] AZT is used in combination with linezolid only in the absence of other treatment options and under strict control of hemoglobin and red blood cell levels.

[21] The combination of AI and IP/b is used only when it is impossible to find an effective NRTI base.

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Drug interactions of PPD drugs for the treatment of HCV infection and ARV-LS

№ p / n	Drugs PPD for the treatment of infection caused by HCV	ARV-LS79	Drug interactions, recommendations for joint Use
1	Sofosbuvir (hereinafter referred to as SOF)	DRV/b	An increase in the concentration of SOF, which does not require correction of drug doses
2	Daclatasvir (hereinafter referred to as DCV)	EFV	The dose of DCV is increased to 90 mg / day
		NVP, ETV80	Decrease in DCV concentration. DCV is not used in conjunction with NVP and ETV
		ATV/r, ATV/c	The dose of DCV is reduced to 30 mg / day
3	Sofosbuvir/velpatasvir (hereinafter referred to as SOF/VEL)	TDF	Increased TDF concentrations requiring closer monitoring of renal function, especially when used with IP/B
		EFV, NVP, ETV	NNRTIs are not used in conjunction with SOF/VEL
4	Sofosbuvir/ledipasvir (hereinafter referred to as SOF/LED)	TDF	Increased TDF concentrations requiring closer monitoring of renal function, especially when used with IP/B or RPV
		LPV/r	Co-administration with SOF/LED can lead to a sharp deterioration in liver function
5	Glecaprevir/pibrentasvir (hereinafter referred to as G/P)	EFV, NVP, ETV	These NNRTIs are not used in conjunction with G/P
		IP/B	IP/B are not used in conjunction with G/P
		BIC	An increase in the concentration of BIC, which does not require correction of drug doses

6	Sofosbuvir/velpatasvir/voxilaprevir[80] (hereinafter referred to as SOF/VEL/VOX)	TDF	Increased TDF concentrations requiring closer monitoring of renal function, especially when used with IP/B
		EFV, NVP, ETV	NNRTIs are not used in conjunction with SOF/VEL/VOX
		ATV/r, ATV/c, LPV/r	IP/B are not used in conjunction with SOF/VEL/VOX
		DRV/r	DRV/r can only be used at a dose of 800/100 mg 1 time per day

[79] ARV-DRUGS ABC, 3TC, FTC, AZT have no significant drug interactions.

[80] It is appointed at the expense of its own funds, funds of legal entities and other sources not prohibited by law, in the presence of medical indications (for health reasons, taking into account individual intolerance) by decision of the medical council, and if it is impossible to carry it out, by the attending physician or the person replacing him, with an entry in medical documents.

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Dose adjustment of ARV-drugs in patients with impaired liver function

№ p / n	Class or individual ARV-LS	Comments
1	ABC	Cirrhosis of the liver severity class A: 200 mg 2 times a day (dosage form for children is used). Cirrhosis of the liver severity class B and C: not used
2	AZT	Cirrhosis of the liver severity class C: the dose is reduced by 50% or the interval between doses is doubled
3	All other NRTIs (except ABC and AZT)	No dose adjustment is required
4	EFV and combinations with tenofovir	Dose adjustment is not required, used with caution in patients with liver disease
5	Other NNRTIs (etv, rpv, dor) and their combinations with tenofovir	Cirrhosis of the liver severity class A and B: dose adjustment is not required. Cirrhosis of the liver severity class C: no safety data
6	LPV/r	No dose adjustment is required
7	ATV	Cirrhosis of the liver severity class A: dose adjustment is not required. Cirrhosis of the liver severity class B: 300 mg per day without a booster. Cirrhosis of the liver severity class C: not recommended for use
8	ATV/c	Cirrhosis of the liver severity class A: dose adjustment is not required. Cirrhosis of the liver severity class B and C: not recommended for use
9	DRV and combinations (DRV/r, DRV/c, TAF/FTC/DRV/c)	Cirrhosis of the liver severity class A and B: dose adjustment is not required. Cirrhosis of the liver severity class C: not recommended for use

10	RAL	No dose adjustment is required
11	DTG	Cirrhosis of the liver severity class A and B: dose adjustment is not required Cirrhosis of the liver severity class C: no safety data
12	BIC (TAF/FTC/BIC)	Cirrhosis of the liver severity class A and B: dose adjustment is not required. Cirrhosis of the liver severity class C: no safety data

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Dose adjustment of ARV-drugs in patients with impaired renal function

№ p/n	ARV-LS	GFR (ml/min)[22]			Hemodialysis82 (after the end of the dialysis session)
		30–49	10–29	<10	
1	ABC	No dose adjustment is required			
2	FTC	200 mg every 24 hours	200 mg each 72 hours	200 mg each 96 hours	200 mg each 24 hours
3	3TC	150 mg every 24 hours	100 mg each 24 hours (loading dose 150 mg)	50-25 mg each 24 hours (loading dose 150 mg)	50-25 mg each 24 hours (loading dose 150 mg)
4	TDF83	300 mg each 48 hours	300 mg every 72–96 hours if there are no alternatives	300 mg each 7 days if there are no alternatives	300 mg each 7 days
5	TAF	25 mg every 24 hours		No data available	every 24 hours
6	AZT	300 mg every 12 hours		100 mg every 8 hours	100 mg each 8 hours
7	ABC/3TC AZT/3TC	The combined form is not used[84]			
8	TDF/FTC	300/200 mg every 48 hours	The combined form is not used[84]		
9	TAF/FTC	25/200 mg every 24 hours	The combined form is used if there are no alternatives		25/200 mg each 24 hours
10	EFV	No dose adjustment is required			
11	RPV	No dose adjustment is required			
12	DOR	No dose adjustment is required (no safety data for GFR<10 ml/min.)			
13	TAF/FTC/RPV	25/200/25 mg every 24 hours	The combined form is used if there are no Alternatives		25/200/25 mg each 24 hours
14	TDF/FTC/RPV	300/200/25 mg every 24 hours	The combined form is not used[85]		
15	TDF/3TC/DOR	300/300/100 mg every 24 hours	The combined form is not used[85]		
16	ATV/r	No dose adjustment is required			Not recommended
17	ATV/c86	No dose adjustment is required			Not recommended
18	DRV/r	No dose adjustment is required			

[22] For the determination of GFR, it is preferable to use the CKD-EPI formula, alternatively the Cockcroft-Gault formulas or aMDRD can be used.

19	DRV/c86	No dose adjustment is required		No data available
20	TAF/FTC/DRV/c	10/200/800/150 mg every 24 hours	The combined form is not used[85]	
21	LPV/r	No dose adjustment is required		
22	RAL	No dose adjustment is required		
23	DTG	No dose adjustment is required		
24	RPV/DTG	No dose adjustment is required		
25	3TC/DTG	The combined form is not used[85]		
26	ABC/3TC/DTG	The combined form is not used[85]		
27	TAF/FTC/BIC	No dose adjustment is required	The combined form is not used[85]	No dose adjustment is required

[82] For prolonged ambulatory peritoneal dialysis, the same doses of ARV-LS can be used as for hemodialysis.

[83] TDF, when used together with PIs, especially boosted ones, exhibits more pronounced nephrotoxicity, this combination should be avoided in patients with chronic kidney disease, risk of chronic kidney disease and (or) a decrease in GFR.

[84] Where the combined form is not used, it is possible to use individual drugs that are part of it with appropriate dose adjustment.

[85] Where the combined form is not used, it is possible to use individual drugs that are part of it with appropriate dose adjustment.

[86] ATV/c and DRV/c are not prescribed with TDF for GFR <70 ml/min.

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Form

Alcohol Use Disorder Questionnaire (AUDIT)

№ p / n	№ Question	Consumption Questions alcohol during the last 12 months	Points					Answer
			0	1	2	3	4	
1	№ 1	How often do you drink alcohol?	Never	1 time per month or less	2-4 times a month	2-3 times a week	4 or more times a week	
2	№ 2	How many standard servings of alcohol do you usually drink during the day?	1–2	3–4	5–6	7–9	10 or more	
3	№ 3	How often do you drink 6 or more standard servings of alcohol?	Never	Less 1 time per month	1 time per month	1 time per week	Daily or almost daily	

4	IF the answer "never" to question No. 1 is received or 0 points are received for questions No. 2 and No. 3, go to questions No. 9 and No. 10. IF the total score for questions 1-3 was >4 for men or ≥3 for women, go to questions 4-10							
5	№ 4	How often in the last year have you had that you could not stop when you started drinking?	Never	Less 1 time per month	1 time per month	1 time per week	Daily or almost daily	
6	№ 5	How often over the past year have you not done what was normally expected of you because of drinking?	Never	Less 1 time per month	1 time per month	1 time per week	Daily or almost daily	
7	№ 6	How often over the past year have you needed to drink in the morning to recover	Never	Less 1 time per month	1 time per month	1 time per week	Daily or almost daily	
		after you drank a lot the day before?						
8	№ 7	How often in the past year have you had feelings of guilt or remorse after drinking?	Never	Less 1 time per month	1 time per month	1 time per week	Daily or almost daily	
9	№ 8	How often in the past year have you been unable to remember what happened the night before because you were drinking?	Never	Less 1 time per month	1 time per month	1 time per week	Daily or almost daily	
10	№ 9	Have you or anyone else been injured as a result of drinking?	No, never	–	Yes, but not last year	–	Yes, during the past year	
11	№ 10	Has your relative, friend, doctor, or other health care provider ever raised concerns about your drinking or suggested that you drink less?	No, never	–	Yes, but not last year	–	Yes, during the past year	
12	Total points (questions No. 1–10)							

Notes:

1. A standard serving of alcohol is 10 grams of pure alcohol; Approximate values for different alcoholic beverages, taking into account the strength and container: a can of beer 0.5 l 5% - 2 standard servings, a bottle of dry wine 750 ml 12% - 7 standard servings, a bottle of strong alcohol (vodka, whiskey, cognac) 500 ml 40% - 16 standard servings.

2. Interpretation of the results of the AUDIT test:

≥8 points in men or >7 points in women indicates a high probability of dangerous or harmful use of alcohol;

≥20 points indicates possible alcohol dependence and the need for specialized treatment.

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Form

Questionnaire for the detection of GAD (GAD-2, GAD-7)

№ p / n	№ Question	How often in the last 2 weeks You've been bothered by the following issues:	Score and Score Assigned				Answer
			Never	A few days	More than half days	Almost every day	
1	№ 1	Increased nervous irritability, restlessness, or irritability	0	1	2	3	
2	№ 2	Inability to cope with excitement	0	1	2	3	
3	Total points (questions No. 1–2)						
4	№ 3	Excessive anxiety on various occasions	0	1	2	3	
5	№ 4	Inability to relax	0	1	2	3	
6	№ 5	Extreme anxiety: "I can't find a place for myself"	0	1	2	3	
7	№ 6	I easily succumb to feelings of anxiety or irritability	0	1	2	3	
8	№ 7	Fear that something terrible may happen	0	1	2	3	

9	Total points (questions No. 1–7)	

Notes:

1. Interpretation of the results of the GAD-2 test based on the answers to the first two questions: the sum of >3 points allows us to consider the GAD probable and requires further examination.

2. Interpretation of the results of the GTR-7 test:
the sum of >8 points allows us to consider the GTR possible;
0-4 points corresponds to the minimum level of anxiety;
5-9 points - moderate level of anxiety; 10-14 points - the average level of anxiety; 15-21 points - a high level of anxiety.

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Form

Patient Health Questionnaire (PHQ-2, PHQ-9) for Depression

№ p / n	№ Question	How often in the last For 2 weeks you have experienced similar experiences, sensations and thoughts	Score and Score Assigned				Answer
			Never	A few days	More than half days	Almost every day	
1	№ 1	Decreased interest or pleasure in what You've been doing	0	1	2	3	
2	№ 2	Low mood, feelings of depression or hopelessness	0	1	2	3	
3	Total points (questions No. 1–2						
4	№ 3	Difficulty falling asleep, superficial sleep or vice versa, excessive sleepiness	0	1	2	3	
5	№ 4	Feeling tired or depressed	0	1	2	3	
6	№ 5	Poor appetite or overeating	0	1	2	3	
7	№ 6	Negative self-image: did you consider yourself a loser (loser), or were disappointed in yourself, or believed that you had let your family down?	0	1	2	3	
8	№ 7	Difficulty concentrating, such as when reading or watching TV	0	1	2	3	

9	№ 8	Slowness of movement and speech, which was noticed by others. Or vice versa - excessive and not peculiar to you fussiness and activity	0	1	2	3	
10	№ 9	You've had thoughts that you'd better die, or that you'd be hurting yourself in some way	0	1	2	3	
11	Total points (questions Nos. 1–9						

Notes:

1. Interpretation of the results of the PHQ-2 depression test by answering the first two questions:

The sum of >3 points allows us to consider the presence of depression probable, requires further examinations with the continuation of the PHQ-9 test.

2. Interpretation of PHQ-9 Depression Test Results:

with a score of 5-9 we are talking about mild depression, it is necessary to conduct a consultation focused on identifying existing problems, recommendations for increasing physical activity and a balanced diet, retesting PHQ-9 at the next medical examination; the sum of >10 points indicates the possibility of a major depressive disorder, recommended
replacement of EFV in the ART regimen;

10-14 points indicate moderate depression and suggest the possibility of using antidepressants by any specialist doctor, taking into account potential drug interactions;

15-19 points indicate moderately severe, and 20-27 indicate a severe depressive disorder and require the involvement of a mental health specialist with the appointment of treatment; A patient who answers yes to the ninth question needs further evaluation
suicidal risk.

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ARV-drug regimens used for HIV AEDs

№ p / n	Age category	Choice of drugs	NRTI-Base	Third ARV-LS
1	Adults and children 10 years and older	Preferred drugs	TDF+XTC87 TAF+FTC	DTG
		Alternative drugs	AZT+3TC	IP/B BIC
2		Preferred drugs	AZT+3TC	DTG

	Children under 10 years of age	Alternative drugs	TDF+XTC87 ABC+3TC	IP/B

87 3TC or FTC.