



On approval of the Instruction on organization of medical care for tuberculosis

Invalidated Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan of December 25, 2017 No. 994. Registered with the Ministry of Justice of the Republic of Kazakhstan on February 19, 2018 No. 16381. Abolished by the Order of the Minister of Health of the Republic of Kazakhstan dated November 30, 2020 No. KR DSM-214/2020

Unofficial translation

Footnote. Abolished by the Order of the Minister of Health of the Republic of Kazakhstan dated November 30, 2020 No. KR DSM-214/2020 (effective ten calendar days after the date of its first official publication).

In accordance with subparagraph 120) of paragraph 1 of article 7 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On people's health and health care system", **I HEREBY ORDER:**

1. To approve the attached Instruction on organization of medical care for tuberculosis.

2. To recognize the order of the acting Minister of health and social development of the Republic of Kazakhstan dated August 22, 2014 No. 19 "On approval of the Instruction on organization and implementation of preventive measures for tuberculosis" (registered in the Register of the state registration of regulatory legal acts No. 9772, published in the legal information system "Adilet" on October 17, 2014) as invalid.

3. The Department of organization of medical care of the Health Ministry of the Republic of Kazakhstan in accordance with the legislation to ensure:

1) the state registration of this order in the Ministry of justice of the Republic of Kazakhstan;

2) within ten calendar days from the date of the state registration of this order to send its copy in paper and electronic form in the Kazakh and Russian languages to the Republican state enterprise on the basis of the right of economic management "Republican center of legal information" for official publication and inclusion in the Reference control bank of regulatory legal acts of the Republic of Kazakhstan;

3) within ten calendar days after the state registration of this order to send its copy to periodic printed publications for official publication;

4) placement of this order in the Internet resource of the Health Ministry of the Republic of Kazakhstan after its official publication;

5) within ten working days after the state registration of this order in the Ministry of justice of the Republic of Kazakhstan to submit information to the legal service Department of the Health Ministry of the Republic of Kazakhstan on execution of the measures, provided for by subparagraphs 1), 2), 3) and 4) of this paragraph.

4. Vice-Minister of health of the Republic of Kazakhstan Aktayeva L. M. shall be authorized to oversee the implementation of this order.

5. This order shall be enforced upon expiry of ten calendar days after its first official publication.

Health Minister

of the Republic of Kazakhstan

Birtanov Y.

"AGREED"

Minister of education and
science of the
Republic of Kazakhstan

_____ Sagadiyev Y. K.

January 15, 2017

"AGREED"

Minister of defense
of the Republic of Kazakhstan

_____ Zhasuzakov S. A.

February 1, 2017

"AGREED"

Minister of internal Affairs
of the Republic of Kazakhstan

_____ Kasymov K. N.

January 22, 2017

"AGREED"

Minister of labor and
social protection of the
Republic of Kazakhstan

_____ Duissenova T. K.

January 4, 2017

Annex 1
to the order of the Health Minister
of the Republic of Kazakhstan
dated December 25, 2017 No. 994

The Instruction on organization of medical care for tuberculosis

Chapter 1. General provisions

1. This Instruction on organization of medical care for tuberculosis (hereinafter – the Instruction) shall be developed in accordance with subparagraph 120 of paragraph 1 of article 7 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On people's health and healthcare system" (hereinafter – the Code) and shall itemize the organization of medical care for tuberculosis.

2. The basic concepts used in this Instruction shall be:

1) pre-extensive drug-resistance - tuberculosis, caused by *Mycobacterium tuberculosis*, the strains of which are resistant to the fluoroquinolone (ofloxacin or levofloxacin) or, at least, one injection drug of the second line (capreomycin, kanamycin or amikacin), but not simultaneously to the two drugs;

2) tuberculosis with extensive drug-resistance - tuberculosis, caused by *Mycobacterium tuberculosis*, the strains of which are resistant to at least isoniazid and rifampicin, and one of the fluoroquinolones and one of three injectable second-line drugs (capreomycin, kanamycin or amikacin);

3) a child (children) - a person under the age of eighteen (adulthood);

4) genetic-molecular methods – the accelerated methods of diagnosis of tuberculosis and tuberculosis with multi-drug resistance on the basis of polymerase chain reaction, which take place at the level of organizations, providing out-patient-polyclinic assistance and anti-TB organizations;

5) drug sensibility test– definition of the spectrum of sensitivity of *Mycobacterium tuberculosis* to anti-TB drugs;

6) cultural methods of diagnosis – the extraction of pure cultures, typing of the extracted strain to the species level and definition of its sensitivity to anti-TB drugs;

7) TB patients from groups with a high risk of isolation from treatment – the persons with co-infection (tuberculosis and human immunodeficiency virus), injecting drugs, alcohol abusers, without a certain residence, prisoners and people released from places of detention;

8) tuberculosis with multidrug-resistance – tuberculosis, caused by *Mycobacterium tuberculosis*, the strains of which are resistant to rifampicin;

9) a sputum conversion in a TB patient with multiple and extensive drug resistance – the disappearance of *Mycobacterium tuberculosis* in the treatment process, confirmed by at least two consecutive negative microscopic investigations and inoculations on solid nutrient media with a period of 1 month;

10) a cessation of bacterial excretion in a TB patient with multiple and extensive drug resistance – completion of the full course of treatment and stabilization of the process in the lungs with a negative bacteriological and microscopic data for 12 months after sputum conversion;

11) an intensive phase – the initial phase of therapy, aimed at eliminating the clinical manifestations of the disease and the greatest impact on the population of M.

tuberculosis (sputum conversion smear and prevention of development of drug-resistant strains);

12) pulmonary tuberculosis with positive sputum smear (bacterial excretion) microscopy – in sputum-smear microscopy prior to treatment, the acid-fast bacilli are detected in at least one portion;

13) pulmonary tuberculosis with negative sputum smear microscopy:

not less than 2 negative results of microscopic investigation of sputum smear for the presence of acid-fast bacilli;

radiologically defined changes corresponding to the active tuberculosis of the lungs ;

the lack of effect during the therapy with antibacterial medications of wide spectrum of action;

14) maintenance phase – the therapy continuation phase, which affects the persisting mycobacterial population and provides further reduction of the inflammatory changes and involution of tubercular process, and also restores the functionality of the body of the patient;

15) latent TB infection – a condition of persistent immune response to antigens of *Mycobacterium tuberculosis* that previously got into organism in the absence of clinical manifestations of active TB;

16) Mantoux test - a specific diagnostic test, intradermal tuberculin Mantoux test with two international tuberculin units;

17) microscopic investigation - a method of detection of acid-fast bacteria in fixed smears;

18) positive (positive) microscopy result – a detection of acid-fast bacilli in a smear ;

19) negative (negative) microscopy result– the absence of acid-fast bacilli in 300 fields of view;

20) complications of extra-pulmonary tuberculosis – abscesses, fistula, neurological disorders, spinal deformity, contracture of joints, Microcystis, hydronephrosis, infertility;

21) multidrug resistant tuberculosis – tuberculosis, caused by *Mycobacterium tuberculosis*, the strains of which are resistant to two or more drugs that is different from tuberculosis with multiple and extensive drug resistance;

22) recombinant tuberculosis allergen – a complex of recombinant proteins for intradermal application in standard dilution, designed for the diagnosis of tuberculosis infection;

23) inoculation – a method for extraction of culture of *Mycobacterium tuberculosis* from pathological material on nutrient medium (dense and liquid);

24) hospital-replacing technologies – day patient facility, hospital at home and mobile team for directly observed treatment;

25) purified protein derivative – a ready form of purified tuberculin in standard dilution;

26) tuberculosis - an infectious air-communicable disease, caused by *Mycobacterium tuberculosis* and transmitted when talking, coughing and sneezing from an infected person to a healthy one with a predominant localization in the lung tissue;

27) cessation of bacterial excretion in a TB patient – receipt of two consecutive negative microscopic investigations of sputum smear upon completion of the full course of treatment with anti-TB drugs of first line in the mode of I and II categories;

28) conversion of sputum smear in a TB patient – the disappearance of acid-fast bacilli in the process of treatment, confirmed by at least two consecutive negative sputum smear microscopies upon completion of the intensive phase;

29) tuberculin – an autoclaved culture filtrate, a waste product of *Mycobacterium tuberculosis*;

30) a turn of tuberculin reaction – a conversion of negative reactions into positive ones, not related to vaccination against tuberculosis, or escalation of reaction on the background of post-vaccination allergy during the year by 6 mm and more.

Chapter 2. Organization of medical care for tuberculosis

3. Health care organizations, providing medical care for tuberculosis for adults and children, shall carry out activities aimed at prevention, detection, diagnosis, treatment of TB patients with the aim of reducing the incidence, prevalence, disability and mortality from tuberculosis.

4. Medical care for tuberculosis shall be provided at 3 levels.

5. Medical care for tuberculosis at the first level shall be provided by the organizations, rendering out-patient-polyclinic assistance and shall include:

1) prevention of TB among general population;

2) early detection of TB among risk groups and mandatory groups through the fluorography screening and tuberculinodiagnosis;

3) identification of TB by general practitioners, local therapists, TB doctors among persons applying with breast complaints and symptoms of intoxication;

4) verification of diagnosis by laboratory and instrumental studies of fluorography positive persons and persons with symptoms of tuberculosis;

5) referral for hospitalization of TB patients in the anti-TB organizations for the specialized medical care;

6) directly observed treatment with anti-TB drugs on an outpatient basis;

7) dynamic monitoring of TB patients;

8) hospital replacing care in day patient facilities, hospital at home or with the assistance of visiting nurses and mobile teams;

9) medical monitoring;

10) registration of medical documentation in the prescribed form.

6. Medical care for tuberculosis at the second level shall be provided by the organizations, providing inpatient care (TB hospital (clinic) in the city of the republican significance and the capital, in the regional center) and shall include:

1) diagnosis of tuberculosis, tuberculosis with multiple and extensive drug resistance using laboratory diagnostic methods, including molecular-genetic methods;

2) treatment of tuberculosis of extra-pulmonary localization;

3) surgical treatment of pulmonary and extra-pulmonary tuberculosis according to medical reasons;

4) experts' advice according to the identified pathology of the disease;

5) accounting and registration of tuberculosis cases, including tuberculosis with multiple and extensive drug resistance, according to the decision of the centralized medical advisory committee;

6) selection and assignment of treatment, in accordance with the existing nosology and clinical protocols of diagnostics and treatment, according to the decision of the centralized medical advisory committee;

7) directly observed treatment;

8) monitoring and treatment of adverse reactions to anti-TB drugs;

9) symptomatic and pathogenetic treatment;

10) daily medical examination, correction of treatment;

11) cohort and statistical analysis;

12) organizational and methodical work;

13) hospital replacing care in day patient facilities and mobile teams;

14) organization of forced and palliative treatment according to the decision of the centralized medical advisory committee;

15) discharge of a patient with documentation and issuance of the abstract of medical records to the patient.

7. Medical care for tuberculosis at the third level shall be provided by a Scientific institution in the field of health care (Republican state enterprise on the basis of the right of economic management "National research center of phthisiopulmonology of the Republic of Kazakhstan" of the Health Ministry of the Republic of Kazakhstan) and shall include:

1) diagnosis of tuberculosis, tuberculosis with multiple and extensive drug resistance using laboratory diagnostic methods, including molecular-genetic methods;

2) consultation of experts in accordance with the detected pathology of the disease;

3) accounting and registration of TB cases, including tuberculosis of multiple and extensive drug resistance, according to the decision of the centralized medical advisory committee;

4) selection and assignment of treatment, in accordance with the existing nosology and clinical protocols of diagnostics and treatment in accordance with the decision of the centralized medical advisory committee;

5) monitoring and treatment of adverse reactions to anti-tuberculosis drugs;

6) symptomatic and pathogenetic treatment;

7) daily medical examination, correction of treatment;

8) surgical treatment of pulmonary tuberculosis and extra-pulmonary localizations according to the medical reasons;

9) cohort and statistical analysis;

10) organizational and methodical work (organization of seminars, meetings, conferences, public awareness campaign, monitoring and evaluation of TB control activities in the country);

11) research;

12) clinical studies of medicinal products and medical devices;

13) participation in multi-center clinical studies;

14) participation in development of regulations, clinical guidelines, standards and clinical protocols of diagnostics and treatment;

15) organization and provision of secondary education for children with TB, TB with multiple and extensive drug resistance;

16) discharge of patients with documentation and issuance of the abstract from medical records to the patient.

8. Diagnosis of tuberculosis and tuberculosis with multiple and extensive drug resistance, registration of all cases, determination of the tactics of treatment and medical monitoring shall be made by the Centralized medical advisory committee.

9. The Centralized medical advisory committee shall consist of a chairman (head of the TB organization), vice-chairman, members (heads of the organizational and methodological department, branches for treatment of TB patients, tuberculosis with multiple and extensive drug resistance, including in children, pharmacist/drug coordinator and a secretary).

Chapter 3. Prevention of tuberculosis

§ 1. Vaccination and revaccination of tuberculosis

10. With the purpose of prophylaxis and prevention of tuberculosis, the healthy newborns, in the absence of medical contraindications, shall be vaccinated with the Calmette-Guerin bacillus in the vaccination room of the perinatal (maternity

department) center on the 2nd – 4th day after birth. Planning, organization and conduct of preventive vaccination shall be carried out in accordance with paragraph 6 of article 144 of the Code of the Republic of Kazakhstan "On People's Health and Healthcare System".

11. The vaccine Calmette-Guerin bacillus shall be injected strictly intra-dermally on the border of upper and middle thirds of the outer surface of the left shoulder in the amount, stipulated in the instructions, supplied with the vaccine.

12. Children who are not vaccinated with the vaccine Calmette-Guerin bacillus in the perinatal (maternity department) center, shall be vaccinated in organizations, providing out-patient-polyclinic assistance: up to two months - without making Mantoux test, after two months – in case of a negative result.

13. Vaccinated newborns, coming from perinatal (maternity department) center and contacting with a sick person discharging bacteria, in case of impossibility of isolation of a TB patient, shall be isolated for a period of not less than 2 months in the Developmental care or the infant Orphanage.

14. The newborns, who are not vaccinated with the vaccine Calmette-Guerin bacillus, shall be discharged from perinatal (maternity department) center only after examination of parents and all persons living together for tuberculosis, according to the statement, issued by the organization, providing out-patient-polyclinic assistance.

15. A newborn baby shall be examined for congenital TB (if possible, placenta is examined) in case if the mother has an active tuberculosis, irrespective of bacteria excretion and drug sensitivity.

16. In case of exclusion of tuberculosis, a newborn shall be isolated and a chemo-preventive treatment (3 months) shall be carried out:

1) 3 months after chemoprophylaxis, a Mantoux test is made with 2 tuberculin units, in case of a negative result, a vaccination with Calmette-Guerin bacillus is made with the isolation from mother for not less than 2 months, for the period of production of immunity;

2) if the result of the Mantoux test is positive and the local tuberculosis is excluded, chemoprophylaxis is continued for up to 6 months.

17. If the mother of a newborn has the active TB with multidrug-resistance and tuberculosis with extensive drug-resistance, the baby is examined for congenital tuberculosis. In case of exclusion of tuberculosis, the vaccination with Calmette-Guerin bacillus is allowed and the child is isolated for 2 months for the period of production of immunity.

18. Revaccination with Calmette-Guerin bacillus vaccine for prevention of tuberculosis shall be made:

1) to the healthy uninfected children with a negative Mantoux test at the age of 6 years (grade 1) in the schools, simultaneously throughout the country in the first month of the beginning of the school year (September). Other vaccinations shall be prohibited at school during this month;

2) persons with doubtful reaction have a repeated Mantoux test with 2 tuberculin units after 3 months and in case of a negative result, the vaccine Calmette-Guerin bacillus is made.

19. The interval between the Mantoux test and revaccination with Calmette-Guerin bacillus shall not be less than three days and no more than two weeks.

20. Contraindications to revaccination of Calmette-Guerin bacillus shall be:

- 1) infection with Mycobacterium tuberculosis or tuberculosis in the past;
- 2) a positive and a doubtful reaction of Mantoux test;
- 3) adverse reactions to the vaccination of Calmette-Guerin bacillus;
- 4) the generalized infection of Calmette-Guerin bacillus, identified in individuals of the first-degree relatives;
- 5) the presence of the human immunodeficiency virus or acquired immunodeficiency syndrome;
- 6) immunodeficiency states, malignancies;
- 7) acute infectious and noninfectious diseases, exacerbation of chronic diseases, including allergic.

21. Individuals who are temporarily exempt from the re-vaccination of Calmette-Guerin bacillus for medical contraindications shall be vaccinated after complete recovery or removal of contraindications.

22. Monitoring of the vaccinated (revaccinated) children shall be held by pediatricians, general practitioners in the organizations, providing out-patient-polyclinic assistance after 1, 3, 6, 12 months.

23. The final result of the vaccination and re-vaccination of Calmette-Guerin bacillus shall be evaluated 1 year after the vaccination based on the size of the scar. Rarely, at the injection site of the Calmette-Guerin bacillus vaccine, a pigment spot is formed.

24. In the absence of a local vaccination reaction (absence of a scar), children shall be recorded and revaccinated (additional vaccination) (only once) 6 months later without prior Mantoux test, 1 year later – in case of a negative Mantoux test.

25. Local (nature and size) and common (peripheral lymph nodes) vaccination reaction to the Calmette-Guerin bacillus vaccine shall be assessed, recorded in the accounting forms No. 063/y, 026/y, 112/y, approved by the order of the acting health Minister of the Republic of Kazakhstan dated November 23, 2010 № 907 (registered in the Register of state registration of normative legal acts of the Republic of Kazakhstan № 6697) (hereinafter – the Order 907).

26. In rare cases, the following forms of local adverse reactions to the injection of the Calmette-Guerin bacillus vaccine shall be observed:

- 1) regional lymphadenitis;
- 2) subcutaneous cold abscess;
- 3) anabrosis;
- 4) keloid scar;
- 5) damage to the bone system (ostitis).

27. Adverse reactions to vaccination shall be established by a phthisiologist on the basis of comprehensive clinical, x-ray and laboratory examinations and a negative result of the text with tuberculous recombinant allergen.

28. Each case of adverse reaction to the Calmette-Guerin bacillus vaccine shall be registered in the National register of TB patients and reported to the heads of medical organizations, territorial department of public health, regional TB dispensary and National research center of Phthisiopulmonology of the Health Ministry of the Republic of Kazakhstan.

29. Information on the nature of the reactions shall be recorded in the accounting forms No. 063/y, No. 026/y, No. 112/y, approved by the Order No. 907. The records shall be filed for all children with reactions.

30. Children with adverse reaction to the Calmette-Guerin bacillus vaccine shall be monitored in III B group of the regular medical check-up for 1 year.

31. The following scope of examination shall be carried out in registration and deregistration:

the general analysis of blood and urine, radiography of the chest, in addition (in deregistration) – a Mantoux test and tuberculous recombinant allergen.

32. In post-vaccination complications of the Calmette-Guerin bacillus vaccine, the reaction to the recombinant TB allergen shall be negative.

33. In case of registration of the 2 case of post-vaccination complications of the Calmette-Guerin bacillus vaccine in children of the first-degree relatives, the pediatrician (general practitioner) shall make an examination to diagnose a primary immunodeficiency (clinical, immunological, genetic).

34. Preventive vaccination against tuberculosis (vaccination and revaccination with the Calmette-Guerin bacillus vaccine), shall be carried out according to the accompanying instructions.

§ 2. Specific prevention for infected children with human immunodeficiency virus

35. Newborns, born from mothers infected with human immunodeficiency virus, in the absence of clinical signs of infection of human immunodeficiency virus and other contraindications, shall be vaccinated with a standard dose of the Calmette-Guerin bacillus vaccine intra-dermally once per calendar period.

36. Newborns, born from mothers infected with human immunodeficiency virus, unvaccinated within calendar periods, shall be vaccinated within 4 weeks of life (neonatal period) without prior Mantoux test. After the fourth week of life the injection of the Calmette-Guerin bacillus vaccine to children shall not be allowed due to the possible development of generalized infection with Calmette-Guerin bacillus.

37. Re-vaccination with the Calmette-Guerin bacillus vaccine to children with undeveloped post-vaccination signs (scar) shall not be made until the child reaches 12 months of age and in some cases 15-18 months (until the confirmation of human immunodeficiency virus infection).

38. If human immunodeficiency virus infection is excluded by 12 months of age, and in some cases 15-18 months, the vaccination with the Calmette-Guerin bacillus vaccine shall be made at a negative result of the Mantoux test.

39. Revaccination of the Calmette-Guerin bacillus vaccine of children infected with the human immunodeficiency virus shall not be carried out due to the risk of generalized infection with Calmette-Guerin bacillus against a background of growing immunodeficiency.

40. If a child is born by a mother infected with human immunodeficiency virus, but is not itself infected with the human immunodeficiency virus, the revaccination with the Calmette-Guerin bacillus vaccine shall be made when the child turns 6 years of age (1st grade) with a negative result of the Mantoux test.

§ 3. Chemoprophylaxis of tuberculosis in children

41. Prophylaxis of latent tuberculosis infection shall be carried out by the chemo-preventive treatment.

42. Chemo-preventive treatment shall be carried out to the children and people living with the human immunodeficiency virus, if the local tuberculosis is excluded:

1) children up to 5 years, contacting with a person discharging bacteria, regardless of the result of the Mantoux test with 2 tuberculin units;

2) contact children from hotbeds of death, previously unknown to anti-TB institutions;

3) children with a positive reaction to recombinant tuberculosis allergen: contact, regardless of the bacteria excretion by the source of infection; with the diagnosed " Infection with Mycobacterium tuberculosis, newly diagnosed";

4) adults and children living with the human immunodeficiency virus.

43. Children, infected with Mycobacterium tuberculosis, contacting with tuberculosis patients with multi-drug resistance and extensive drug resistance, shall not receive chemoprophylaxis with isoniazid; they are observed under III A group of

regular medical check-up in compliance with the interval of the Mantoux test with 2 tuberculin units and (or) tuberculous recombinant allergen and other methods of examination for tuberculosis - every 6 months, for medical reasons - more often.

44. All children under 1 year of life, contacting with a person, discharging bacteria, shall receive chemoprophylaxis after vaccination with Calmette-Guerin bacillus with observance of 2-month interval after vaccination.

45. Chemoprophylaxis shall also be done for children, infected with Mycobacterium tuberculosis, treated with immune suppressive drugs: basic hormone therapy 1 month or more (prednisone at a dose

≥

15 mg/day or equivalent), cytostatic in connection with organ transplantation and genetically engineered biological drugs. Chemoprophylaxis for children with a diagnosis of "Infection with Mycobacterium tuberculosis, newly diagnosed" shall be held for a period of 1 month prior to treatment with genetically engineered biological drugs and shall continue, on the background of the genetically engineered biological drugs, with isoniazid up to 6 months or isoniazid and rifampicin for 3 months.

46. Chemoprophylaxis for children with latent tuberculosis infection shall be assigned before the start of treatment with antagonists of tumor necrosis factors -α, organ transplantation and hematopoietic stem cell transplantation, with isoniazid and rifampicin for a period of 3 months.

47. Chemoprophylaxis of infected individuals with human immunodeficiency virus shall be assigned by doctors - phthisiatricians only after excluding of the active TB according to the results of a comprehensive clinical and radiological study.

48. Chemoprophylaxis of tuberculosis in children infected with the human immunodeficiency virus over 12 months of life and adults shall be done only once while establishing a positive status for human immunodeficiency virus, regardless of the presence or absence of contact with a TB patient.

49. Chemoprophylaxis in children infected with the human immunodeficiency virus under 12 months shall be carried out in case of contact with TB patients.

50. Isoniazid shall be the main medication for chemoprophylaxis.

51. Daily dose of isoniazid shall be taken once daily, at the rate of 10 mg/kg (maximum 300 mg/day).

52. Chemoprophylaxis shall be done only once. Course duration is 6 months. Simultaneously with isoniazid, the multivitamins containing vitamin B shall be assigned (pyridoxine – 25 mg per day).

53. A contraindication for chemoprophylaxis shall be epilepsy, organic lesions of the central nervous system, liver and kidney disease with functional abnormality.

54. When adverse reactions to a dose of isoniazid appear, an additional examination (blood, urine) shall be conducted and the drug shall be canceled for 5-7

days. Desensitizing therapy shall be assigned. In case of appearance of intolerance following the reassignment of isoniazid, chemoprophylaxis shall be canceled.

55. After viral hepatitis, chemoprophylaxis shall be assigned not earlier than 6 months after the disappearance of all clinical manifestations, upon the conclusion of the infectious disease specialist. Chemoprophylaxis shall be carried out on the background of hepatoprotectors for this group of people.

56. Chemoprophylaxis shall be assigned and monitored by doctors-phthisiatricians of the organizations, providing out-patient-polyclinic assistance.

57. Chemoprophylaxis shall be carried out in the organizations, providing out-patient-polyclinic assistance, in preschool institutions of sanatorium type and in children's anti-tuberculosis sanatoria.

58. Chemoprophylaxis shall be carried out under the direct supervision of each dose by the medical employees of organizations, providing out-patient-polyclinic assistance (clinic, medical station, outpatient clinic, department of general practitioners), the organized groups (school, kindergarten, secondary school) and institutions of sanatorium type (sanatoria, health group, children's anti-tuberculosis sanatorium).

59. Chemoprophylaxis for individuals infected with human immunodeficiency virus shall be made by medical employees of organizations, providing out-patient-polyclinic assistance and AIDS centers (acquired immune deficiency syndrome).

60. Chemoprophylaxis shall be carried out after the receipt of the informed oral or written voluntary consent of the patient (parents or official representatives).

61. Data on chemoprophylaxis shall be recorded in the medical records of an ambulatory patient in the form 025/y, in the medical records in the form TB-01/y, approved by the Order No. 907 and shall be recorded daily in the "control sheet of the completed treatment."

Chapter 4. Identification of patients with TB diagnosis § 1. Detection of tuberculosis

62. Identification of TB patients shall be carried out by healthcare professionals of all specialties of medical organizations regardless of the form of ownership, when applying for medical assistance in outpatient and inpatient organizations, during the conduct of mandatory preventive medical examinations, as well as immunization against tuberculosis.

63. The methods of detection of tuberculosis shall be:

1) a smear microscopy among persons with clinical signs of the disease. Sputum collection and delivery to a laboratory for research shall be carried out in all medical organizations within two days. 2 sputum samples shall be collected, one of which is the

morning portion. Collection of samples during one day shall be allowed with the interval between the two portions at least 30 minutes. Sputum for the study of tuberculosis shall be stored in a refrigerator for 3 days;

- 2) fluoroscopy in population with a high risk of the disease of tuberculosis;
- 3) tuberculin diagnostics in children of a "risk group".

64. Microscopic investigation of sputum and, if accessible, genetic-molecular method of diagnosis in the organizations, providing ambulatory and polyclinic assistance, shall be made for the individuals in the presence of cough, lasting more than two weeks (the cough is the main symptom in patients with pulmonary (infectious) tuberculosis) and one or more of the following clinical symptoms:

- 1) weight loss;
- 2) sweating;
- 3) chest pain;
- 4) hemoptysis;
- 5) general weakness and fatigue;
- 6) long-lasting increase in body temperature.

65. In the presence of the aforementioned symptoms, the health specialist shall conduct the diagnostic algorithm of examination of a patient with suspected tuberculosis in accordance with Annex 1 to this Instruction.

66. In organizations, providing out-patient-polyclinic assistance, the patients with complaints about cough shall be served out of turn and provided with medical disposable masks.

67. In cases where there is radiological suspicion of tuberculosis, but sputum smear microscopy is negative in the absence of complaints about chest pain and symptoms of intoxication, a patient shall receive a consultation of TB specialists to confirm the diagnosis without a diagnostic algorithm.

68. The cases with clinical and radiological suspicion of tuberculosis upon the established contact with a TB patient shall be consulted with a doctor - phthisiologist to confirm the diagnosis without a diagnostic algorithm.

69. In cases of suspected extra-pulmonary TB, the specialists of the organizations, providing out-patient-polyclinic assistance, shall conduct the additional studies: radiological, instrumental and laboratory (computer and magnetic resonance tomography of the brain, spine, joints, kidneys, organs of abdominal cavity and small pelvis, laparoscopy, cytological, histologic, bacterioscopic and bacteriological examination of punctates, aspirates, biopsies for *Mycobacterium tuberculosis*).

70. In the absence of sputum in children, the washings of the stomach (the bronchi) or induced sputum, nasopharyngeal aspirate, obtained after bronchodilation and inhalation with 5% solution of sodium chloride, in the morning on an empty stomach during 3 days, shall be studied.

71. Upon detection of acid-fast bacilli, a TB patient shall be sent to the anti-TB organization, where he takes additional laboratory tests and receives an appropriate anti-TB treatment.

72. In case of negative results of sputum smear microscopy and increase in symptoms, suspicious for tuberculosis, a patient shall be sent for a consultation to the doctor- phthisiatrician.

73. TB patients shall be informed by medical workers of the anti-TB medical organizations, providing out-patient-polyclinic assistance, using reminders for TB patients.

74. Detection of tuberculosis by means of fluorography shall be conducted among the target population: with high risk of disease and subject to compulsory fluorography examination.

75. The list of population groups with a high risk of the disease subject to mandatory annual fluorography survey for tuberculosis shall include:

- 1) persons who have contact with TB patients, regardless of bacterial excretion;
- 2) persons, registered at the treatment centers with chronic obstructive pulmonary disease, diabetes mellitus, alcoholism, drug addiction, human immunodeficiency virus/ acquired immune deficiency syndrome, receiving immunosuppressive therapy;
- 3) persons with residual effects in the lungs of any etiology;
- 4) persons, released from places of imprisonment;

76. The list of persons subject to compulsory annual fluorography survey for tuberculosis shall include:

- 1) employees of medical organizations;
- 2) the staff of medico-social institutions (organizations);
- 3) conscripts for military service;
- 4) students of higher and secondary specialized educational institutions, students of specialized schools;
- 5) children of 15-17 years of age;
- 6) women in the postpartum period before discharge from the maternity hospital;
- 7) family members of a newborn without vaccination against tuberculosis prior to his discharge from perinatal (maternity department) center;
- 8) group of persons, receiving special social services in medico-social institutions (organizations) of stationary type, psycho-neurological dispensaries;
- 9) persons who arrived in Kazakhstan for permanent residence;
- 10) prisoners on remand and convicted (twice a year);
- 11) employees of internal affairs bodies, employees of specialized security service, patrol, road patrol and local police, remand centers and correctional institutions (1 per year);

the military personnel, providing security for the facilities of the penitentiary system, exercising control and supervision over behavior of persons held in institutions of penal system, those escorting prisoners and persons in detention, as well as those participating in protection of public order (twice a year);

12) compulsory-duty servicemen (twice a year);

13) members of the Armed forces, other troops and military formations of the Republic of Kazakhstan;

14) employees of the food processing industry, catering and food trade;

15) staff of preschool institutions, comprehensive and specialized schools, lyceums and gymnasiums;

16) the staff of higher and secondary special educational institutions;

17) persons who arrived in the Republic of Kazakhstan for temporary residence, including for labor migration.

77. The neglected TB cases shall be the new cases of tuberculosis with the following clinical forms:

1) subacute and chronic disseminated tuberculosis;

2) tuberculous meningitis with complications;

3) caseous pneumonia;

4) fibrous-cavernous pulmonary tuberculosis;

5) extra-pulmonary tuberculosis with complications.

78. Clinical analysis of the neglected cases of tuberculosis, deaths among newly diagnosed patients and relapses of tuberculosis, regardless of the cause, as well as the newly diagnosed tuberculosis in children with bacterial excretion, shall be conducted together by TB organizations, the organizations, providing out-patient-polyclinic assistance and territorial bodies of the state authority in the sphere of sanitary and epidemiological welfare of the population, with obligatory drawing up of the protocol of the analyses and action plan. The organization, providing out-patient-polyclinic assistance shall be responsible for the timely detection of new TB cases and relapses in individuals, deregistered from dispensary records.

79. The procedure of the conduct of the controlled outpatient treatment at the place of residence shall be reflected in detail in medical records and medical records of the patient in the form No. TB – 01/y or in the medical records of the patient according to the form TB-01/y - IV category, the supplementary sheet to the medical record of the TB patient, approved by the Order 907.

80. In organizations, providing out-patient-polyclinic assistance, the use of anti-TB drugs for treatment of non-tubercular diseases, and their sale at pharmacies without a prescription shall not be allowed.

81. Foreigners and persons without citizenship, located on the territory of the Republic of Kazakhstan and having tuberculosis, shall receive medical care in

accordance with the order of the Minister of health and social development of the Republic of Kazakhstan dated April 1, 2015 № 194 "On approval of the list of the acute diseases dangerous to others, for which the foreigners and persons without citizenship, temporarily staying in the Republic of Kazakhstan, shall have the right to receive the guaranteed volume of free medical assistance" (registered in the Register of state registration of normative legal acts of the Republic of Kazakhstan No. 11317).

82. In case of extra-pulmonary tuberculosis, the diagnosis shall be made on the basis of bacteriological, cytomorphological studies or on the basis of clinical and radiological data, indicating the active extra-pulmonary TB. A patient with extra-pulmonary tuberculosis with multi-organ involvement shall be recorded in accordance with the most severe localization process.

83. If it is impossible to withdraw a diagnosis of extra-pulmonary tuberculosis, the final verification shall be carried out by specialists of anti-TB medical organizations through an open biopsy.

84. Pulmonary tuberculosis with a positive sputum smear result (a person discharging bacteria) shall be diagnosed in a patient, who:

1) prior to treatment, had acid-fast bacteria not less than twice in sputum smear microscopy;

2) in sputum smear microscopy, acid-fast bacteria are once detected, and in radiological examination the pathological changes are revealed that, according to the conclusion of the doctor-phthisiatrician, correspond to the active pulmonary tuberculosis.

85. The diagnosis of pulmonary tuberculosis with negative sputum smear microscopy shall be made on the basis of anamnesis, clinical and radiological data, corresponding to the specific active process, the results of molecular genetic studies with bacteriological or histological confirmation of the disease.

86. In the absence of bacteriological or histological confirmation, a final decision shall be made at the centralized medical advisory committee given the nature of the radiological changes in the lungs, the presence of aggravating factors and activity of the person with pathological changes in the lungs.

87. A positive result of inoculation in case of negative results of sputum smear microscopy shall indicate the presence of active tuberculosis in a patient and shall confirm the diagnosis.

§ 2. Diagnosis of tuberculosis by tuberculin Mantoux test with 2 tuberculin units

88. To diagnose tuberculosis in children, a tuberculin Mantoux test with 2 tuberculin units shall be applied with the aim:

1) to identify individuals newly infected with *Mycobacterium tuberculosis*, and hyperergic reactions to tuberculin;

2) to select the groups of people for vaccination and revaccination with the vaccine Calmette-Guerin bacillus;

3) to early detect the disease.

89. The following shall be subject to examination with the Mantoux test with 2 tuberculin units:

1) children who have been in contact with TB patient (family, relative, school/residential, apartment, etc);

2) children older than 2 months prior to vaccination and re-vaccination;

3) children from high-risk groups.

90. High risk groups for TB disease shall include the children:

1) from families where parents are infected with the human immunodeficiency virus, from places of deprivation of freedom, alcohol and drug addicts, with low standard of living, migrants;

2) registered in dispensary for diabetes mellitus, non-specific lung disease, malnutrition (body mass deficiency), human immunodeficiency virus infection, receiving immunosuppressive therapy (glucocorticoids, cytostatic drugs, genetically engineered biological drugs, and others), persons with disabilities;

3) unvaccinated and those with undeveloped sign of the vaccine Calmette-Guerin bacillus.

91. The results of the Mantoux test and tuberculous recombinant allergen shall be evaluated 72 hours later by measuring the size of the infiltration (papule) in millimeters (hereinafter mm), using a ruler with millimeter divisions, and the size of the infiltrate, transversal with respect to the axis of the forearm, shall be registered. In the absence of infiltration, a hyperemia shall be measured and registered.

92. The result of the Mantoux test shall be valuated as follows:

1) negative – the absence of the infiltration and hyperemia or the presence of "injection reaction" (0 - 1mm);

2) questionable – infiltration 2 – 4 mm or only hyperemia of any size without infiltration;

3) positive – infiltration (papule) 5 mm or more;

4) hyperergic – infiltration 15 mm or more, or vesiculo necrotic changes and/or lymphangitis, lymphadenitis, regardless of the size of the infiltrate.

93. Tuberculin Mantoux test shall identify both infectious and post-vaccination allergy. The following shall be taken into account in complex in the differential diagnosis of the nature of the allergy:

1) the dynamics and intensity of a positive tuberculin reaction;

2) the presence and the size of post-vaccination scars of Calmette-Guerin bacillus;

3) the time passed after the vaccination with Calmette-Guerin bacillus (questionable or positive reactions with papules the sizes of 5 - 11 mm up to 5 years do not exclude the post-vaccination allergy);

4) the presence or absence of contact with a TB patient;

5) the presence of clinical signs of the disease.

94. Post-vaccination allergy shall be characterized by questionable or positive reactions with papules the sizes of 5 - 11 mm.

95. Hyperergic reactions shall not relate to the post-vaccination allergy.

96. Children with allergic mood shall receive a pre-desensitization (5 days before the test and 2 days on the background of the Mantoux test with 2 tuberculin units), sanitation of the foci of infection, deworming.

97. The doctor-phthisiatrician of organization, providing out-patient-polyclinic assistance shall receive the children:

1) with newly diagnosed positive tuberculin reaction;

2) with hyperergic tuberculin Mantoux test with 2 tuberculin units;

3) with the growth of tuberculin sensitivity by 6 mm and more.

98. The doctor- phthisiatrician of organization, providing out-patient-polyclinic assistance shall consult the tuberculin positive children, conduct additional studies for medical reasons and define the reasons for the conduct of the diagnostic algorithm. The entire period of additional investigation of tuberculin positive people shall not exceed 1 month.

99. Individuals shall be considered as infected with *Mycobacterium tuberculosis*, if, in the availability of reliable data on the dynamics of sensitivity to tuberculin under the Mantoux test with 2 tuberculin units, they have:

1) a positive reaction (a papule the size of 5 mm or more) for the first time, not associated with immunization with the Calmette-Guerin bacillus vaccine (a turn of tuberculin skin test);

2) a steady (for 4-5 years) continuing reaction with an infiltrate the size of 12 mm or more;

3) an increased sensitivity to tuberculin (by 6 mm and more) within 1 year (in tuberculin positive children).

100. When conducting a differential diagnosis to establish the etiology of tuberculin sensitivity, in the organizations, providing out-patient-polyclinic assistance, an injection with the tuberculous recombinant allergen shall be made in another forearm.

101. For the contact children with a negative result of the Mantoux test with 2 tuberculin units during the initial examination, the test shall be repeated after 8-10 weeks.

102. The tuberculosis recombinant allergen medication shall be applied in case of a positive Mantoux test with 2 tuberculin units in the organizations, providing out-patient-polyclinic assistance.

1) to detect tuberculosis infection;

2) for a differential diagnosis of tuberculosis with other diseases;

3) for a differential diagnosis of post vaccination and infectious allergy;

4) to determine the activity of tuberculosis process. 103. Recombinant tuberculosis allergen shall not be used for selection for revaccination (vaccination) of Calmette-Guerin bacillus.

104. Reaction to recombinant TB allergen shall be:

1) negative – in the absence of infiltration (papule) and hyperemia or the presence of injection reaction (in the form of a hematoma or lividity the size of 2-3mm);

2) questionable – in the presence of hyperemia of any size without infiltration;

3) positive – in the presence of infiltration (papule) of any size.

4) hyperergic – if the size of infiltration is 15 mm or more, and in case of vesiculo necrotic changes and/or lymphangitis, lymphadenitis, regardless of the size of the infiltrate.

105. In case of exclusion of local tuberculosis, the children with newly positive Mantoux test with 2 tuberculin units shall be diagnosed with: "Infection with Mycobacterium tuberculosis, newly diagnosed", and they shall be monitored in the III B group of regular medical check-up.

106. Persons, infected with Mycobacterium tuberculosis, the newly identified chemo-preventive treatment shall be assigned in case of a positive reaction to recombinant tuberculosis allergen, if negative – shall not be assigned.

107. Persons with repeated hyperergic reactions to tuberculin and (or) recombinant tuberculosis allergen, shall be screened carefully to identify local tuberculosis. With the exclusion of local tuberculosis, they shall not be subject to dispensary registration and re-chemoprophylaxis.

108. Every patient who is planned for treatment with antagonists of tumor necrosis factors

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organ transplantation (recipient and donor) and transplantation of hematopoietic stem cells, shall be examined for tuberculosis.

109. Children, unvaccinated with the Calmette-Guerine vaccine and receiving long-term immunosuppressive therapy (corticosteroids, cytostatics, etc.), shall be tested for TB twice a year – every 6 months, for medical reasons - more often.

110. The risk group for tuberculosis shall be formed by local pediatrician, or general practitioner from among the number of attached children. In the records of the child's development (form 112/y, approved by the Order No. 907), the local

pediatrician (general practitioner) shall draw up an epicrisis – a rationale for registering the child in the risk group for tuberculosis indicating the risk factors.

111. With the purpose of selection of children for revaccination with the vaccine Calmette - Guérine bacilli, the Mantoux test with 2 tuberculin units shall be made at the school to the children aged 6 years (grade 1), in the first month of the school year (September). Other vaccinations shall be suspended this month in the schools.

112. In order to comply with the two-month interval before the Mantoux test, the revaccination with the vaccines of diphtheria tetanus and measles rubella epiparasites shall be made two months before the beginning of the school year. The Mantoux test with 2 tuberculin units and recombinant TB allergen shall be made by the authorized and specially trained medical personnel.

113. Children with the established diagnosis "Infection with Mycobacterium tuberculosis, newly diagnosed" shall receive other immunizations after completion of the course of the controlled chemoprophylaxis, patients – upon completion of a full course of chemotherapy.

114. The results of the Mantoux test and (or) recombinant tuberculosis allergen shall be recorded in the records of preventive inoculations according to the form № 063/y, in the medical records of the child according to the form № 026/y, in the records of the child's development in the form No.112/y, approved by the Order No. 907, indicating:

1) the institution that issued the standard tuberculin and (or) recombinant tuberculosis allergen, series, control number and validity;

2) the date of the tuberculin test and (or) recombinant tuberculosis allergen;

3) the results of the Mantoux test and (or) the test with tuberculous recombinant allergen in the form of the size of infiltration or hyperemia in millimeters, in the absence of the infiltration and hyperemia – negative.

115. Contraindications for the Mantoux test and recombinant tuberculous allergen shall be:

1) intolerance to tuberculin or recombinant TB allergen;

2) acute, chronic infectious and somatic diseases in the period of exacerbation, except for the cases suspicious for tuberculosis;

3) common skin diseases;

4) allergic conditions (acute);

5) epilepsy;

6) quarantine for childhood infections in the groups.

116. The Mantoux test shall be allowed at least 2 months after the disappearance of all clinical symptoms of the disease.

117. To identify contraindications, a doctor (a nurse, in the absence of a physician), prior to the Mantoux test, shall study the medical records and conduct an examination and medical checkup.

118. The Mantoux test and tuberculous recombinant allergen shall not be made in children's groups, where there is quarantine for childhood infections (shall be made after the lifting of the quarantine).

119. Tuberculinodiagnosis for children from risk groups shall be made before the preventive vaccinations against various infections. The interval between the Mantoux test with 2 tuberculin units and other vaccinations should be 2 months.

120. The Mantoux test and (or) recombinant tuberculosis allergen shall not be made at home. Children, contacting with a TB patient, shall have a Mantoux test and (or) recombinant tuberculous allergen in the organizations, providing out-patient-polyclinic assistance.

121. The Mantoux test shall not be made for children infected with the human immunodeficiency virus as the negative or questionable reaction does not exclude the infection with *Mycobacterium tuberculosis* and the presence of active tuberculosis.

122. To identify the source of infection of children with newly identified positive reaction to the Mantoux test, the parents and all cohabiting persons shall be examined for tuberculosis.

123. In educational institutions (a school, a pre-school organization), the tuberculinodiagnosis shall be made by a nurse of the clinic in accordance with the schedule of visiting the infant institutions, approved by the order of the head of the organization of out-patient-polyclinic assistance.

124. Unorganized children of early and preschool age shall have the Mantoux test with 2 tuberculin units in the organizations, providing out-patient-polyclinic assistance.

125. Individuals with the established diagnosis "infection with *Mycobacterium tuberculosis*, newly diagnosed" shall receive other immunizations after completion of the course of controlled chemoprophylaxis.

126. Children from the foci of tuberculosis shall receive the Mantoux test and (or) recombinant tuberculous allergen in the organizations, providing out-patient-polyclinic assistance.

127. Methodological guidance for the conduct of the Mantoux test and (or) recombinant tuberculous allergen shall be made by the children's doctor - phthisiatrician of the organization of out-patient- polyclinic assistance.

§ 3. Laboratory diagnosis of tuberculosis

128. Laboratory service for diagnosis of tuberculosis shall be represented by a network of laboratories of medical organizations and anti-tuberculosis medical institutions divided into three levels depending on the tasks and functions:

I level – the peripheral (district) laboratories in the organizations, providing out-patient-polyclinic assistance and anti-tuberculosis organizations;

1) II level – oblast /regional laboratories in anti-TB medical organizations;

2) III level – central - national reference laboratory at the National research center of Phthisiopulmonology of the Health Ministry of the Republic of Kazakhstan.

129. Laboratories of the I level shall be represented by bacterioscopic laboratories.

The main functions of the laboratories at the district level shall be the conduct of smear microscopy, molecular genetic methods, participation in the external quality assessment system of laboratory research.

130. Laboratories of the II level shall perform the functions of laboratory of the I level, and additionally: the external quality assessment of the work of laboratory of the I level; training of personnel for the labs of the I level; determine the annual demand for consumables, reagents, laboratory equipment of the I level; cultural studies on dense and liquid nutrient media; the definition of the test for drug susceptibility of strains of Mycobacterium tuberculosis to anti-TB drugs on a dense and liquid media; the accelerated diagnosis of tuberculosis using molecular genetic technologies and the monitoring of the bacteriological laboratories of the I level.

131. Laboratory of the III level shall provide coordination of the activities of the laboratories of the I and II levels in accordance with national and international standards; bacteriological examination; external quality control of the laboratory network of the Republic of Kazakhstan; analysis of accounting data on the conducted examinations, development and substantiation of the list of required laboratory equipment in accordance with specifications; interaction with the supranational reference laboratory for external quality assessment of microbiological research; the conduct of scientific – practical and operational studies; expertise of projects for laboratory tests for tuberculosis; provision of expert opinions and proposals to the authorized body in the field of health care on improvement of the activities of clinical and diagnostic laboratories in the diagnosis of tuberculosis; training for laboratory staff ; monitoring of the level of qualification of the laboratory personnel of the anti-TB organizations (training, preparation and retraining of specialists); monitoring of bacteriological laboratories of the I and II levels; regular collection and analysis of statistical data from laboratory studies, the prevalence of drug resistance of the strains of Mycobacterium tuberculosis circulating in the territory of the Republic of Kazakhstan; examination and development of regulatory and methodological documents, accounting and reporting forms; the systematic organization and improvement of methods of intra-laboratory quality control and microbiological research and development, testing and introduction of new methods of laboratory diagnostics of tuberculosis.

132. Laboratory confirmation of the diagnosis of tuberculosis shall be made in accordance with the algorithm of laboratory diagnostics of tuberculosis in accordance with Annex 2 to this Instruction.

133. The algorithm for the diagnosis of tuberculosis shall include: the study of 2 portions of pathological material (from one portion the inoculation is made on liquid and dense medium, microscopy with sediment; from the second portion – inoculation is made on dense medium and smear microscopy); molecular genetic studies are carried out according to the results of microscopy: in negative - Xpert MTB/RIF, in positive – Geno Type

®MTBDR;

in the absence of the Geno Type

®MTBDR;

in the laboratory, regardless of the microscopy result, Xpert MTB/RIF shall be made.

134. In case of suspected TB, the algorithm for the laboratory diagnosis of tuberculosis shall be carried out in accordance with Annex 2 to this Instruction "Diagnosis", scheme 1. The algorithm for the control of chemotherapy in the patients of I, II and IV categories shall be conducted in accordance with the "Control of chemotherapy," schemes 2, 3.

135. Critical concentrations for the drugs of the first and second line for the test of the drug susceptibility shall be determined in accordance with Annex 3 to this Instruction.

Chapter 5. Registration and accounting of TB patients

136. Registration of patients with tuberculosis shall be carried out by 3 categories:

1) I (first) category – all the new cases of pulmonary and extra-pulmonary tuberculosis with bacterial excretion or without bacterial excretion;

2) II (second) category – recurrent cases of tuberculosis ("relapse", "treatment failure", "treatment after interruption", "other");

3) IV (fourth) category - the TB cases with laboratory-confirmed tuberculosis with multiple or extensive drug-resistance, multidrug resistant tuberculosis with the "treatment failure" result in the modes of I, II, and IV categories.

137. During the registration of the disease, tuberculosis shall be divided into the following types:

1) "a new case" – a patient that has never taken anti-TB drugs or who took them less than one month;

2) "a relapse" – a patient that previously received treatment with anti-TB drugs of the first line with the "cured" result or "treatment completed", but with subsequently established bacterial excretion;

3) "a treatment failure" – a patient after ineffective first or repeated course of treatment with anti-TB drugs of the first line;

4) "a treatment after interruption" – a patient with positive result of sputum smear microscopy, resuming treatment after a break lasting 2 months or more;

5) "transferred" – a patient who arrived for treatment or further treatment from other organization with TB – 09 form, approved by the Order No.907 and (or) an abstract from the patient records or medical records, where he was registered as a TB patient. At the end of the treatment, his result shall be submitted to the anti-TB organization of the initial registration;

6) "other" – all recurrent TB cases, which are not relevant for these types of registration (pulmonary tuberculosis without bacterial excretion, and extra-pulmonary tuberculosis). Each case requires histological and (or) bacteriological confirmation.

138. Registration of patients with laboratory-confirmed tuberculosis with multi-drug resistance, tuberculosis with extensive drug-resistance, tuberculosis with pre - extensive drug-resistance or suspicion of them, shall be made under category IV. Category IV shall include the TB patients:

1) with laboratory-confirmed tuberculosis with multidrug-resistance – if the result of resistance to rifampicin is received by any bacteriological (BAKTEK, Lowenstein-Jensen) or molecular genetic method;

2) with multi-resistant tuberculosis with the result "treatment failure " in the modes of I and II categories (with a high probability of development of tuberculosis with multi-drug resistance);

3) a laboratory-confirmed tuberculosis with extensive drug-resistance and tuberculosis with pre-extensive drug-resistance;

4) with the failures of treatment with anti-TB drugs of the second line (with a high probability of development of TB with extensive drug-resistance);

5) patients who in previous episodes of the disease had tuberculosis with multidrug resistance, but who completed the course of treatment with anti-TB first-line drugs with outcome "cured", "treatment completed" in the event of recurrence of the disease;

6) patients who in previous episodes of the disease had tuberculosis with multidrug resistance, and who completed the course of treatment with anti-TB drugs of the second line with the outcome "cured", "treatment completed", in the event of recurrence of the disease;

7) patients who in previous episodes of the disease had tuberculosis with multidrug resistance, and who completed the course of treatment with anti-TB drugs of the first or second line with the outcomes "violation of regime", at the re-taking of treatment.

Chapter 6. TB treatment § 1. Inpatient treatment of TB patients

139. Hospitalization of tuberculosis patients in anti-tuberculosis hospitals shall be made in accordance with the results of sputum smear microscopy, molecular genetic methods, drugs sensitivity test and the assigned treatment regime in accordance with the epidemiological status within the guaranteed volume of free medical care through the portal "Hospitalization Bureau" in the following specialized departments:

- 1) for TB patients with the preserved sensitivity to rifampicin;
- 2) for patients with tuberculosis without bacterial excretion;
- 3) for tuberculosis with multiple and extensive drug-resistance;
- 4) for treatment of tuberculosis in children;
- 5) surgical treatment of pulmonary and extra-pulmonary tuberculosis;
- 6) for palliative care;
- 7) for tuberculosis patients in the mental hospitals.

140. The medical care for tuberculosis at the inpatient level shall include:

- 1) provision of emergency and planned qualified, specialized and highly specialized inpatient care to the patients with tuberculosis;
- 2) conduct of laboratory and instrumental examination according to clinical protocols with subsequent interpretation of the examination results;
- 3) selection of the scheme and assignment of the treatment, in accordance with the existing nosology and clinical protocols shall be made by the decision of the centralized medical advisory committee;
- 4) a daily examination of TB patients by a phthisiologist and visits of the head of the department;
- 5) organization of consultations and councils of relevant specialists (if indicated);
- 6) registration and maintenance of medical documentation in accordance with the Order No. 907;
- 7) analysis of the efficiency of the work of the hospital departments and quality of medical care, development and fulfillment of actions to improve the quality of medical care and reduction of hospital deaths.

141. Each department for treatment of TB patients with bacterial excretion shall be divided in accordance with the data on drug sensitivity. Patients with bacterial excretion with unknown drug sensitivity shall be kept in single rooms or boxes until the results of drug susceptibility test are received.

142. Emergency department of a hospital shall accept and register patients to receive emergency and routine medical care for tuberculosis.

143. The planned hospitalization shall be carried out not later than 30 minutes after the patient applies to the emergency department of a hospital.

144. In case of emergency hospitalization, in the emergency department of anti-TB medical associations, a doctor - phthisiologist shall examine the patient not later than 10 minutes after the application.

145. The doctor- phthisiologist shall make a decision on hospitalization of the patient to the relevant department or for outpatient treatment.

146. The doctor- phthisiatrician shall draw up the medical records of the patient in the form No. 003/y, approved by the Order No. 907, which describes the general condition of the patient, the complaints, anamnesis of the disease and life in details, epidemiological anamnesis, data of objective examination, the revealed pathological changes, clinical assessment of the laboratory and functional studies, and a preliminary diagnosis is made.

147. The patient (parents or legal representatives) shall fill in the informed consent to treatment and the diagnostic and treatment activities necessary in the near future according to the form No. TB – 014/y, approved by the Order No. 907.

148. When they receive medical care, the patients shall have comprehensive information about the state of health, including data on possible risks and benefits of the proposed treatment methods, information about the possible consequences of refusal of treatment, information on diagnosis, prognosis and plan of therapeutic interventions in an intelligible form, as well as an explanation of the reasons for discharge from the hospital or transfer to another medical organization.

149. The doctor- phthisiatrician of the hospital shall make an initial examination of the patient on the day of receipt within 1 hour, make a record about the first check-up in the form No. 003/y, approved by the Order No. 907, make a provisional diagnosis with justification, prescribe the necessary volume of additional laboratory and instrumental examination, and inform about the assigned therapeutic and diagnostic activities.

150. The diagnostic and treatment activities, drug supply, organization of medical nutrition and appropriate care of the patient shall be made from the date of admission to the hospital.

151. Clinical diagnosis shall be established not later than three days from the date of the admission of the patient to the hospital. Except for the cases, difficult in diagnosis, at that, the form № 003/y, approved by the Order No. 907, shall indicate the reason for the delay in making the diagnosis, identify the additional diagnostic tests and specialist consultations. On the day of the establishment of the clinical diagnosis, a corresponding record shall be made in the medical record (the substantiation of the clinical diagnosis) and the protocol of the medical advisory committee shall be drawn up.

152. Medical records on the patient shall be submitted to the centralized medical advisory committee for confirmation of the diagnosis, definition of the treatment category, accounting in the register log in the forms No. TB – 03/y and TB – 11/y, approved by the Order No. 907, not later than 1 day.

153. Information about the diagnosis of active TB in a hospital and (or) bacteria excretion shall be submitted to the anti-TB organizations and territorial bodies of the state authority in the sphere of sanitary and epidemiological welfare of the population at the place of residence of the patient for recording and registration of the TB case in the forms № 089/y and 058/y, approved by the Order No. 907.

154. Patients, admitted to the hospital, shall undergo a sanitary processing. Depending on the condition of the patient, a sanitization shall be carried out fully or partially.

155. If medically required, the consultative and diagnostic study shall be held within specialized medical organizations in coordination with the heads of these healthcare organizations.

156. Pregnant women, receiving treatment for tuberculosis, tuberculosis with multidrug-resistance, and tuberculosis with extensive drug-resistance, shall be hospitalized in specialized medical organizations for childbirth.

157. Patients in hospital shall be subject to a daily examination by the doctor-phthisiatrician. The entry in the patient's medical records shall be made depending on the severity of his condition (at least 3 times a week in mild and moderate condition of the patient and daily if in serious condition).

158. Head of the department shall examine the patients with tuberculosis, tuberculosis with multidrug-resistance, tuberculosis with extensive drug-resistance not less than once a week with the entry in the medical records of the patient.

159. In difficult situations, to verify the diagnosis and determine the tactics of treatment, a consultation with the specialists of the regional and national levels in person or remotely (telemedicine, online mode, the postal service) shall be held.

160. Surgical treatment of tuberculosis patients shall be conducted if medically required after the consultation of phthisio-surgeon before completion of the course of treatment.

161. When determining the indications for surgical intervention and its volume, the following shall be taken into account:

- 1) clinical form, phase and prevalence of tuberculosis;
- 2) the results of drug susceptibility test of *Mycobacterium tuberculosis* to anti-TB drugs according to the data of molecular-genetic and cultural methods;
- 3) mode, scheme and duration of chemotherapy;
- 4) the age, general condition of the patient, the status of the function of individual organs and systems;
- 5) comorbidities.

162. Indications for surgical intervention in the treatment of various forms of pulmonary tuberculosis shall be:

1) absence of clinical or bacteriological response to chemotherapy after 1 - 6 months of treatment;

2) formation of cavity changes (the rigid, thick-walled cavities larger than 3-5 cm in diameter, tuberculoma with decomposition);

3) in the presence of a wide spectrum of drug resistance when the scheme of treatment has no adequate number of effective drugs with preserved sensitivity;

4) the presence of complications of pulmonary tuberculosis (hemoptysis, hemorrhage, bronchopleural fistula, pleural empyema, spontaneous pneumothorax).

163. Selection of patients for surgical treatment shall be made:

1) by a phthisio-surgeon of the anti-TB medical organizations;

2) with participation of a surgeon at the central medical advisory committee when establishing the final clinical diagnoses and treatment categories of TB patients, as well as during the transfer from one treatment category to another.

164. Types of surgery in pulmonary tuberculosis shall be:

1) emergency operations shall be conducted:

in case of the profuse pulmonary bleeding, the following types of surgery are conducted: a tourniquet bandage of lobar bronchus, vessel with the lung parenchyma; transthoracic occlusion of the main bronchus; lung resection; valve bronchial blocking and pneumonectomy;

in case of intense spontaneous pneumothorax with the signs of increasing respiratory distress: pleural puncture; thoracocentesis and Bulau drainage; endoscopic clipping of the fistula and resection of the lung;

2) emergency operations are conducted in patients with recurrent pulmonary bleeding, unstopable by other methods of treatment in the form of the following operations: valve bronchial blocking; segmental resection; lobectomy; pneumonectomy and transthoracic occlusion of the main bronchus;

3) the planned surgical operations are carried out in the following clinical forms of tuberculosis:

in case of tuberculomas of large size (more than 2 cm in diameter), regardless of the presence of decomposition and bacteria excretion, or tuberculoma of small sizes (less than 2 cm in diameter) with the presence of decomposition and bacterial excretion, a lung resection, segmental resection, and lobectomy are performed;

in case of cavernous tuberculosis with the presence of isolated, thin-walled cavities in one or two or more segments, without radiographic signs of activity and bacteria excretion, the following types of surgery are performed: segmental resection; lobectomy; bilobectomy and thoracomyoplastic;

in case of primary tuberculosis complex with the formation of tuberculoma or cavity in the place of the pulmonary component, tumor-like bronchadenitis, the lung

resection and all types of resection in combination with lymphonodectomy are performed;

in case of tuberculosis of intrathoracic lymph nodes when there is an abnormality of bronchial patency of a segment, a lobe of the lung or bronchial glandular fistula with the threat of contamination (the presence of large paratracheal, tracheobronchial lymph nodes or bronchonodular fistula), resistant to the local and general chemotherapy, the lymphonodectomy is indicated;

in case of fibrous-cavernous pulmonary tuberculosis, the segmental resection, lobectomy, bilobectomy, pneumonectomy, thoracomyoplastic and thoracomyoplastic with the use of a silicone implant are performed;

in case of cirrhotic tuberculosis of the lung with recurrent hemoptysis, bacterial excretion, the lobectomy, bilobectomy, pneumonectomy are performed;

in case of exudative tuberculous pleurisy, the pleurocentesis, thoracocentesis, Bulau drainage are performed;

in case of caseomes of pleura, the excision of pleura is made;

in case of testaceous pleurisy: decortication of the lung in combination with pleurectomy;

in case of pleural empyema with bronchial fistula or without it: valve bronchial blocking and thoracocentesis with Bulau drainage are indicated.

After sanation of empyemas cavity in unilateral lesions, decortication of the lung, pleurectomy with possible resection of the pathological foci, pleuropneumonectomy, pleurectomy in combination with thoracomyoplastic, pleurectomy in combination with lung resection and thoracomyoplastic with closure and plasticity of bronchial fistula are performed.

165. Contraindications to surgery shall be:

- 1) low functional reserves of respiratory system and cardiovascular system;
- 2) extensive destruction of lung tissue, not leaving possibility to select any surgical method of treatment;
- 3) lung dysfunction: forced expiratory volume is less than 1.5 l and 2.0 l in the planning of lobectomy and pneumonectomy, respectively;
- 4) active tuberculosis of the bronchi;
- 5) the presence of severe concomitant diseases, the impossibility of compensation, the evolved dysfunctions;
- 6) body mass index under 40 - 50% of the weight requirement;
- 7) inability to make an effective treatment plan after surgery.

166. Terms and conditions of surgical interventions in patients with tuberculosis, tuberculosis with multidrug-resistance and extensive drug-resistance of pulmonary localization shall be:

1) stabilization of the specific process in the lungs; 2) definition of indications for surgical treatment by the doctors council;

3) the conduct of all types of surgical interventions on the intensive phase of treatment. The possibility of surgical intervention at the maintenance phase of treatment is solved by a centralized medical advisory committee;

4) the scheme of preoperative chemotherapy is carried out strictly in accordance with the therapeutic category (I, II, IV category);

5) post-operative chemotherapy: the intake of anti-TB drugs shall be restored not later than the second day after surgery in accordance with the scheme of treatment that the patient received before surgery.

167. In case of tuberculosis of spine, the surgical intervention (abscessotomy, necrectomy, fistulectomy, spondylosyndesis, decompression of the spinal cord) shall be performed in case of destruction of the vertebral bodies, complicated by abscesses, spinal disorders, spinal instability, internal and external fistulas.

168. In case of tuberculosis of the joints, the surgeries (abscessotomy, necrectomy, fistulectomy, synovectomy, economical resection of the joint, arthrodesis, corrective osteotomy) shall be performed for all the forms of specific arthritis with destructive process, including the complications with contractures, abscesses and fistulas.

169. In case of tuberculosis of peripheral lymph nodes, the surgical interventions (lymphadenectomy, abscessotomy, fistulectomy and fistulotomy) shall be carried out in the presence of hyperplastic lymphoid tissue, caseous necrosis of lymph node, abscess and fistula.

170. In case of tuberculosis of the urinary system, the surgeries (nephrectomy, nephroureterectomy, partial nephrectomy, cavernotomy, internal drainage, percutaneous nephrostomy, indirect ureterocystoanastomosis) shall be carried out in the presence of a widespread destructive changes in the kidney with disabled kidney function; solitary cavities or systems of cavities, which are located in the pole or poles of the kidneys and the structure of the ureter.

171. In case of tuberculosis of the genital tract in men, the surgical treatment shall be carried out in the presence of an abscess, fistula and the absence of effect from conservative therapy.

172. To verify tuberculosis process, the following types of diagnostic operations shall be carried out: thoracoscopy with biopsy of pleura and lung; thoracotomy with biopsy of pleura; needle or open biopsy of bone, soft tissue and peripheral lymph nodes in case of tuberculosis of extra-pulmonary localizations.

173. Criteria for discharge of a TB patient from the hospital shall be:

1) lack of bacterial excretion and lack of the need for round the clock medical observation;

2) availability of two negative results of microscopy, taken sequentially with the intervals of not less than 10 calendar days in patients with initial bacterial excretion;

3) the common outcomes of inpatient treatment (convalescence, improvement, without changes, deterioration, death and transfer to another medical organization); avoiding intake of anti-TB drugs and violation of the hospital mode are the basis for transfer to hospitals for compulsory treatment of TB patients in the specialized anti-TB medical organizations (regional, municipal and district (inter-district) TB dispensaries (hospitals)) and the discharge shall be made in accordance with the rules of compulsory TB treatment in specialized TB institutions and their discharge, approved by the order of the acting health Minister of the Republic of Kazakhstan dated November 17, 2009 No. 729 (registered in the Register of the state registration of regulatory legal acts No. 5959).

174. At the discharge from the hospital, an abstract from the medical records of the patient shall be drawn up, indicating the full clinical diagnosis, the volume of the conducted diagnostic investigations, therapeutic interventions, recommendations for further treatment and observation of the patient.

175. At the discharge of the patient from the hospital, his medical records: "An abstract from the medical records of the patient" in the form № 027/y, the medical records of the patient with tuberculosis in the form TB – 01/y or in the form No. TB – 01/y - category IV, a referral for transfer of the patient with tuberculosis in the form No . TB – 09/y, approved by the Order No. 907, shall be submitted to the anti- TB medical organizations and organizations, providing outpatient-polyclinic assistance to continue treatment and (or) observation.

176. Upon receipt of the medical documentation of the organization, providing outpatient-polyclinic assistance and (or) of anti-TB organizations, the detachable slip in the form No. TB-09/y, approved by the Order No. 907, shall be submitted back to the hospital.

177. In case of death of a patient in the hospital, the post-mortem examination shall be carried out in accordance with the Rules of the autopsy, approved by the order of Minister of health and social development of the Republic of Kazakhstan dated February 25, 2015 № 97 "On approval of the Provisions on activities of organizations and (or) structural units of healthcare organizations, performing pathological diagnosis and the Rules of the autopsy " (registered in the Register of the state registration of regulatory legal acts No. 10577).

178. Medical records and x-ray archive after the patient's discharge from the TB hospital shall be archived and stored for 25 years.

§ 2. Outpatient treatment of TB patients

179. Outpatient treatment shall be conducted in outpatient departments of anti-TB medical organizations, the organizations, providing out-patient-polyclinic assistance or in conditions of hospital-replacing technologies.

180. Patients without bacterial excretion shall be subject to outpatient treatment.

181. Patients with an initial bacterial excretion shall be transferred to outpatient treatment after receiving two negative results of microscopy, taken sequentially with the intervals of not less than 10 calendar days.

182. The organizations, providing out-patient-polyclinic assistance once a month, receive anti-TB drugs from territorial anti-TB organizations and have a permanent minimum stock of drugs for at least 7-day consumption. Accounting and spending of anti-tuberculosis drugs for outpatient treatment are recorded in the register of anti-TB drugs in the form No. TB 12/y, approved by the Order No. 907. The report on movement of anti-TB drugs (form No. TB – 13/y, approved by the Order 907) shall be submitted to anti-TB medical organization on a monthly basis.

183. 10 calendar days prior to transfer for outpatient treatment, the patient, taking anti-TB drugs in fractional mode, shall be transferred to a single dose mode, except for anti-TB drugs of the 5th group.

184. Within 10 calendar days prior to transfer of the patient to outpatient treatment, the consulting physician and the head of the department shall specify the information about the terms of continuation of treatment: place of the directly observed treatment, availability of anti-TB drugs, possibility of diagnostics and treatment of adverse reactions, the form of social assistance.

185. When sending for the outpatient treatment, the medical records in the form No. TB – 01/y or in the form No. TB – 01/y - category IV, approved by the order No. 907, shall be submitted to the office of the directly observed treatment of the anti-TB organizations or organizations, providing out-patient-polyclinic assistance.

186. Chemist of the organizations, providing outpatient-polyclinic assistance shall inform the physician about the TB patient, who arrived for the first time for outpatient treatment.

187. Patients with tuberculosis, receiving specific treatment, not less than once in 10 days, if indicated – more often, shall be examined by doctors of anti-tuberculosis medical institutions or district doctors of the organizations, providing outpatient-polyclinic assistance, depending on the place of the directly observed treatment.

188. In outpatient departments of anti-TB medical organizations or organizations, providing out-patient-polyclinic assistance, the conditions for symptomatic and pathogenetic treatment for side effects of anti-TB drugs and comorbidities in TB patients, receiving specific treatment, shall be provided.

189. TB patients from high risk groups shall be provided with psychosocial support from a social worker and a psychologist.

190. Load per a chemist shall be not more than 20 patients a day.

191. Hospital-replacing care shall be provided to the TB patients with multi-drug resistance and tuberculosis with extensive drug-resistance who do not need round-the-clock medical supervision.

192. A day patient facility shall be arranged in the anti-TB medical organizations and organizations, providing out-patient-polyclinic assistance to the TB patients without bacterial excretion or after reaching a conversion of sputum smear, who do not need round-the-clock supervision of a physician, if adverse reactions to anti-TB drugs and exacerbation of comorbidities occur. Stay of a TB patient in the day patient facility shall not exceed 30 calendar days, accompanied by the examination and supervision by the doctor and paramedical personnel, diagnostic and treatment activities, the controlled intake of anti-TB drugs, provision with once-daily hot meals and psychosocial support.

193. A home care shall be organized with the aim of the directly observed treatment of tuberculosis patient without bacterial excretion or after reaching a conversion of sputum smear, not needing round-the-clock medical supervision. A home care shall be available for the patients with concomitant diseases that prevent daily attendance for treatment in a tuberculosis medical organization or organizations, providing out-patient-polyclinic assistance, not having the opportunity to visit the offices for the directly observed treatment, with the temporary mobility problems - the elderly, pregnant women, women with infants, single mothers and people with disabilities, human immunodeficiency virus/acquired immune deficiency syndrome.

194. The mobile group shall provide the directly observed treatment to TB patients without bacterial excretion or after reaching a conversion of sputum smear, not needing round-the-clock supervision of a doctor, and not having the possibility of obtaining the controlled treatment in other conditions of hospital replacing technologies (women in antenatal and postpartum period, women with children of preschool age, patients with reduced mobility).

195. Load per a mobile group shall be not more than 10 patients per 1 group per day.

196. The doctor- phthisiatrician shall control the treatment of the patient every 10 working days, going together with the mobile group to the people with tuberculosis.

§ 3. Regimen of treatment

197. Tuberculosis treatment shall be carried out continuously in two phases:

1) phase one: the intensive phase is carried out at the hospital; subsequently, after the conversion of the smear, it continues on an outpatient basis. Patients without

bacterial excretion are initially sent for treatment in outpatient conditions and also hospital-replacing conditions upon the decision of the centralized medical advisory committee;

2) phase two: the maintenance phase is carried out in outpatient, hospital-replacing conditions. The maintenance phase of treatment in a hospital for clinical or social reasons shall be decided by the centralized medical advisory committee.

198. Treatment of TB patients, including the control of intake of all prescribed medicines, shall be conducted under the direct supervision of a qualified health professional. A meeting is held with the patient before treatment about the need of taking the assigned anti-TB drugs with the subsequent signing of the informed consent in the form No. TB – 14/ approved by the Order No.907.

199. During the treatment of the patients, the monthly weight control and correction of the doses of medication shall be performed.

200. Treatment of TB patients shall be carried out with anti-TB drugs within the guaranteed volume of free medical care, in accordance with Annex 4 to this Instruction

201. Treatment of patients of the I category:

1) an intensive phase is carried out from two to four months, depending on the severity and prevalence of tuberculosis process on a daily basis 7 days a week. If the intensive phase is performed on an outpatient basis – 6 days a week. Prior to treatment, the cultural examination of the sputum with the drug sensitivity test of Mycobacterium tuberculosis to anti-TB drugs is performed;

2) the treatment is carried out with four anti-TB drugs: isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) or streptomycin (S) in the respective weight dosages, with priority given to ethambutol. Streptomycin is used not more than 2 months;

3) at the end of two months, the transfer to a maintenance phase of treatment is made in case of a negative result of double studies of sputum smear for Mycobacterium tuberculosis;

4) if by the end of the second month, the sputum smear remains positive - cultural research is re-conducted on solid and liquid media with the drug susceptibility test and the intensive phase is extended for one month;

5) if the result of the double studies of the sputum smear is negative at the end of the third month, the patient is transferred to a maintenance phase of treatment;

6) if at the end of the third month, the sputum smear remains positive, the intensive phase is extended for another month;

7) if the result of the double studies of the sputum smear is negative at the end of the fourth month, the patient is transferred to a maintenance phase of treatment;

8) if at the end of the fourth month of treatment the sputum smear remains positive or bacteria excretion has resumed, the outcome "treatment failure" is determined;

9) in the presence of poly-resistance and clinical and radiological worsening of the process without bacterial excretion, the patient is transferred to the category 4 on the clinical indications;

10) in the absence of conversion of sputum smear at the end of intensive phase (1 category – 4 months, 2 category – 5 months) with anti-TB drugs of the first line, regardless of the results of drug susceptibility test, the outcome "treatment failure" is determined;

11) if the patient has a confirmed tuberculosis with multiple or extensive drug-resistance, he is transferred to IV category and the outcome of treatment is defined as "Transferred to IV category";

12) maintenance phase is conducted during four months on a daily basis (6 days per week) with two drugs – isoniazid (H) and rifampicin (R);

13) when identifying mono-resistance to isoniazid before starting the treatment, a maintenance phase is carried out with ethambutol added;

14) in severe cases, the maintenance phase is extended to seven months.

202. Treatment of patients of II category:

1) the intensive phase is carried out from three to five months, depending on the severity and prevalence of tuberculosis process on a daily basis 7 days a week. If the intensive phase is performed on an outpatient basis – 6 days a week. Prior to the treatment, the cultural examination of a sputum with drug susceptibility test is carried out;

2) the treatment is carried out with five anti-TB drugs for two months: isoniazid (H), rifampicin (R), pyrazinamide (Z), ethambutol (E), streptomycin (S) corresponding to the weight dosages. Then the treatment continues with four anti-TB drugs: isoniazid (H), rifampicin (R), pyrazinamide (Z), ethambutol (E);

3) in case of negative result of double studies of sputum smear for Mycobacterium tuberculosis at the end of three months, the patient is transferred to a maintenance phase of treatment;

4) if by the end of the third month the sputum smear remains positive, then a second drug susceptibility test is performed and intensive phase is extended for one month;

5) if the result of the double study of the sputum smear is negative at the end of the fourth month, the patient is transferred to a maintenance phase of treatment;

6) if at the end of the fourth month the sputum smear remains positive, the intensive phase is extended for another month;

7) if the result of the double study of the sputum smear is negative at the end of the fifth month, the patient is transferred to a maintenance phase of treatment;

8) if at the end of the fifth month, the sputum smear remains positive, the outcome "treatment failure" is determined and he is reregistered into IV category;

9) if the results of the drug susceptibility test confirm the presence of multi-drug resistance, then, irrespective of the duration and effectiveness of the received treatment regimen for II category, the patient is reregistered in the IV category and the outcome of treatment is defined as "Transferred to IV category";

10) a maintenance phase is held for five months on a daily basis (6 days a week) with three anti-TB drugs – isoniazid (H), rifampicin (R), ethambutol (E).

203. The recommended daily dosages of anti-TB drugs for the treatment of sensitive tuberculosis in adults shall be assigned in accordance with Annex 4 to this Instruction.

204. Upon receipt of the results of the drug susceptibility test, confirming the multi-drug resistance, within 5 working days, the medical documentation of the patient shall be submitted to the centralized medical advisory committee for re-registration into the IV category and for resolving the issue on appointment of anti-TB drugs of the second line.

205. Tactics (detection, diagnosis, treatment and monitoring) and regimens of TB treatment for TB patients, infected and uninfected with human immunodeficiency virus shall be the same.

206. The total duration of treatment of children with miliary tuberculosis, tuberculous meningitis and tuberculosis of bones and joints shall be 12 months: for patients of category I the intensive phase is up to 4 months, maintenance phase – up to 8 months; for patients with category II the intensive phase is up to 5 months, maintenance phase – up to 7 months.

207. In the scheme of treatment of children, streptomycin is used only in tuberculous meningitis and in the treatment regimen of category II during the first 2 months.

208. For the children with common and complicated forms of pulmonary tuberculosis and extra-pulmonary localization (I and II categories), the intensive phase of treatment is conducted in a hospital, the duration of which is decided by a centralized medical advisory committee, in accordance with standard treatment regimens.

209. For the children, in the absence of positive dynamics and clinical and radiological progression of TB on the background of the treatment with anti-TB drugs of the first line with negative results of bacterioscopic and culture studies, in a timely manner, a consultation by correspondence or face-to-face consultation of national level experts is held to determine further tactics of treatment.

210. Children with tuberculosis without bacterial excretion shall be transferred into maintenance phase of treatment on the basis of x-ray-tomographic dynamics of the process.

211. The decision on conducting the maintenance phase of treatment of children in inpatient or outpatient conditions shall be taken by the centralized medical advisory committee.

212. A maintenance phase of treatment for children shall be held on a daily basis.

213. The standard scheme and the recommended daily doses of anti-tuberculosis medicines for the treatment of sensitive TB in children with one-component anti-TB drugs in the mode of I and II category shall be assigned in accordance with Annex 4 to this Instruction.

214. Measures taken in case of interruption of TB treatment shall be taken according to the Annex 5 to this Instruction.

215. Pathogenetic therapy shall be carried out in accordance with the phase of tuberculous process, individual indications and contraindications in the background of the basic chemotherapy course.

216. Treatment outcomes of tuberculosis patients: 1) "cured" – the results of sputum smear bacterioscopy are negative at the end of treatment and at least in one previous study;

2) "treatment completed" – the patient took all the prescribed doses of anti-TB drugs during the scheduled period of time, but does not meet the criteria for "cured" or "treatment failure" categories;

3) "treatment failure" – the patient:

has a positive result of sputum smear microscopy by the end of the intensive phase while maintaining the sensitivity of *Mycobacterium tuberculosis* to at least rifampicin, in the absence of test data on drug susceptibility and poly-resistance;

has the resumed bacterial excretion after conversion of the sputum smear;

the initial negative result of microscopy became positive by the end of the intensive phase of treatment while maintaining the sensitivity of *Mycobacterium tuberculosis* to at least rifampicin, in the absence of test data on drug susceptibility and poly-resistance ;

the initial negative result of microscopy became positive in maintenance phase of treatment, regardless of test data on drug susceptibility;

4) "died" – a patient died during treatment, regardless of the cause of death;

5) "violation of regimen" – the patient interrupted treatment for two months or more;

6) "transferred" – a patient, released for assignment or continuation of TB treatment at another facility with the form TB 09/y, approved by the Order No. 907 and an abstract from the medical records of a stationary or ambulatory patient;

7) "transferred to IV category" - a patient with laboratory-confirmed tuberculosis with multiple or extensive drug resistance, a patient with suspected tuberculosis with multiple or extensive drug-resistance in extra-pulmonary TB and a sick child with a contact with multidrug resistance without bacterial excretion.

217. The outcome "treatment failure" in patients with extra-pulmonary TB and in children with pulmonary tuberculosis without bacterial excretion shall be determined by the results of clinical and radiological studies.

218. "Therapeutic success" – is the number of cases with the registered outcome of treatment "cured" and "treatment completed".

219. Treatment of patients of IV category:

1) based on the use of standard, short-term and individual treatment regimens with the use of certain anti-TB drugs from all five groups in accordance with the classification of the World health organization;

2) the treatment regimens for category I and II are not used for the patients registered in IV category;

3) is conducted under the direct control of intake of all prescribed drugs by the specially trained health worker;

4) is carried out continuously in two phases:

the first phase - an intensive phase - is carried out in hospital, subsequently, after reaching a conversion of the smear, continues on an outpatient basis. Patients without bacterial excretion are initially sent for treatment in outpatient and inpatient conditions by the decision of the centralized medical advisory committee;

the second phase – a maintenance phase - is carried out in ambulatory or hospital-replacing conditions. The maintenance phase of treatment in a hospital for clinical or social reasons is decided by the centralized medical advisory committee.

220. Classification of anti-TB drugs:

1) group 1 – oral anti-TB first-line drugs: isoniazid (H), rifampicin (R), pyrazinamide (Z), ethambutol (E);

2) group 2 – injectable drugs: kanamycin (Km), capreomycin (Cm) or amikacin (Am);

3) group 3 – drugs from the group of fluoroquinolones: levofloxacin (Lfx), moxifloxacin (Mfx);

4) group 4 – other anti-TB drugs of the second line: protionamide (Pto), cycloserine (Cs), paraaminosalicylic acid (Pas);

5) group 5 – Bedaquiline (Bdq), Delamine (Dlm), (Linezolid (Lzd), clofazimine (Cfz), imipenem-cilastatin (Imp/Cls), amoxicillin-clavulanate (Amx/Clv).

221. The purpose and regimen of treatment for IV category shall be defined by the centralized medical advisory committee, which approves the treatment plan, the dose and frequency of intake of anti-TB drugs.

222. Before the assignment of a treatment for IV category, a meeting with a patient (with parents (guardians) of children) is held about compulsory full course of chemotherapy. In each case, the form TB 14/y, approved by the Order No. 907 – "the Informed consent of the patient for treatment" is drawn up.

223. Treatment for IV category shall be assigned only when there is a complete set of anti-TB drugs for the entire course of treatment (12 months) in accordance of the recommended daily dose (mg) of anti-TB drugs for adults, in accordance with Annex 4 to this Instruction.

224. The standard regimen of treatment is assigned to the TB patients with multi-drug-resistance and in the intensive phase includes at least 4 anti-TB drugs of the second line, one of them in injectable form.

Pyrazinamide is used throughout the course of treatment based on tolerability. Other anti-TB drugs of the first line while maintaining sensitivity to them are also included in the treatment regimen.

While maintaining the sensitivity of Mycobacterium tuberculosis to ethambutol, the drug is included in the treatment regimen of category IV both on the intensive phase and maintenance phase of treatment. Ethambutol is also included in the treatment regimen when taking the patient to the standard treatment regimen according to the results of molecular genetic methods to confirm the results of resistance to this drug on the WASTES or dense medium of Lowenstein - Jensen.

225. Intensive phase: the standard regimen is carried out for 8-12 months, until the receipt of two negative inoculation results. Standard treatment regimen for category IV is:

Cm/Km/Am + Lfx (Mfx) + Pto + Cs (PAS) + Z ± E.

226. In maintenance phase in the standard regimen, at least three anti-TB drugs of the second line are applied with the obligatory inclusion of the drug of the fluoroquinolone group.

227. Maintenance phase for the standard regimen is carried out within 12 months. The standard treatment scheme is: Lfx (Mfx) + Pto + Cs (PAS) + Z.

228. General treatment according to standard regimen is 20-24 months: intensive phase: 8-12 months; maintenance phase – 12 months.

229. Intensive phase of treatment for children without bacterial excretion at the beginning of treatment and with a limited process may be reduced to 6 months by the decision of the centralized medical advisory committee.

230. Microscopic and cultural examination of the sputum for the patients receiving treatment according to the standard regimen shall be performed: in the intensive phase – monthly, in the maintenance phase - on a quarterly basis.

231. Transfer to maintenance phase for the standard regimen is carried out in the presence of two consecutive negative results of sputum inoculations, taken at monthly intervals, in the presence of positive clinical and radiological dynamics.

232. Transfer to maintenance phase on a standard regimen of the patients with initial negative results of inoculation and (or) microscopy is carried out after 8 months of treatment in an intensive regimen.

233. Taking of medications according to the standard regimen is carried out on a daily basis 7 days a week in the intensive phase, 6 days a week - in maintenance phase of treatment. If the intensive phase is performed on an outpatient basis – 6 days a week

234. Short-term treatment regime is prescribed to the patients with tuberculosis with multiple drug resistance with limited specific lesions in the lung tissue, mostly without bacterial excretion, while maintaining sensitivity to fluoroquinolones and injectable anti-TB drugs of the second line or in the absence of suspicion for tuberculosis with pre – extensive drug-resistance and tuberculosis with extensive drug-resistance. In the intensive phase in short-term regimen, Cm/Km/Am + Mfx + Pto (Cs) + H (high doses) + E+Z + Cfz are assigned from 4 to 6 months. In the maintenance phase from 5 to 6 months - Mfx + Pto (Cs) + E+Z + Cfz. Short-term treatment regimen is applied in the framework of pilot projects.

235. The individual regimen is used for the treatment of tuberculosis with multi-drug resistance, tuberculosis with pre-extensive drug-resistance, extensive drug resistance and the treatment regimen consists of BDQ and (or) delamanid and anti-TB drugs of all 5 groups to which the sensitivity of Mycobacterium tuberculosis is preserved. Individual treatment regime is applied in the framework of pilot projects.

236. The daily dose of anti-TB drugs in the hospital is made in one or two intakes, on an outpatient basis – one intake. Patients, taking anti-TB drugs fractionally in the hospital, at least 2 weeks before the discharge, are transferred to a single dose intake.

237. Treatment for IV category is assigned based on weight with its monthly control and correction of dosages of anti-TB drugs as it increases.

238. General analysis of blood and urine, biochemical blood tests are performed prior to the treatment, subsequently during the intensive phase monthly, in maintenance phase - on a quarterly basis, if indicated - more often.

Rehberg test, calculation of creatinine clearance and electrolyte balance are determined before the start of treatment for IV category in all patients and in the future – if indicated.

239. An electrocardiogram is made prior to treatment for IV category and later based on indications; ultrasound examination of abdominal cavity organs and thyroid gland, determination of the titer of thyroid-stimulating hormone, CT scan, fibrogastroduodenoscopy, fiber-optic bronchoscopy, consultation of specialists (

cardiologist, ophthalmologist, neurologist, endocrinologist, psychotherapist, otolaryngologist, and others) are held if indicated.

240. Organization of outpatient phase of treatment of patients receiving treatment for IV category: outpatient treatment is conducted in outpatient TB departments of anti-TB medical organizations and organizations, providing out-patient-polyclinic assistance;

1) patients without bacterial excretion in the absence of marked symptoms of intoxication, complications, concomitant diseases and allergic reactions to drugs;

2) patients with an initial bacterial excretion after receiving two negative results of microscopy, taken sequentially at intervals of not less than 10 calendar days;

injections of capreomycin or aminoglycoside for the patients are made in the treatment room of the dispensary departments of anti-TB organizations or organizations, providing outpatient –polyclinic assistance;

patients of IV category, receiving a specific treatment, not less than once in 10 days, if indicated – more often, are examined by district doctors of anti- TB organizations or organizations, providing out-patient-polyclinic assistance, depending on the place of the directly observed treatment;

in the outpatient departments of anti-TB organizations or organizations, providing out-patient-polyclinic assistance the conditions for symptomatic and pathogenetic treatment for side effects of anti-TB drugs and comorbidities in patients of IV category, receiving specific treatment, are provided;

3) in case of registration of adverse reactions in a TB patient to anti-tuberculosis drugs, the symptomatic and pathogenetic drugs are used to stop the adverse reactions; the frequency, time of intake and method of injection of drugs are reviewed or the dose of the drug is temporarily reduced; in the absence of a positive effect, the drug is temporarily (for 2-3 days) cancelled, or is replaced by its analogue.

4) in case of adverse reactions, such as a convulsive seizure, collapse, anaphylaxis, acute psychosis, hepatitis, gastritis, all anti-TB drugs are canceled. After the persistent elimination of side reactions, the canceled medications are assigned from the less toxic to more toxic drug.

5) Preventive measures to adverse reactions of anti-TB drugs of the second line are: creation of the optimistic atmosphere in the department and in the environment of the patient; daily monitoring of tolerability to anti-TB drugs on the stationary phase and in the presence of complaints during the visit of the patient to a medical facility for outpatient treatment; periodic assignment of vitamin B6, calcium, magnesium, enzymes, improving the function of the gastrointestinal tract, choleric agents; lipotropic and hepatotropic drugs, antihistamines, detoxification therapy, therapeutic plasmapheresis in case of allergic reactions.

6) at the outpatient phase of treatment, all TB patients with multidrug resistance receive a psychosocial support;

7) to hold the patients in treatment, various methods of material stimulation (a monthly cash payment, food packages, hot meals, reimbursement of travel expenses and others) are used on a regular basis at the outpatient phase of treatment, as well as health care workers responsible for directly observed treatment.

241. The treatment of children for IV category shall be conducted in accordance with the general principles of treatment of tuberculosis with multiple drug resistance.

242. Treatment of patients who have discontinued their intake of anti-TB drugs of the second line for 2 months or more, shall start in standard regimen of the intensive phase of IV category until the receipt of the results of drug susceptibility test to anti-TB drugs of the second line, and the treatment scheme shall be adjusted based on the data of drug susceptibility.

243. In the cases of absence of conversion of sputum by microscopy method by the 4 month and inoculation by the 6 months of treatment with anti-TB drugs of the second line, the TB patients with multidrug resistance shall have a consultation by correspondence or face-to-face consultation with experts of the third level.

244. In case of preservation of bacterial excretion according of the sputum smear microscopy results and/or inoculation after 10 months of directly observed treatment of tuberculosis with multiple drug resistance and after 15 months of tuberculosis with extensive drug-resistance, the treatment of TB patients of IV category is terminated.

245. After termination of anti-TB treatment, a patient with a bacterial excretion shall be transferred to the department of the symptomatic treatment.

246. The patient shall stay in the symptomatic treatment department until abacillation of bacillary excretion (negative results of sputum smear microscopy and inoculation).

247. The patient and his family shall be informed about the reason for termination of anti-TB treatment. The specified patients shall receive psychological support and symptomatic treatment with observance of anti-epidemic measures.

248. Registration of results of treatment of patients of IV category:

1) cured:

a patient who completed full course of treatment for IV category and has at least five negative results of sputum inoculation for the last 15 months of treatment, carried out sequentially at the intervals of a month;

a patient, who completed the full course of treatment for IV category with a positive result of inoculation over the past 15 months of treatment, but without clinical and radiological signs of worsening of the condition, and has 3 subsequent negative results of the inoculations, carried out sequentially at intervals of 3 months;

a patient with negative sputum smear microscopy at 0 month of treatment, but who previously was the person discharging bacteria, and who in the process of treatment received the sufficient number of negative inoculations for the outcome "cured";

2) treatment completed – a patient who completed full course of treatment according to IV category, but does not meet the definition "cured" or "treatment failure";

3) treatment failure – a patient:

receiving or completed treatment according to IV category, has at least 2 positive results from 5 sputum inoculations for the last 15 months of treatment or a positive result in any of the three inoculations, made during the period of treatment;

receiving treatment for IV category, has a bacterial excretion in microscopy methods or inoculation after 10 months of treatment;

receiving treatment for IV category, has no conversion of the sputum by the microscopy method over the past 12 months;

receiving treatment for IV category, whose treatment cannot be completed because of intolerance to anti-TB drugs;

4) died – a patient who dies of any cause during the treatment for IV category;

5) violation of regimen – a patient who interrupted the treatment for IV category for two months or more;

6) transferred – a patient, who left this medical organization for another, and the result of treatment for IV category is unknown. The result "transferred" is given only in the presence of the detachable slip in the form No. TB-09/y, approved by the Order No . 907, and documentary confirmation that the patient is taken to dispensary registration by the host party and continues treatment. This result is intermediate and upon completion of the full course of treatment the final outcome will be given.

249. Indicators of the effectiveness of treatment with anti-TB drugs of the second line of tuberculosis patients with multiple drug resistance are: the achievement of sputum conversion by microscopy and inoculation in the 12th months of treatment in 85% of cases of pulmonary tuberculosis with bacterial excretion, the indicator of therapeutic success - in 75% of all cases with multidrug resistance.

250. Palliative care for patients with tuberculosis, not treatable by specific treatment, is carried out in accordance with the order of the Health Minister of the Republic of Kazakhstan dated November 14, 2013 № 657 "On approval of the Standard of organization of palliative care of the population of the Republic of Kazakhstan" (registered in the Register of the state registration of regulatory legal acts No. 8956).

Chapter 7. Dispensary registration of TB patients

251. Dispensary registration and observation shall be conducted on the following groups:

- 1) zero group (0) – persons with questionable active tuberculosis;
- 2) the first group (I) – persons with active TB;
- 3) the second group (II) – persons with inactive tuberculosis;
- 4) the third group (III) – persons with an increased risk of tuberculosis.

252. The 0 (zero) group shall observe:

the individuals with suspected tuberculosis, in whom, after the standard diagnostic algorithm for TB in organizations, providing outpatient polyclinic assistance, it is impossible to remove or confirm the activity of the process in the lungs or other organs ;

1) children that need clarification of the nature of tuberculin sensitivity and the differential diagnosis, that are not in the dispensary register in anti-TB organizations.

253. Persons of the 0 group shall undergo laboratory, clinical and radiological, instrumental and other methods of examination, including tuberculin diagnostics (children with a positive Mantoux test with 2 tuberculin units also undergo the test with recombinant tuberculous allergen). The patients with extra-pulmonary localization, the activity of tuberculous process shall be confirmed by other clinical and laboratory studies.

254. Individuals of the 0 group shall not be allowed to use anti-TB drugs. The observation period is up to 4 months. When establishing the active TB, the patient is transferred to I group. When establishing the infectious etiology of the nature of the tuberculin skin test, the child is transferred to the III B group.

255. Patients with active forms of tuberculosis of any localization with bacterial excretion and without bacterial excretion are observed in I group,:

- 1) I A – new tuberculosis cases (category I);
- 2) I B – recurrent TB cases (category II);
- 3) I C - the cases of drug-resistant tuberculosis (category IV);
- 4) I D – the patients:

that completed the course of treatment with anti-TB drugs of the second and/or third line with the outcome "treatment failure";

the patients with bacterial excretion, who have the outcome "treatment failure" as a result of complete intolerance to anti-TB drugs.

256. After the decision of the centralized medical advisory committee on abacillation of bacteria excretion is made, the patient is removed from the epidemiological accounting as a person discharging bacteria.

257. Patients of groups I A, I B and I C are assigned to the standard chemotherapy regimens according to the categories of treatment. Dispensary observation of TB patients (characteristics of groups, observation periods, the required actions and results

) is carried out in accordance with Annex 6 to this Instruction. When the treatment outcome is "cured" or "treatment completed", the patients are transferred to the II group of regular medical check-up.

258. Patients of the I D group shall not receive treatment with anti-TB drugs. If indicated, the symptomatic (pathogenetic) therapy is carried out, including collapsotherapy and surgical methods.

259. In the II group there are persons with inactive tuberculous process after the successful completion of the course of treatment.

260. In the event of a relapse of tuberculosis, the patient is transferred to I B or I C group of regular medical check-up, depending on the previous episode of treatment.

261. In the III group, people with higher risk of TB disease are observed and divided into the following subgroups:

1) III A - those, contacting with patients with active form of tuberculosis; from a previously unknown foci of death from TB;

2) III B - children "infected with Mycobacterium tuberculosis, newly diagnosed";

3) III C - children with adverse reactions to the vaccine Calmette-Guerin bacillus.

262. The registration and regular medical check-ups of TB patients shall be made in anti-tuberculosis medical organizations at the place of actual residence, work, study or military service, regardless of registration.

263. When changing the place of residence of the patient, the doctor - phthisiatrician shall register him for regular medical check-ups at the place of the new residence within 10 calendar days.

264. The patient shall be removed from the regular medical check-ups of the anti-TB medical organization in the event of a separation for 1 year on the basis of documents from the internal affairs bodies of the Republic of Kazakhstan, confirming the failure of his search.

265. Patients of IV category, receiving treatment for IV category, shall be observed in I C group of dispensary register.

266. Patients of IV category, not treatable by specific treatment, shall be observed in the I D group of dispensary register.

267. Patients of IV category, observed in I D group, shall not receive treatment with anti-TB drugs.

268. Patients of IV category, observed in I D group, shall receive the symptomatic treatment, treatment of complications of the main disease and concomitant pathology in the specialized hospitals.

269. Patients of category IV, observed in I D group, shall be observed in the outpatient conditions at the conclusion of the epidemiologist of the Department of

public health and the doctor-phthisiatrician subject to the living conditions (a separate living space with natural ventilation, the absence of co-habiting children and pregnant women).

270. Patients of IV category, observed in I D group of dispensary register, shall undergo microscopic and culture examination of the sputum for Mycobacterium tuberculosis once a year.

271. Patients of IV category, observed in I D group of dispensary register, shall undergo clinical tests, x-rays and other types of instrumental investigations if indicated.

272. After completing the full course of treatment for IV category, the patients with outcome "cured" and "treatment completed" shall be transferred to the II group of the dispensary register, where they are observed for two years.

273. Patients of IV category shall need social protection and support.

274. Pathogenetic therapy shall be carried out in accordance with the phase of tuberculous process, individual indications and contraindications in the background of the basic chemotherapy course.

275. The nutrition of patients, receiving treatment for IV category, shall be carried out 5 times a day and its calorie content should be at least 6 thousand calories.

276. Prevention of adverse reactions to anti-TB drugs shall be done throughout the course of treatment for IV category, regardless of the phase of treatment:

1) a daily intake of glutamic acid during the entire period of treatment with cycloserine and periodic preventive assignment of vitamins of group "b";

2) potassium supplements while taking injectable anti-TB drugs of the second line;

3) assignment of hepatoprotectors, enzymes, improving the function of gastrointestinal tract if indicated.

277. A medical report on admission of TB patients to work and study shall be issued by the centralized medical advisory committee of the anti-tuberculosis organization.

278. All persons who have successfully completed a full course of treatment in the modes of I, II and IV categories for TB treatment with the outcomes "cured" and "treatment completed" shall be allowed to study and work.

279. In the course of treatment, the TB patients with the limited process, without bacterial excretion or with persistent conversion of sputum smear, being at the ambulatory phase, regardless of category and phase of treatment, having a satisfactory condition, good tolerability of anti-TB drugs and adherence to the controlled intake of anti-TB drugs, shall be permitted to study or work by the decision of the centralized medical advisory committee.

280. In the treatment process, the following TB patients shall not be allowed to study or work:

1) with bacterial excretion, the marked destructive changes in the lungs, complications of specific process, severe adverse reactions to anti-tuberculosis drugs, low adherence to the controlled intake of anti-TB drugs;

2) the staff of the perinatal centers (maternity departments), children's hospitals (departments), departments of pathology of newborns and premature infants; pre-school institutions (nurseries/kindergartens, infant orphanages, children's sanatorium) and elementary school organizations, regardless of the form and the diagnosis of tuberculosis.

Chapter 8. Interagency cooperation for continuity of treatment of TB patients, released from penal system

281. The medical service of the penal system shall:

1) submit in advance the information on TB patients to be released, to the anti-TB organizations, 1 month before the release, upon release upon completion of the sentence, and 15 calendar days in case of release on parole according to the order of the Minister of internal affairs of the Republic of Kazakhstan dated August 19, 2014 No. 530 "On approval of the Rules of organization of anti-TB care in penitentiary system, the List of diseases, which are the basis for release from serving a sentence, the Rules of medical examination of prisoners, submitted for the release from serving a sentence in connection with illness" (registered in the Register of state registration of regulatory legal acts of the Republic of Kazakhstan No. 9762);

2) ensure delivery of TB patients to the specialized departments of the anti-TB organization for the forced treatment, by the court decision, released from the penal system;

3) in case of the liberation of the patient from the courtroom within 5 calendar days from the date of release, inform the territorial anti-TB organizations;

4) after the liberation, during a month, submit information to the anti-TB organizations about the actually released TB patients;

5) interact with non-governmental organizations to ensure continuity of treatment of tuberculosis patients after their release;

282. Anti-tuberculosis organization of the health care system shall:

1) receive information about TB patients with incomplete treatment a month before the release from penitentiary system in writing;

2) provide further treatment of TB patients, released from institutions of the penal system, including patients with forced treatment by court decision, in anti-TB organizations;

3) inform departments of internal affairs bodies and the medical service of penal system about the registration of patients, released from the penitentiary system;

4) in case if the patient does not show up within 5 calendar days from the date of release from institutions of the penal system, inform the units of the internal affairs bodies;

5) in case when the internal affairs bodies establish the location of the patient that has not arrived, send a vehicle with accompanying personnel to transport the patient;

6) cooperate with non-governmental organizations to provide TB patients with psychosocial support until the full completion of the specific treatment.

Annex 1

to the Instruction on organization
of medical care for tuberculosis

Diagnostic algorithm of examination of patients with suspected tuberculosis

Suspected tuberculosis

Microscopy* KUB(-) Microscopy KUB (-) Microscopy KUB+ Microscopy KUB+
MG**TB neg MG TB + MG TB neg MG TB +

X-ray and conclusion

Broad-spectrum antibiotics

Repeated X-ray

Improvement No improvement

Repeated microscopy

KUB - KUB +

Doctor's Consultation of phthisiatrician Tuberculosis

conclusion if indicated

No TB

* Microscopic examination of sputum is carried out from 2 samples.

** MG (molecular genetic study) is carried out with 1 portion of the pathological material.

Note: in the absence of bacteriological or histological confirmation, the final decision is made by the centralized medical advisory commission, taking into account the nature of radiological changes in the lungs, the presence of aggravating factors and the type of activity of the person with pathological changes in the lungs.

Annex 2

to the Instruction on organization
of medical care for tuberculosis

Algorithms for laboratory diagnosis of tuberculosis

Diagnostics (Scheme 1)

2 samples

1 sample 2 sample

NaOH-NALC NaOH-NALC

MGIT ЛЙ¹ Microscopy Microscopy ЛЙ*

MGIT MGIT¹ MGIT KUB- KUB+

contam neg pos

MBT- Identification MG

MBT+ RIF neg

RIF resist DST MGIT RIF sens

1 line

DST MGIT DST MGIT RIF resist

2 line 1-2 line

MG 2 line

Chemotherapy control (Scheme 2)

2 samples

1 category – in the end of the 2nd month

2 category – in the end of the 3rd month

1 sample 2 sample

NaOH-NALC

Inoculation Л-Й Microscopy

MBT+ MBT- KUB+ KUB-

DST 1-2 line MGIT

Microscopy

1 category – in the end of the 3rd month

2 category – in the end of the 4th month

KUB+ KUB-

Microscopy

1 category – in the end of the 4th month

2 category – in the end of the 5th month

KUB+ KUB -

Results of all investigations shall be submitted to the doctor!

Algorithms for laboratory diagnosis of multidrug-resistant tuberculosis (Scheme 3)

Intensive phase (monthly)

2 samples

Inoculation ЛЙ Microscopy

MBT- MBT+ MBT+ MBT-

≥2 month the degree of positive result is not reducing (3+, 2+, 1+)

DST 2 line

Maintenance phase (quarterly)

2 samples

Inoculation ЛЙ Microscopy

MBT- MBT+

DST 2 line

Results of all investigations shall be submitted to the doctor!

Annex 3
to the Instruction on organization
of medical care for tuberculosis

Critical concentrations for first and second-line drugs for drug sensitivity testing

Group	Medication	Method	Critical concentrations mcg / ml	
			Lowenstein–Jensen	MGIT 960
Group 1 First-line oral anti-TB drugs	Isoniazid	Liquid, dense	0,2	0,1
	Rifampicin	Liquid, dense	40,0	1,0
	Ethambutol	Liquid, dense	2,0	5,0
	Pyrazinamide	Liquid	-	100
Group 2 Injectable anti-TB drugs	Streptomycin	Liquid, dense	4,0	1,0
	Kanamycin	Liquid, dense	30,0	2,5
	Amikacin	Liquid	30,0	1,0
	Capreomycin	Liquid, dense	40,0	2,5
Group 3 Fluoroquinolone medications	Levofloxacin	Liquid, dense	-	1,0
	Moxifloxacin	Liquid, dense	1,0	0,25/ 1,0
Group 4 Oral bacteriostatic anti-TB drugs of 2 line	Protonamide	Liquid, dense	40,0	2,5
Other medications	Linezolid	Liquid		1,0
	Bedaquiline	Liquid		1,0
	Delamanid	Liquid		0,06
	Clofazimine	Liquid		0,5

Annex 4
to the Instruction on organization
of medical care for tuberculosis

Recommended daily doses (mg) of anti-TB drugs for treatment of sensitive tuberculosis in adults

Name of medication	Weight (kg)			
	30-39	40-54	55-70	over 70
Intensive phase - daily intake				
Isoniazid	200 mg	300 mg	300 mg	400 mg
Rifampicin	300 mg	450 mg	600 mg	750 mg
Pyrazinamide	1000 mg	1500 mg	2000 mg	2000 mg
Ethambutol	600 mg	800 mg	1200 mg	1600 mg
Streptomycin (1g)	500 mg	750 mg	1000 mg	1000 mg

Maintenance phase - daily intake				
Isoniazid	200 mg	300 mg	300 mg	400 mg
Rifampicin 150 mg	300 mg	450 mg	600 mg	750 mg
Ethambutol 400 mg	600 mg	800 mg	1200 mg	1600 mg

Note: the maximum daily dose of Rifampicin in fixed-dose combination anti-tuberculosis drugs is 750 mg.

Daily doses of fixed-dose combination anti-tuberculosis drugs for adults, taking into account the weight ranges of patients.

Weight range (kg)	Intensive phase		Maintenance phase
	2-5 months depending on the effectiveness and category of treatment		4-5 months depending on the category of treatment
	RHZE 150mg+75mg+ 400mg+275mg	RHZ 150mg+75mg +400mg	RH 150mg+75mg
Number of tablets in assignment of combination anti-tuberculosis drugs with fixed doses			
30-37	2	2	2
38-54	3	3	3
55-70	4	4	4
71 and more	5	5	5

Permissible daily dose fluctuations (maximum permissible limits) in adults: isoniazid - 4-6 mg / kg, rifampicin - 8-12 mg / kg, pyrazinamide - 20-30 mg / kg, ethambutol - 15-20 mg / kg.

The recommended daily doses of anti-tuberculosis drugs for treatment of sensitive tuberculosis in children weighing 5-25 kg

Calculation and permissible fluctuations of daily doses of first-line anti-TB drugs for children weighing up to 25 kg (World Health Organization, 2014)			
Medications	Calculation of daily dose in mg / kg	Permissible daily dose fluctuations in mg / kg	Maximum daily dose (mg)
Isoniazid	10	10-15	300
Rifampicin	15	10-20	600
Pyrazinamide	35	30-40	2000
Ethambutol	20	15-25	1200

Note:

For children weighing more than 25 kg, calculation of the dosage of anti-tuberculosis drugs is carried out as for adults.

Permissible daily dose fluctuations (maximum permissible limits) in adults when taken daily: isoniazid - 4-6 mg / kg, rifampicin - 8-12 mg / kg, pyrazinamide - 20-30 mg / kg, ethambutol - 15-20 mg / kg.

Fixed-dose combination anti-TB drugs

Age groups	Number of tablets	
	Intensive phase	Maintenance phase

	RHZ(75/50/150)	E (100)	RH(75/50)	E * (100)
4-7 kg	1	1	1	1
8-11 kg	2	2	2	2
12-15 kg	3	3	3	3
16-24 kg	4	4	4	4
25 kg	transition to adult dosages and dosage forms			

Note:

For children weighing more than 25 kg, the daily dose of anti-TB drugs is prescribed at the rate of mg / kg / day within the maximum permissible daily dose.

During the first 2 months of the intensive phase of treatment in the mode of II category, streptomycin is additionally prescribed - 15-20 mg / kg / day, the maximum daily dose is 1000 mg.

For the treatment of children weighing up to 5 kg, mono-preparations are used.

* with mono-resistance to H, E is additionally prescribed (100 mg).

Daily doses of anti-tuberculosis drugs in the treatment of sensitive tuberculosis in children with single-component anti-tuberculosis drugs weighing 5-30 kg

Name of medication	Weight (kg)		
	5-10	11-20	21-30
Intensive phase - daily intake			
Isoniazid	50 – 100 mg	100 - 200 mg	200 – 300 mg
Rifampicin	75 – 150 mg	150 - 300 mg	225 - 450 mg
Pyrazinamide	175 - 350 mg	385 - 700 mg	735 - 1000 mg
Ethambutol	100 – 200 mg	200 - 400 mg	400 - 600 mg
Maintenance phase - daily intake			
Isoniazid	50 – 100 mg	100 - 200 mg	200 – 300 mg
Rifampicin	75 – 150 mg	150 - 300 mg	225 - 450 mg
Ethambutol	100 – 200 mg	200 - 400 mg	400 - 600 mg

Note: dosages of drugs for children weighing up to 5 kg are calculated in mg / kg / day.

The recommended daily doses (mg) of anti-tuberculosis drugs for treatment of multidrug-resistant and extensively drug-resistant tuberculosis

Name of medication	Weight (kg)			
	<33 kg	33-49 kg	50-70 kg	>70 kg
Intensive phase - daily intake				
Pyrazinamide (Z)	30-40 mg/kg	1000-1500	1500-2000	2000
Ethambutol (E)	25 mg/kg	800 -1200	1200-1600	1600-2000
Isoniazid (N)	300	400-500	600	600
Kanamycin (Km) (1 g)	15-20 mg/kg	500-750	1000	1000

Capreomycin (Cm) (1 g)	15-20 mg/kg	500-750	1000	1000
Amikacin (Am) (1 g)	15-20 mg/kg	500-750	1000	1000
Levofloxacin (Lfx)	500	500	750-1000	1000
Moxifloxacin (Mfx)	400	400	400	400
Protionamide (Pto)	15-20 mg/kg	500	750	1000
Cycloserine (Cs)	15-20 mg/kg	500	750	1000
Para-aminosalicylic acid (PAS)	1500 mg/kg	8000	8000	8000
Linezolid (Lzd)	-	600	600	600
Clofazimine (Cfz)	-	200	200	200
Bedaquiline (Bdq)	-	400	400	400
Delamanid (Dlm)	-	200	200	200
Amoxicillin clavulanate (Amx-Clv)	With a weight of up to 50 kg - based on a dose of amoxicillin 35 mg per 1 kg of body weight; with a weight of 50 kg and above - 2000 mg of amoxicillin			
Maintenance phase - daily intake				
Pyrazinamide (Z)	30-40 mg/kg	1000-1500	1500-2000	2000
Levofloxacin (Lfx)	500	500	750-1000	1000
Moxifloxacin (Mfx)	400	400	400	400
Protionamide (Pto)	15-20 mg/kg	500	750	1000
Cycloserine (Cs)	15-20 mg/kg	500	750	1000
Para-aminosalicylic acid (Pas)	1500 mg/kg	8000	8000	8000
Ethambutol (E)	25 mg/kg	800	1200	1600
Linezolid (Lzd)	-	600	600	600
Clofazimine (Cfz)	-	100	100	100
Bedaquiline (Bdq)	-	200	200	200
Delamanid (Dlm)	-	200	200	200
Amoxicillin clavulanate (Amx-Clv)	With a weight of up to 50 kg - 1500 mg of amoxicillin; With a weight of 50 kg and above - 2000 mg of amoxicillin			

The recommended daily doses (mg / kg) of anti-tuberculosis drugs for children

Medication	Daily dose, mg / kg / day	Frequency of intake	Maximum daily dose
Kanamycin (Km)	15-30	once a day	1 g
Amikacin (Am)	15-30	once a day	1 g
Capreomycin (Cm)	15-30	once a day	1 g
Levofloxacin (Lfx)	7,5-10	once a day	750 mg
Moxifloxacin (Mfx)	7,5-10	once a day	400 mg
Protionamide (Pto)	15-20	twice a day	1 g
Cycloserine (Cs)	10-15-20	1 or 2 times a day	1 g
Para-aminosalicylic acid (PAS)	150-200	2 or 3 times a day	8 g

Pyrazinamide (Z)	30-40	once a day	2 g
Ethambutol (Eto)	25	once a day	1,6 g
Amoxicillin-clavulanate (Amx / Clv)	Amoxicillin 80 With a weight of 50 kg and above - 2000 mg of amoxicillin		2000
Linezolid (Lzd)	10 mg for children <10 years; 300 mg for children ≥10 years old	twice a day	600 mg
Clofazimine (Kfz)	2-3		200
Delamanid (6-11 years old)	50 mg	Twice a day for 6 months	100 mg
Delamanid (12-17 years old)	100 mg	Twice a day for 6 months	200 mg

Note:

1. Moxifloxacin is not recommended for children weighing 1.0-13.9 kg;
2. Cycloserine and para-aminosalicylic acid are not recommended for children weighing 1.0-2.9 kg;
3. Levofloxacin is prescribed to children up to 5 years of age twice a day (daily dose of 15-20 mg / kg) and once a day for children over 5 years of age (daily dose of 7.5-10 mg / kg).

Annex 5
to the Instruction on organization
of medical care for tuberculosis

Measures taken in case of interruption of anti-tuberculosis therapy

1. Break less than 1 month		
Find the patient. Find out and eliminate the reason for stopping the treatment. Continue the treatment and extend it to compensate for the missed doses of anti-TB drugs.		
2. Break from 1 to 2 months		
Initial actions		Subsequent actions
1) Find the patient; 2) find out and eliminate the reason for discontinuation of treatment; 3) microscopy of sputum smear, 2 times; 4) continue treatment until sputum microscopy results are obtained.	The result of sputum smear microscopy is negative or the patient has extra-pulmonary tuberculosis	Continue the treatment and extend it to compensate for the missed doses of anti-TB drugs
	At least 1 positive sputum smear test result received	Investigate the sputum by cultural methods with the drug sensitivity test. Continue the previously prescribed treatment regimen until the receipt of the results of the drug sensitivity test. Further tactics depend on the results of the drug sensitivity test and the decision of the centralized medical advisory committee.
3. Break for 2 months or more		

<p>1) Find the patient; 2) find out and eliminate the reason for discontinuation of treatment; 3) microscopy of sputum smear, 3 times; 4) do not begin treatment until the results of sputum microscopy are obtained</p>	<p>The result of sputum smear microscopy is negative or the patient has extra-pulmonary tuberculosis</p>	<p>The decision is made by the centralized medical advisory committee: If there is no data on drug sensitivity test or laboratory-confirmed multidrug-resistant tuberculosis, then examine the sputum or other biological material for drug sensitivity, re-register the patient into category II under the type “Other” and start treatment from the intensive phase of II category</p> <p>If during the break of treatment, the laboratory confirmation of multidrug-resistant tuberculosis is obtained, then re-register the patient under the type “Other” to IV category and start treatment with second-line anti-tuberculosis drugs</p>
	<p>At least 1 positive sputum smear test received</p>	<p>If there is no data on drug sensitivity test or laboratory-confirmed multidrug-resistant tuberculosis, then examine the sputum for drug sensitivity, re-register the patient into II category under “Treatment after break” type and start treatment from the intensive phase of II category</p> <p>If during the break of treatment, the laboratory confirmation of multidrug-resistant tuberculosis is obtained, then re-register the patient under the type “Treatment after a break” to IV category and begin treatment with second-line anti-tuberculosis drugs</p>

Annex 6

to the Instruction on organization of medical care for tuberculosis

Clinical observation of TB patients (characteristics of groups, time of observation, necessary actions and results)

Group	Characteristics	Time of observation	Actions	Results
Zero group (0) – diagnostic				
				Laboratory tests (general urine analysis, general blood analysis, microscopy and sputum)

0	<p>Persons with questionable activity of the tuberculosis process</p> <p>Children who need to clarify the nature of tuberculin sensitivity and differential diagnosis, who are not registered in the TB medical organizations</p>	6 month	<p>inoculation of Mycobacterium tuberculosis), clinical and X-ray examinations — when taken and removed from dispensary registration. Instrumental and other research methods - if indicated. Tuberculin diagnosis, test with a recombinant tuberculosis allergen in children when taken and removed from the dispensary registration. Anti-TB drugs are not used.</p>	<p>Removal from the register.</p> <p>When active tuberculosis is detected, transfer to the group:</p> <ol style="list-style-type: none"> 1) I A - if a new case; 2) I B - if a recurrent case; 3) I C - if the case of TB with multi-drug resistance; 4) when establishing the infectious etiology of a tuberculin test, it is transferred to group IIIB (children).
First group (I) – active tuberculosis				
			<ol style="list-style-type: none"> 1) General blood analysis, general urine analysis, biochemical blood test - monthly on the intensive phase, in the middle and at the end of the maintenance phase of treatment, if indicated - more often; 2) double bacterioscopy, inoculation on dense media, Xpert MTB / RIF , Geno Type MTBDR®, BACTEC - once before the start of chemotherapy; 3) double bacterioscopy: 	<p>Transfer to group:</p> <ol style="list-style-type: none"> 1) II – if the outcome of the treatment is "cured" or "treatment completed";

I A	New cases of tuberculosis	During the entire course of treatment	<p>after 2 months of intensive phase, at the end of the 3rd and 4th month of treatment in the absence of smear conversion;</p> <p>4) double bacterioscopy in the middle and at the end of the maintenance phase of treatment in patients with initially positive smear;</p> <p>5) inoculation with the drug sensitivity test after 2 months of treatment in the absence of smear conversion;</p> <p>6) X-ray tomography before the start of chemotherapy, in the process of treatment with an interval of 2-3 months (more often according to indications);</p> <p>7) Mantoux test with 2 tuberculin units (test with a recombinant tuberculosis allergen) prior to the start of chemotherapy for children, later - according to indications.</p> <p>Standard treatment regimens in the mode of category I.</p>	<p>2) IB – if the outcome is "treatment failure" with the preserved sensibility;</p> <p>3) IC – when establishing resistance to R or at the outcome "treatment failure" with multi-resistance. In the outcome "violation of the regimen", the patient is removed from the dispensary registration of the anti-TB medical organization within 1 year on the basis of documents from the territorial bodies of the Ministry of Internal Affairs, confirming the ineffectiveness of his search.</p>
			1) General blood analysis, general urine analysis,	

<p>IB</p>	<p>Recurrent TB cases</p>	<p>biochemical blood test – monthly in the intensive phase, in the middle and at the end of the maintenance phase of treatment, if indicated - more often;</p> <p>2) double bacterioscopy, inoculation on dense media, Xpert MTB / RIF , Geno Type MTBDR®, BACTEC - once before the start of chemotherapy;</p> <p>3) double bacterioscopy: after 2 months of intensive phase, at the end of the 4th and 5th month of treatment in the absence of smear conversion;</p> <p>4) double bacterioscopy in the middle and at the end of the maintenance phase of treatment in patients with initially positive smear;</p> <p>5) inoculation with the drug sensitivity test after 3 months of treatment in the absence of smear conversion;</p> <p>6) X-ray tomography before the start of chemotherapy, in the process of treatment with an</p>	<p>Transfer to group:</p> <p>1) II – if the outcome of the treatment is "cured" or "treatment completed";</p> <p>2) IB – when establishing resistance to R or if the outcome is "treatment failure";</p> <p>If the outcome is "violation of the regimen", the patient is removed from the dispensary registration of the anti-TB medical organization within 1 year on the basis of documents from the territorial bodies of the Ministry of Internal Affairs, confirming the</p>
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		<p>interval of 2-3 months (more often according to indications);</p> <p>7) Mantoux test with 2 tuberculin units (test with a recombinant tuberculosis allergen) prior to the start of chemotherapy for children, later - according to indications.</p> <p>Standard treatment regimens in the mode of category II.</p>	<p>ineffectiveness of his search.</p>
		<p>1) General blood analysis, general urine analysis, biochemical blood test – monthly in the intensive phase, in the maintenance phase of treatment – quarterly, if indicated - more often;</p> <p>2) double bacterioscopy, inoculation on dense media, Geno Type MTBDR®sl, BACTEC - once before the start of chemotherapy;</p> <p>3) bacterioscopy and inoculation (Lowenstein–Jensen) – 2 times monthly during the intensive phase, quarterly – in the maintenance phase of treatment;</p>	<p>Transfer to group:</p> <p>1) II – in case of outcome "cured" or "treatment completed";</p> <p>2) I D - in case of outcome "treatment failure"</p> <p>In case of "violation of the regimen", the patient is removed from the</p>

IC	Patients with multidrug-resistant tuberculosis who receive treatment in IV category	<p>4) inoculation on dense media and BACTEC with the drug susceptibility test for second-line anti-TB drugs before the start of chemotherapy and during ≥ 2 months the degree of positive results (3 +, 2 +, 1 +) of microscopy and / or inoculation during the treatment of the intensive phase do not decrease;</p> <p>5) X-ray tomography before the start of chemotherapy, in the process of treatment with an interval of 2-3 months (more often according to indications);</p> <p>6) Mantoux test with 2 tuberculin units (test with recombinant tuberculosis allergen) before the start of chemotherapy for children, in the dynamics - according to indications.</p> <p>Standard treatment regimens in the mode of IV category.</p>	<p>dispensary registration of the TB medical organization within 1 year on the basis of documents from the territorial bodies of the Ministry of Internal Affairs, confirming the ineffectiveness of his search.</p> <p>The decision to re-register for IC group of the dispensary registration of patients, who previously violated the regimen, shall be taken by the centralized medical advisory committee.</p>
		1) Complete blood count, urinalysis, biochemical blood test - 1 time in half a year, according to	Transfer to group: 1) IC - when prescribing an effective treatment

I F	Patients with active tuberculosis who are not subject to specific treatment	Until cessation of bacterial excretion or determination of other tactics of treatment	indications - more often; 2) double microscopy and inoculation on solid media and X-ray studies - once every six months	regimen with new anti-TB drugs; 2) II - until the receipt of negative results of inoculation on dense media during the last 2 years.
The second group (II) - inactive tuberculosis				
II	Persons with inactive tuberculosis who have a "cured" or "treatment completed" outcome	1 year - with small residual changes	Examination 2 times a year (complete blood count, urinalysis, sputum microscopy, inoculation on dense media, X-ray tomography). Additional methods of examination according to indications.	Removal from the register
		2 years - with large residual changes		
The third group (III) - persons with an increased risk of tuberculosis				
III A	Contact with TB patient.	The entire contact period and 1 year after effective chemotherapy of the patient	Examination 2 times a year (laboratory, clinical and radiological studies). Children - Mantoux test with 2 tuberculin units, recombinant tuberculous allergen test. Persons with a negative Mantoux test with 2 tuberculin units during the initial examination, the test is repeated after 8-10 weeks. Additional diagnostic methods according to indications.	Removal from the register. Transfer to group IA - when active tuberculosis is detected.
	Children in contact with patients with active tuberculosis, regardless of bacteria excretion			
	From previously unknown foci of death from tuberculosis	1 year		

III B	Mycobacterium tuberculosis infection, newly diagnosed	1 year	<p>During registration and deregistration - general urine analysis, complete blood count, a Mantoux test with 2 tuberculin units, a recombinant tuberculosis allergen test and an x-ray examination. Microscopy of sputum according to indications. Chemoprophylaxis regimen - according to the order.</p>	<p>Removal from the register. Transfer to group IA - when active tuberculosis is detected.</p>
III C	Adverse reactions to the injection of Calmette-Guerin Bacillus	1 year	<p>During registration and deregistration - general urine analysis, complete blood count, a Mantoux test with 2 tuberculin units, a recombinant tuberculosis allergen test, Ultrasound examination of peripheral (axillary) lymph nodes and X-ray examination. Consultation of extra-pulmonary tuberculosis specialist. The regimen of chemoprophylaxis - according to the methodical recommendations "Management of cases with adverse reactions to BCG vaccination."</p>	<p>Removal from the register.</p>

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