On approval of the Rules of Forming the List of Medicinal Products and Medical Devices for Free and (or) Preferential Outpatient Provision for Certain Categories of Citizens of the Republic of Kazakhstan with Certain Diseases (Health Conditions)

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan No. KR DSM-68 of July 29, 2021. Registered with the Ministry of Justice of the Republic of Kazakhstan on July 30, 2021 under No. 23783

Unofficial translation

Under paragraph 131 of the Rules for the Organisation and Procurement of Medicinal Products, Medical Devices and Specialised Therapeutic Products within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, pharmaceutical services, approved by Decree of the Government of the Republic of Kazakhstan No. 375 of June 4, 2021, **I HEREBY ORDER:**

1. That the attached Rules of Forming the List of Medicinal Products and Medical Devices for Free and (or) Preferential Outpatient Provision for Certain Categories of Citizens of the Republic of Kazakhstan with Certain Diseases (Health Conditions) shall be approved.

2. That, as per the procedure established by law, the Department of Drug Policy of the Ministry of Health of the Republic of Kazakhstan shall provide:

1) the state registration hereof with the Ministry of Justice of the Republic of Kazakhstan;

2) placement hereof on the website of the Ministry of Health of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration hereof with the Ministry of Justice of the Republic of Kazakhstan, submission to the Legal Department of the Ministry of Health of the Republic of Kazakhstan of information on the implementation of measures under sub-paragraphs 1) and 2) of this paragraph.

3. That the Supervising Vice-Minister of Health of the Republic of Kazakhstan shall be in charge of the execution hereof.

4. That this order shall be put into effect ten calendar days after the date of its first official publication.

Minister of Health
of the Republic of Kazakhstan *A. Tsoy*

Approved
by Order of the Minister of Health
of the Republic of Kazakhstan
No. KR DSM-68 of July 29, 2021

Rules of Forming the List of Medicinal Products and Medical Devices for Free and (or) Preferential Outpatient Provision for Certain Categories of Citizens of the Republic of Kazakhstan with Certain Diseases (Health Conditions)

Chapter 1. General provisions

1. These Rules for Forming the List of Medicinal Products and Medical Devices for Free and (or) Preferential Outpatient Provision for Certain Categories of Citizens of the Republic of Kazakhstan with Certain Diseases (Health Conditions) (hereinafter – the Rules) have been developed under paragraph 131 of the Rules for the Organisation and Procurement of Medicinal Products, Medical Devices and Specialised Therapeutic Products within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, pharmaceutical services approved by Decree of the Government of the Republic of Kazakhstan No. 375 of June 4, 2021 and establish the procedure for forming a list of medicines and medical devices for free and (or) preferential outpatient provision of certain categories of citizens of the Republic of Kazakhstan with certain diseases (health conditions) (hereinafter - the list of outpatient drug provision).

2. Basic terms used herein:

1) competent authority in the field of health care (hereinafter referred to as the competent authority) - the central executive body responsible for management and inter-sectoral coordination in the field of health protection of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines and medical devices, quality of medical services (aid);

2) medicinal product - a medicinal product that is or contains a substance or combination of substances that comes into contact with the human body, intended to treat, prevent human diseases or restore, correct or change their physiological functions through pharmacological, immunological or metabolic effects, or to diagnose diseases and the human condition;

3) state expert organisation in the field of circulation of medicinal products and medical devices - state monopoly entity performing production and economic activities in the field of health care to ensure safety, efficiency and quality of medicinal products and medical devices (hereinafter - the state expert organisation);

4) international nonproprietary name of the medicinal product - the name of the medicinal product recommended by the World Health Organisation;

5) clinical protocol - scientifically proven recommendations for prevention, diagnosis, treatment, medical rehabilitation and palliative care for a particular disease or health condition of a patient;

6) the list of medicinal products and medical devices for free and (or) preferential outpatient provision for certain categories of citizens of the Republic of Kazakhstan with

certain diseases (conditions) – the list of medicinal products, medical devices and specialised therapeutic products procured from the budget and (or) assets of the Social Medical Insurance Fund as part of a guaranteed volume of free medical care and (or) in the system of compulsory social medical insurance when providing primary health care and specialised medical care in outpatient care, comprising the names and characteristics of medicinal products, medical devices and specialised therapeutic products broken down by certain categories of citizens of the Republic of Kazakhstan with certain diseases (health conditions);

7) Kazakhstan National Drug Formulary - a list of medicinal products with proven clinical safety and effectiveness, as well as orphan (rare) drugs, serving as a compulsory basis for the development of drug formularies of medical organisations and the formation of lists of procurement of the medicinal products within the guaranteed volume of free medical care and (or) in the compulsory social health insurance system;

8) medical devices - medical products and medical equipment;

9) compulsory social health insurance - a complex of legal, economic and organisational measures to provide medical aid to consumers of medical services financed by the assets of the social health insurance fund;

10) guaranteed volume of free medical care - the volume of medical aid provided out of budgetary funds.

3. The list of outpatient medication coverage shall comprise the names of diseases and categories of citizens subject to free and/or preferential provision of medicinal products, medical devices and specialised therapeutic products, indications for prescription of medicinal products and the names of medicinal products, medical devices and specialised therapeutic products specifying their characteristics.

4. The name of diseases shall be formed with the coding of the International Statistical Classification of Diseases and Problems (hereinafter - ICD-10), the name of medicinal products with the anatomical-therapeutic-chemical (ATC) code of the classification of medicinal products.

Chapter 2. The order of formation of the list of medicinal products and medical devices for free and (or) preferential outpatient provision of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions)

5. Diseases shall be added to the list of outpatient drug coverage in the presence of:

1) the list of socially significant diseases approved by Order No. KR DSM-108/2020 of the Minister of Health of the Republic of Kazakhstan dated September 23, 2020 (recorded in the Registry of State Registration of Regulatory Legal Acts under No. 21263);

2) the list of chronic diseases that are subject to dynamic monitoring, approved by Order No. KR DCM-109/2020 of the Minister of Health of the Republic of Kazakhstan dated September 23, 2020 (recorded in the Registry of State Registration of Regulatory Legal Acts under No. 21262);

3) the list of orphan diseases, approved by Order No. KR DSM-142/2020 of the Minister of Health of the Republic of Kazakhstan dated October 20, 2020 (recorded in the Registry of State Registration of Regulatory Legal Acts under No. 21479);

4) a clinical protocol for indications for medical use of a medicinal product or medical device for providing medical care in outpatient care.

6. Categories of citizens and indications for prescribing medicinal products shall be established as per epidemiological data on the prevalence of disease (condition) in certain categories of population based on the analysis provided by the subordinate organisation of the competent authority, responsible for health technology assessment issues (hereinafter referred to as the Centre).

7. The procedure for inclusion of the medicinal products and medical devices in the list of outpatient pharmaceutical provision shall include the following:

1) submission of an application by the manufacturer or its official representative in the Republic of Kazakhstan (hereinafter referred to as the applicant) to the Centre;

2) professional expertise by the Centre;

3) preparation of a professional expert opinion by the Centre for the Formulary Commission;

4) consideration and decision-making by the Formulary Commission based on the conclusions of the professional appraisal;

5) establishment of an outpatient pharmaceutical provision list by the competent authority.

8. The applicant shall submit an application to the Centre in the form laid down in Annex 1 hereto.

The application shall be drawn up in Kazakh or Russian and signed by the applicant's authorised representative.

The application shall be accompanied by:

1) the dossier drawn up as per the form prescribed in Annex 2 hereto;

2) materials (articles, summaries, from scientific and medical publications) supporting the information contained in the dossier in its original language in full texts, translated into Kazakh or Russian.

The materials referred to in this paragraph shall be provided in hard copy and electronically in two copies.

The package of documents submitted on paper shall be lined and the pages shall be numbered. On the reverse side of the last page the following entry shall be made: “In total ___ pages, numbered ___ pages”, that shall be certified by the signature of the applicant's authorised person.

9. Upon receipt of the materials specified in paragraph 8 hereof, the Centre shall verify the completeness and correctness of the submitted documents, within a period not exceeding 5 (five) working days.

Following the results of the inspection, the Centre shall prepare a statement indicating the observations made (if any) in the form laid down in Annex 3 hereto, to be forwarded to the applicant within ten (10) working days for the elimination of the observations.

If the applicant fails to submit the requested material or written justification within ten (10) working days as part of the remedial action, the Centre shall discontinue consideration of the application and the dossier for inclusion on the outpatient pharmaceutical provision list.

If the documents submitted are complete and correct, or if the observations are rectified within ten (10) working days, the materials shall be submitted for professional expertise.

10. The Centre shall undertake the professional examination within a period not exceeding forty (40) working days under a contract concluded with the applicant as provided by civil law.

11. In the course of the professional examination, the following examinations shall be performed by the Centre within the time limits laid down in paragraph 10 hereof:

1) the availability of the medicinal product in the Kazakhstan National Formulary approved under sub-paragraph 46) of Article 7 of the Code;

2) the availability of an approved reference price for a medicinal product, considering the dosage form, dose, concentration and volume, or the technical specification of a medical product under the guaranteed volume of free medical care (GVFMC) and/or the Compulsory Social Health Insurance (CSHI) approved under paragraph 3 of Article 245 of the Code;

3) availability of the anatomical-therapeutic-chemical (ATC) classification code;

4) compliance of the international non-proprietary name of the medicinal product and its dosage form or the technical specifications of the medical device and its packaging and performance characteristics with the State Register of Medicinal Products and Medical Devices;

5) compliance of the indications for medical use of the medicinal product or medical device with the clinical protocols for which medicinal products and medical devices are recommended for outpatient medical care, and the instructions for medical use of the medicinal product or medical device;

6) availability of the medicinal product in international evidence-based medicine data sources and international clinical guidelines;

7) the presence of clinical and/or clinical-economic (pharmaco-economic) advantage or equivalence of a medicinal product or medical device over the medicinal products or medical devices available on the list of outpatient pharmaceutical provision when treating a particular disease or condition at the outpatient level in the health care context of the Republic of Kazakhstan.

12. Based on the results of the professional expertise, within no more than 5 (five) working days, the Centre shall prepare a conclusion in the form specified in Annex 4 hereto accompanied by the supporting documents referred to in subparagraphs 1), 2), 3), 4), 5), 6), 7) of paragraph 11 hereof (hereinafter - conclusion).

13. The Formulary Commission shall examine the opinion submitted by the Centre and shall assess the conformity of the medicinal product with sub-paragraphs 1), 2), 3), 4), 5), 6), 7) or the medical device with sub-paragraphs 2), 3), 4), 5), 6), 7) of paragraph 11 hereof, in the light of which the decision on the inclusion of the medicinal product or medical device in the list of outpatient pharmaceutical provision shall be taken.

14. When a medicinal product included in the List of Essential Medicinal Products of the World Health Organisation for the treatment of a socially significant disease, the list whereof is established under subparagraph 158) of paragraph 1 of Article 1 of the Code, the Formulary Commission may consider the inclusion of a medicinal product or medical device in the List of Outpatient Pharmaceutical Provision upon the initiative of the competent authority.

15. A decision to exclude medicinal products, medical devices and specialised therapeutic products from the list of outpatient pharmaceutical provision shall be considered by the Formulary Commission upon the initiative of the competent authority if one of the following grounds exists:

1) exclusion of a medicinal product, with reference to the dosage form, from the KNF (Kazakhstan National Drug Formulary);

2) the inclusion of alternative medicinal products and medical devices with proven clinical and/or pharmacoeconomic advantages and/or patterns of action and/or greater safety in the diagnosis, prevention, treatment or rehabilitation of diseases, syndromes and conditions ;

3) if there is evidence of toxicity or a high incidence of undesirable side-effects from the use of medicinal products and medical devices provided by the public authority responsible for the circulation of medicinal products and medical devices;

4) suspension of the use of medicinal products and medical devices of specialised therapeutic products in the Republic of Kazakhstan by decision of the public authority in the field of circulation of medicinal products and medical devices;

5) cancellation of state registration of medicinal products and medical devices by a decision of public authorities in the field of circulation of medicinal products and medical devices;

Annex 1
to the Rules of Forming the List of
Medicinal Products and Medical
Devices for Free and (or)
Preferential Outpatient Provision
for Certain Categories of Citizens
of the Republic of Kazakhstan
with Certain Diseases
(Health Conditions)
Document form

Application for inclusion of a medicinal product or medical device in the list of medicinal products and medical devices for free and/or preferential outpatient provision for certain categories of citizens of the Republic of Kazakhstan with certain diseases (health conditions)

1. Information about the applicant:

1) name of organisation;

2) Full name of the person in charge, position;

3) location of the applicant organisation (legal address, actual address);

4) BIN, bank details;

5) telephone and/or fax number;

6) e-mail:

2. General information on the claimed medicinal product (hereinafter referred to as the medicine) or medical device (hereinafter referred to as the medical device) as per the State Register of Medicinal Products and Medical Devices:

1) trade name of the medicinal product or medical device;

2) the international non-proprietary name of the medicinal product or the technical specification of the medical device or the composition of the medicinal product (active ingredients and excipients) or the kit of the medical device proposed for inclusion;

3) dosage form and dose, drug concentration or performance characteristics of the medical device;

4) pharmacotherapeutic group of medicinal products and ATC code or type of medical device, as per the Global Medical Device Nomenclature (GMDN);

5) information on the state registration of the claimed medicinal product or medical device in the Republic of Kazakhstan (date and number of the registration certificate shall be indicated; a copy of the registration certificate shall also be attached to the application);

6) the mode of administration of the medicinal product or the conditions of use of the medical device.

3. Information for inclusion of a medicinal product or medical device in the outpatient pharmaceutical provision list:

1) the stated indication (disease or condition) and target group of patients (category of citizens) to be included in the list of outpatient pharmaceutical provision;

2) availability of a medicinal product or medical device in the Kazakhstan National Drug Formulary;

3) approved ceiling price of a medicinal product, considering dosage form, dose, concentration and volume, or the medical device, depending on the packaging and performance characteristics, under the GVFMC and/or CSHI system;

4) the applicant's proposals regarding the possibility of cost or risk-sharing arrangements and possible discounts and/or schemes to ensure patient accessibility;

If the dossier includes confidential information, it shall be indicated which information is confidential and justification shall be provided for the confidential nature of the information.

Position of the applicant's authorised person _____ Signature

Full name _____ Date _____

Notes:

Notes: The application shall not exceed 5 pages and shall be based on a summary of the information in the dossier.

Annex 2
to the Rules of Forming the List of
Medicinal Products and Medical
Devices for Free and (or)
Preferential Outpatient Provision
for Certain Categories of Citizens
of the Republic of Kazakhstan
with Certain Diseases
(Health Conditions)
Document form

Dossier of medicinal product or medical device for inclusion in the list of medicinal products and medical devices for free and/or preferential outpatient provision for certain categories of citizens of the Republic of Kazakhstan with certain diseases (health conditions)

1. Information on a medicinal product (hereinafter referred to as a medicinal product) or a medical device (hereinafter referred to as a medical device) as per the State Register of Medicinal Products and Medical Devices:

1) trade name of the medicinal product or medical device:

2) international non-proprietary name of the medicinal product or the technical specification of the medical device or the composition of the medicinal product (active ingredients and excipients) or the kit of the medical device proposed for inclusion:

3) dosage form and dose, concentration of the medicinal product or performance characteristics of the medical device:

4) the pharmacotherapeutic group of the medicinal product and the anatom-therapeutic-chemical code (hereinafter referred to as ATC) code or type of medical device, in accordance with the Global Medical Device Nomenclature (GMDN):

5) information on the state registration of the claimed medicinal product or medical device in the Republic of Kazakhstan (date and number of the registration certificate shall be indicated; a copy of the registration certificate shall also be attached to the application):

6) the mode of administration of the medicinal product or the conditions of use of the medical device.

2. Information:

1) on the availability of medicinal products in the Kazakhstan National Drug Formulary;

2) on the availability of an approved ceiling price for a medicinal product, given the dosage form, dose, concentration and volume, or the medical device, given the package and performance characteristics, under the GVFMC and/or CSHI system.

3. List of trade names of medicinal products or medical devices registered in the territory of the Republic of Kazakhstan with similar international non-patented name of the medicinal product, with regard to dosage form, dose, concentration and volume, or technical characteristics of the medical device with regard to the set and operational characteristics (as per the State Register of Medicinal Products and Medical Devices at the time of application submission):

4. Justification of the applicant's proposals regarding the possibility of an agreement on cost or risk sharing and possible discounts and/or schemes to ensure patient accessibility:

5. Information on the efficiency and safety of the medicinal product or medical device for the indications provided, in line with the clinical protocols under which the product or medical device is recommended for outpatient medical care, as per the instructions for medical use of the product or medical device (a copy of the instructions for medical use of the product or medical device shall be attached to the application):

6. Data on epidemiology and disease burden among the target patient cohort and details on the potential impact of the medicinal product or medical device in use, data on the clinical, economic and social clinical, economic and social value of the medicinal product or medical device, and the use of the product or medical device reflecting the actual experience of patients (where available):

7. Evidence of clinical and/or clinical-economic (pharmacoeconomic) advantage or equivalence of a medicinal product or medical device over existing medicinal products or medical devices with similar indications on the outpatient pharmaceutical provision list:

8. Details of the impact of the medicinal product or medical device on the burden of disease and the public health budget, including centralised purchasing.

* Materials (articles, summaries, from scientific and medical publications) supporting the efficacy and safety of the medicinal product shall be attached to the dossier in the form of annexes. These materials shall be filed in their original language as complete texts, with abstracts translated into Kazakh or Russian. Submissions in the original language other than English shall be accompanied by a translation into Kazakh or Russian. Translations of materials shall be certified by signature.

Annex 3
to the Rules of Forming the List of
Medicinal Products and Medical
Devices for Free and (or)
Preferential Outpatient Provision
for Certain Categories of Citizens
of the Republic of Kazakhstan
with Certain Diseases
(Health Conditions)

Document form

Opinion on verification of the application and dossier for inclusion of a medicinal product or medical device in the list of medicinal products and medical devices for free and/or preferential outpatient provision for certain categories of citizens of the Republic of Kazakhstan with certain diseases (health conditions)

1. Information about the applicant:

1) name of organisation;

2) Full name of the person in charge, position;

3) location of the applicant organisation (legal address, de facto address);

4) telephone and/or fax number;

5) e-mail.

2. Data on the declared medicinal product (MP) or medical device (MD):

1) trade name of the medicinal product or medical device;

2) international non-proprietary name of the medicinal product or technical description of the medical device or composition of the medicinal product (active ingredients and excipients) or the kit of the medical device proposed for inclusion;

3) dosage form and dose, medicinal product concentration or performance characteristics of the medical device;

4) pharmacotherapeutic group and ATC code or type of medical device, according to the Global Medical Device Nomenclature (GMDN);

5) information on the state registration of the claimed medicinal product or medical device in the Republic of Kazakhstan (date and number of the registration certificate shall be indicated; a copy of the registration certificate shall also be attached to the application);

6) the mode of administration of the medicinal product or the conditions of use of the medical device.

3. An opinion on the completeness and correctness of the documents submitted:

1) assessment of the completeness of the documents and materials submitted;

2) assessment of the layout of the application and the materials submitted;

3) assessment of the submission of information under paragraph 8 hereof;

4) consistency between the application and the paper-based and electronic materials.

4. Comments

Annex 4
to the Rules of Forming the List of
Medicinal Products and Medical
Devices for Free and (or)
Preferential Outpatient Provision
for Certain Categories of Citizens
of the Republic of Kazakhstan
with Certain Diseases
(Health Conditions)
Document form

Opinion of professional expertise for inclusion of a medicinal product or medical device in the list of medicinal products and medical devices for free and (or) preferential outpatient provision for certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions)

1. Information about the applicant:

1) name of organisation;

2) Full name of the person in charge, position;

3) location of the applicant organisation (legal address, de facto address);

2. Data on the declared medicinal product (MP) or medical device (MD):

1) trade name of the medicinal product or medical device;

2) international non-proprietary name of the medicinal product or technical description of the medical device or composition of the medicinal product (active ingredients and excipients) or the kit of the medical device proposed for inclusion;

3) dosage form and dose, medicinal product concentration or performance characteristics of the medical device;

4) pharmacotherapeutic group and ATC code or type of medical device, according to the Global Medical Device Nomenclature (GMDN);

5) information on the state registration of the claimed medicinal product or medical device in the Republic of Kazakhstan;

6) the mode of administration of the medicinal product or the conditions of use of the medical device.

3. Opinion on the results of the professional review for inclusion in the outpatient pharmaceutical provision list:

The results of the analysis of the medicinal product submitted by the applicant and/or found by the applicant's own application review organisation:

1) information on the availability of the medicinal product in the Kazakhstan National Formulary;

2) information on the availability of an approved reference price for a medicinal product, including dosage form, dose, concentration and volume, or a medical device, including packaging and performance characteristics, under the GVFMC and/or CSHI system;

3) availability in the clinical protocols of the Republic of Kazakhstan;

4) In the international evidence-based medicine data sources and international clinical guidelines:

In the British National Formulary and/or the British National Formulary for Children (year of manufacture) _____

_____

_____

In the Cochrane Library (scientific publications database)

_____

_____

(describe in detail the availability of systematic reviews (hereinafter referred to as SRs), meta-analyses, randomised controlled clinical trials (hereinafter referred to as RCTs) indicating reference to SRs, RCTs,CTs)

In the WHO List of Essential Medicines (month and year of manufacture)

_____

_____

At the European Medicines Agency _____

_____

At the Food and Drug Administration of the United States of America _____ _____

_____

In Medline (PubMed) (electronic database of scientific publications)

_____

_____

(if no data are available in the Cochrane Library, describe in detail the availability of systematic reviews, meta-analyses, RCTs with reference to SRs, RCTs, CTs)

In the British Medical Journal Best Practice _____

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_____

At the UK National Institute of Health and Medical Excellence

_____

_____

Use other credible sources of international clinical guidelines where appropriate:

5) Results of a cost-benefit analysis of the medicinal product as per the applicant's application:

Analysis criteria	Analysis result	Percentage of deviation
1. The reported cost of a course/ application or annual treatment (diagnosis, rehabilitation, etc.) of a medicinal product	above the cost of the reference medicinal product	
	corresponds to the cost of the reference medicinal product	
	lower than the cost of the reference medicinal product	
Analysis by scale of assessment of costs presented		
2. Cost-effectiveness benefits of the medicinal product compared to the reference medicinal product	the use of the medicinal product leads to a reduction in the overall cost of health care (budgetary impact)	
	the use of the medicinal product does not increase the overall cost of health care (budgetary impact)	

	the use of the medicinal product requires an increase in the total cost of health care under the state guarantee programme for free health care (budgetary impact)	

6) Results of analysis of other data on the applicant's application:

Analysis criteria	Compliance
The need for the use of medicinal products for the diagnosis, prevention, treatment or rehabilitation of diseases (health conditions) that prevail in the morbidity and mortality patterns of the citizens of the Republic of Kazakhstan (for inpatient, hospital-replacement and emergency care) and those managed at the outpatient level (for outpatient-polyclinic care) based on the statistical data provided in the application	
The need for medicinal products for the prevention, treatment and rehabilitation of socially significant diseases and diseases that pose a risk to others, managed at the outpatient level	
The need for medicinal products for the prevention, treatment and rehabilitation of exclusively orphan (rare) diseases managed at the outpatient level	
Availability of reproduced medicinal products registered in the Republic of Kazakhstan	
Availability of confirmation from an expert body of data on therapeutic equivalence and/or bioequivalence for generic medicinal products with a similar pharmacological mechanism of action for the treatment of a specific disease (health condition)	
Availability of analogues in the List	

7) Application analysis and conclusions on the clinical and cost-effectiveness of the medicine:

_____

_____

_____.

Composition of experts (surname, first name, patronymic (if any), position)

_____

_____;

Signatures and printed indication of the head of the organisation that performed the analysis:

_____

(Surname, first name, patronymic (if any) of the head of the organisation)