On approval of the Rules for healthcare technology assessment

Invalidated Unofficial translation

Order of the acting Minister of Healthcare of the Republic of Kazakhstan No. KR DCM85 as of May 22, 2019. Registered with the Ministry of Justice of the Republic of Kazakhstan on May 23, 2019, No. 18717. Abolished by the Order of the Minister of Health of the Republic of Kazakhstan dated November 30, 2020 No. KR DSM-215/ 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-215/2020 (effective after ten calendar days after the date of its first official publication).

In accordance with paragraph 2 of Article 64-1 of the Code of the Republic of Kazakhstan "On Public Health and the Healthcare System" as of September 18, 2009, I hereby ORDER:

1. To approve the appended Rules for healthcare technology assessment.

2. In accordance with the procedure established by the legislation of the Republic of Kazakhstan, the Medical Care Department of the Ministry of Healthcare of the Republic of Kazakhstan shall:

1) ensure state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) within ten calendar days of the state registration of this order, send its copy in Kazakh and Russian in paper-based and electronic forms to the Republican State Enterprise with the Right of Economic Management "Republican Center of Legal Information" of the Ministry of Justice of the Republic of Kazakhstan for its official publication and inclusion into the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan;

3) place this order on the website of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

4) within ten working days of the state registration of this order, submit information about the implementation of measures, provided for in subparagraphs 1), 2) and 3) of this paragraph, to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan.

3. The control over the execution of this order shall be assigned to the supervising deputy minister of healthcare of the Republic of Kazakhstan.

4. This order shall take effect ten calendar days of its first official publication.

Approved by
Order № KR DCM-85 as of May 22, 2019
of the acting Minister of Healthcare of the
Republic of Kazakhstan

Rules for healthcare technology assessment

Chapter 1. General provisions

1. These Rules for healthcare technology assessment (hereinafter referred to as the Rules) are developed in accordance with paragraph 2 of Article 64-1 of the Code of the Republic of Kazakhstan “On Public Health and the Healthcare System” as of September 18, 2009 (hereinafter referred to as the Code) to regulate relations connected with the assessment of healthcare technologies in the Republic of Kazakhstan, including the stages of filing an application, its consideration and making a decision to assess healthcare technology, which will scientifically substantiate the adoption of a decision to introduce and use, and (or) to inhibit the use of healthcare technology.

2. The following terms are used in the Rules:

1) a healthcare organization - a legal entity operating in the field of healthcare;

2) the authorized body for healthcare (hereinafter referred to as the authorized body) - the central executive body exercising the leadership and intersectoral coordination in the field of public health, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, turnover of pharmaceuticals and medical devices, quality control of medical services;

3) healthcare technology assessment (hereinafter referred to as the HTA) - comprehensive assessment of the comparative proven clinical and clinical-economic (pharmacoeconomic) effectiveness and safety of healthcare technologies, as well as economic, social and ethical implications of their use;

3. The HTA objects are healthcare technologies proposed for entering in (removal from) the lists of compensation within the guaranteed volume of free medical care (hereinafter referred to as the GVFMC) or in the system of compulsory social health insurance (hereinafter referred to as the CSHI).

4. The HTA working body is an organization subordinate to the authorized body, which organizes and implements HTA (hereinafter referred to as the working body).

Chapter 2. HTA procedure

5. The HTA main objectives are as follows: assessment of the clinical and clinical-economic effectiveness and safety of healthcare technologies, as well as economic, social and ethical implications of their use for the healthcare system.

6. A HTA requester (hereinafter referred to as the applicant) can be either:

1) the authorized body, or

2) CSHI fund, or

3) healthcare entities, or

4) entities in the field of turnover of pharmaceuticals and medical devices, or

5) professional associations in the fields of healthcare and turnover of pharmaceuticals and medical devices.

7. HTA is carried out at the national and regional levels, as well as at the level of healthcare organization to identify priority technologies.

8. The main objectives of identifying priority technologies for HTA are as follows:

1) the HTA shall meet the needs of the healthcare system;

2) efficient use of budgetary funds and assets of the social health insurance fund;

3) the process of selecting priority technologies shall be open and transparent.

9. Priority technologies are identified by the working body; depending on the results of this identification, the working body prioritizes technologies for conducting HTA within a state order.

10. The HTA of non-priority technologies is carried out by applicants or the working body, and also by legal entities and individuals in accordance with paragraph 3 of Article 57 of the Code of the Republic of Kazakhstan "On Public Health and the Healthcare System" as of September 18, 2009, under a relevant agreement.

11. HTA-associated costs shall be borne by the applicant, unless healthcare technology is included in the list of priority technologies and its HTA is carried out within a state order.

12. The HTA result is the HTA report sent to the applicant after its completion, which shall contain the following information:

1) the epidemiology and burden of a disease, for which the healthcare technology is used;

2) current approaches to medical care (standard medical care) for a disease, for which the healthcare technology is used, and their limitations;

3) review of the healthcare technology in the field of its application;

4) comparative analysis of clinical research data on the healthcare technology in the field of its application;

5) review of recommendations on the healthcare technology in the field of its application in foreign clinical guidelines and reports on the assessment of the healthcare technology in the field of its application;

6) analysis of the results of foreign economic studies of the healthcare technology in the field of its application;

7) clinical analysis based on the critical assessment of evidence;

8) economical evaluation;

9) assessment of financial implications of the introduction and dissemination of the healthcare technology at the level of the healthcare system;

10) ethical considerations and social aspects of the use of the healthcare technology in the field of its application (if applicable);

11) analysis of prospects for the healthcare technology in the field of its application from the perspective of the healthcare system.

13. HTA reports on priority technologies conducted by legal entities and individuals shall be sent to the working body for quality assessment.

14. The quality of the HTA report is assessed according to the checklist provided for in Appendix 1 to these Rules and an opinion shall be drawn up based on the results of the quality assessment of the HTA report.

15. The HTA report and positive opinion of the working body based on the results of the quality assessment of the HTA report are submitted to the Joint Commission for the Quality of Medical Services (hereinafter referred to as the JCQ) established by the Regulation on the JCQ activities approved by Order No. 614 of the Minister of Healthcare of the Republic of Kazakhstan as of August 17, 2017 "On approval of the Rules for the establishment of a joint commission for the quality of medical services and the Regulation on its activities" (registered in the State Registration Register of Regulatory Legal Acts under No. 15671).

16. After the HTA completion, the working body shall enter the application, the HTA report and the JCQ decision into the HTA electronic database and post it on the official website.

Clause 1. Procedure for assessing healthcare technologies at the national level

17. At the national level, the HTA is carried out in order to scientifically substantiate the entering (removal) of health technologies in (from) the lists of compensation under the GVFMC or CSHI.

18. To conduct the HTA at the national level, as part of a state order, the authorized body, together with the working body, shall identify priority technologies for conducting the HTA.

19. The list of priority healthcare technologies for conducting the HTA at the national level within the state order (hereinafter referred to as the list of priority technologies) shall be approved by the JCQ decision.

20. The types and methods of HTA are as follows:

1) brief review of the effectiveness and safety of healthcare technology (brief review);

2) economical evaluation;

3) full-HTA;

4) mini-HTA;

5) multi-criteria decision analysis.

21. The rules for a brief review of the effectiveness and safety of health technology are as follows:

1) brief review is carried out in order to promptly provide scientific evidence of the proven clinical and clinical-economic effectiveness and safety of healthcare technologies, for making a clinical (political) decision;

2) brief review of each technology is carried out by two experts simultaneously, independently of one another;

3) brief review is carried out within 30 working days.

22. The rules for conducting economical evaluation are as follows:

1) economical evaluation is the comparison of the healthcare technology under assessment with similar healthcare technologies included in the compensation list in terms of cost and health implications, and identification of advantages of one technology over another;

2) economical evaluation is carried out by at least two experts;

3) the duration of economic analysis depends on the complexity of healthcare technology, and also on the choice of the method of economical evaluation (cost-effectiveness analysis, cost-utility analysis, modeling) and ranges from 2 (two) to 8 (eight) months.

23. The rules for conducting a full-HTA are as follows:

1) full-HTA includes all of the above assessment methods. Within a full HTA, it is only allowed to assess ethical, organizational, social and legal aspects of introduction of technologies under assessment;

2) because of their input intensity and significant investment of financial resources, full HTA reports are mainly used to determine and formulate health policies (national screening programs, vaccination programs);

3) full HTA is conducted by a working group of at least three HTA experts;

4) the duration of a full HTA is at least 9 (nine) months.

24. The rules for conducting a mini-HTA are as follows:

1) when conducting a mini-HTA, the technology is assessed from the point of its effectiveness and safety, it is necessary to provide information on the costs and financial impact of introduction of the technology under assessment;

2) a mini-HTA is conducted by a working group of at least two HTA experts;

3) the duration of a mini-HTA is from 2 (two) to 4 (four) months.

25. The rules for making multi-criteria decision analysis are as follows:

1) multi-criteria analysis can be additional to other types of HTA, and also used as an independent assessment method;

2) multi-criteria analysis is carried out by two experts simultaneously, independently of one another;

3) multi-criteria analysis is carried out within 30 (thirty) working days.

26. The rules for submitting a HTA application are as follows:

1) the applicant submits an application for conducting the HTA and materials in written and electronic forms to the working body or legal entity, in accordance with the requirements in Appendix 2;

2) the working body or legal entities check the completeness of the submitted documents and request additional materials and documents;

3) in case of submission of an incomplete set of documents as required by the rules for the formation and submission of an application, or discovery of false information, it is necessary to send a reasoned refusal to conduct HTA to the applicant within 10 (ten) working days of the application's submission;

4) the working body or legal entities conduct the HTA within the time frames specified in these Rules;

5) in the course of the HTA, the working body or legal entities request additional explanations or clarifications from the applicant about specific provisions in the submitted documents and materials;

6) the HTA time frame is suspended for the time of submission of requested documents by the applicant. The time frame for addressing concerns by the applicant is not included in the HTA time frame;

7) the working body or legal entities terminate the HTA in case of a failure to provide a complete set of documents or to address concerns at the HTA stage;

8) based on the HTA result, a report is prepared in accordance with the form in Appendix 3 to these Rules.

27. The HTA report is considered at a regular JCQ meeting.

28. Based on submitted materials, the JCQ makes one of the following decisions:

1) to approve the healthcare technology for use with a recommendation to either enter or not to enter it in the compensation lists;

2) to refuse to approve the use of the healthcare technology and enter it in the compensation lists giving the rationale for the refusal.

29. Applications for conducting the HTA, with regard to which the JCQ has decided to refuse to enter the healthcare technology in the compensation lists, shall be re-submitted by applicants after new data are presented that give evidence to clinical effectiveness, safety and cost-effectiveness of the technology, but not earlier than two years of the JCQ decision.

30. The JCQ decision is documented in the minutes and published on the official website of the authorized body within 10 (ten) working days.

31. In case of a positive JCQ decision, the applicant makes preliminary calculations of the cost of the technology, agrees them with the compulsory health insurance fund and submits them to the budget commission of the authorized body.

32. With account of the amount of financial resources available for an ensuing year , the budget commission of the authorized body takes one of the following decisions:

1) to approve the entering of the healthcare technology in the compensation lists indicating the name;

2) to refuse to approve the entering of the healthcare technology in the compensation lists.

33. In case of a positive decision of the budget commission, the authorized body enters the technology into the compensation lists.

34. If the applicant disagrees with the JCQ decision based on the HTA results, it can appeal against it within one month by applying to the authorized body.

Clause 2. Procedure for conducting HTA at the regional level and at the level of a healthcare organization

35. To make decisions within the local budget, the Healthcare Department of a region, the capital, cities of republican significance (hereinafter referred to as the healthcare department) and (or) a healthcare organization shall:

1) identify the priority of healthcare technology;

2) select the type and method of HTA in accordance with paragraph 20 of Clause 1 of these Rules;

3) conduct HTA independently or involving legal entities or individuals in accordance with paragraph 10 of these Rules;

4) set up commissions of the healthcare department or healthcare organization to consider the HTA results.

36. At the regional level, the HTA is achieved by:

1) developing and introducing new healthcare technologies;

2) purchasing pharmaceuticals, medical devices, medical technical products and equipment for the provision of medical care within the GVFMC or in the CSHI system ;

3) developing documents regulating the volume and quality of medical care (standards for the provision of medical care, algorithms, lists, forms).

37. Based on the submitted materials, the commission of a healthcare department or healthcare organization takes one of the following decisions:

1) to approve the introduction and use of the healthcare technology;

2) to refuse to approve the introduction and use giving rationale for the refusal.

3) to enter in/remove from the purchase lists of pharmaceuticals, medical devices, medical technical products and equipment for the provision of medical care, also within the GVFMC or in the CSHI system;

4) to enter /remove healthcare technologies in/from documents regulating the volume and quality of medical care (standards for the provision of medical care, algorithms, lists, forms), also within the GVFMC or in the CSHI system.

38. The decision of the commission of a healthcare department or healthcare organization on the consideration of the HTA results is documented in the minutes within 10 (ten) working days.

39. In case of a positive decision of the commission, the applicant introduces the technology within the current local budget of the healthcare department and (or) healthcare organization.

40. The healthcare department organizes and performs the control, monitoring and analysis of the HTA process at the regional level and submits a report to the working body on an annual basis.

41. The working body makes annual analysis of the conducted HTAs at the regional level and submits it to the authorized body.

Appendix 1 to
the Rules for healthcare
technology assessment
Form

Checklist for assessing the quality of healthcare technology assessment reports

Title of the report	Reporting organization	Date of the report's submission

I. General aspects

Section	Sufficient	Partial	Insufficient
	5 points	3 points	1 point
1. Contact details are indicated for further communications.			
2. Information on experts involved in the preparation of the report and their qualifications			
3. Documented information on the presence or absence of a conflict of interest			
4. Data on sufficiency of the report's review			
5. Brief summary in a non-technical language known by broad audience			

Note:

Number of points in this section	Maximum	Total	Percent
	25		

II. Approaches

Section	Sufficient	Partial	Insufficient
	5 points	3 points	1 point
6. Need for assessment in terms of decision-making (			

MoH/CMIF) is substantiated and clearly stated			
7. Statement of the research purpose of conducting the assessment is methodically correct and substantiated			
8. Scope of the assessment is clearly defined			
9. Description of the healthcare technology properly represents its features			

Note:

Number of points in this section	Maximum	Total	Percent
	20		

III. Methodology

10. Data on information sources and literature search strategies are provided					
Search strategy	Trustworthy databases	Search period	Limitations of language	Primary sources	Other information sources

Note:

Complete list of studies included	List of excluded studies	Inclusion criteria	Exclusion criteria

11. Information based on the assessment and interpretation of individual data and information			
The method of data extraction is described	The critical assessment method is described (for assessing the quality of literature)	The data synthesis method is described	Assessment results are clearly presented, for example, in the form of proof tables

Note:

Number of points in this section	Maximum	Total	Percent
	70		

IV. Assessment aspects (some aspects may be ignored, depending on the HTA objectives)

Medical-legal implications	Economic analysis is presented	Ethical implications	Social implications	Other perspectives were considered (interested parties, patients, consumers)

Note:

Number of points in this section	Maximum	Total	Percent
	25 or (__)		

V. Resume

Section	Sufficient	Partial	Insufficient
	5 points	3 points	1 point

12. The opinion is worded clearly and comprehensibly			
13. The findings of the assessment are substantiated and supported by relevant data			
14. Suggestions for further action regarding the technology are available and stem from the opinion and conclusions			

Note:

Number of points in this section	Maximum	Total	Percent
	70		

"O"-marked cell indicators are rated on a scale of 5 to 1 points: 5 - fully consistent; 4 – consistent; 3-partly consistent; 2- inconsistent for many key points; 1 - fully inconsistent

Appendix 2 to
the Rules for healthcare
technology assessment
Form

Application for conducting healthcare technology assessment

Information on the applicant

Legal entity:	Individual:
Name of company: Surname, name, patronymic (if any) of the head: BIN: Surname, name, patronymic (if any) of the contact person for the issues related to the claimed healthcare technology:	Surname, name, patronymic (if any): IIN: ID number: Issued by and when:
Address:	
Telephone: Fax:	

E-mail

The objective of the healthcare technology assessment:

1) approval of the claimed healthcare technology;

2) inclusion of the claimed healthcare technology in the compensation lists;

3) other (indicate).

Information on the healthcare technology

1. Name of healthcare technology

2. Indication (s) for the use of the healthcare technology (indicating the code of the International Classification of Diseases, if applicable)

3. The burden of disease (condition), which is an indication for the use of the claimed technology in Kazakhstan (for example, morbidity and prevalence, mortality, incapacitation and disability, impact on quality of life) with links to sources

4. Target population (for example, patients with atrial fibrillation refractory to drug therapy)

5. Information on alternative healthcare technologies most frequently used (established clinical practice) for the claimed indication (s) (if available, indicate the code from the Tariff list for medical services within the guaranteed volume of free medical care and (or) the DRG list and (or) Types of high-tech medical services) indicating the cost with links to sources.

6. The claimed healthcare technology is offered in exchange for or in addition to current practice.

7. Brief description of the claimed healthcare technology (the essence of the technology, doses, frequency of use, technique, diagnostic criteria, sensitivity (for diagnostic methods).

8. How it will impact the healthcare system and (or) expected results: primary and secondary ones (increase in the disease detection rate or improvement of a therapy choice process or reducing side effects).

9. The need for the claimed technology (for example, the lack of alternative methods of treatment or the number of patients per year in need of the claimed technology)

10. Information on the registration of pharmaceuticals and medical devices (if applicable), number and term of the registration.

11. The advantages of the claimed technology.

12. The disadvantages and (or) limitations of the claimed technology.

13. Experience in the application of the claimed technology with links to sources according to the table:

Country	Research in progress or completed	Limited use	Widely applied	Recommended by clinical practice guidelines

Technology cost information

14. Technology costs according to the table (with links):

Salary costs for medical personnel + social contributions per unit of service	Consumables, pharmaceuticals, chemical agents, medical dressing, disposable supplies and medical services				
	name	unit of measurement	quantity	price, tenge	amount, tenge
Total					

15. Information on the full market value of the application of the claimed technology with the calculations.

16. The list of publications and (or) studies on the clinical effectiveness of the technology according to the table:

Study a	Level of evidence	Population b	Comparator	Outcome	Effect size with (95% CI and (or) p-value)

a. list of studies with titles, for example, Smith (2007) with links.

b. list of patients who can be included in the study and the number of patients included in the study.

c. cumulative effect (for example, the possibility of discrepancies in results, relative risk, odds ratio) of the impact of the new technology and the implications of an alternative treatment method, if any, or in the absence of comparative evidence, the effect without treatment or using placebo.

17. The list of publications and (or) studies (of technology safety) according to the table:

Study a	Level of evidence	Population b	Outcome c	New technology		Comparator	
				/Nc (%)	95% CI	/Nd (%)	95% CI

a. list of studies with titles, for example, Smith (2007) with links.

b. number of population and number of patients included in the study

c. list of major and minor side effects indicated in the studies

d. n= number of patients with results, N = number of patients included in the study

18. If the claimed technology is a diagnostic method according to the table:

Study a	Level of evidence and study design	Population b	Disease prevalence among the population under study	Link to study	Success rate (for example, sensitivity, specificity and accuracy) [95% CI]
Study 1					

a. list of studies with titles, for example, Smith (2007).

b. list of patients who can be included in the study and the number of patients included in the study

19. The results of the economical evaluation of the claimed technology.

20. The indirect and social costs of the new technology (for example, the time spent by the patient, the costs associated with delaying recovery). For diagnostic tests, it is important to include the treatment of false-positive cases, delays in the treatment of false-negative cases, and the treatment of complications of undetermined diseases.

Applicant: _____ I guarantee the accuracy and completeness of the information contained in the materials of the application for conducting the healthcare technology assessment

Date of completion: _____Signature of the Applicant * "____" _____ 20___
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Appendix 3 to
the Rules for healthcare
technology assessment
Form

Healthcare technology assessment report

The healthcare technology assessment report consists of the following details:
1) Front page:
name of the performing organization;
the report's title;
authors (position, specialty, academic rank);
name of the client organization (ministry, university, medical facility);
date of the report's completion (month, year).
2) Statement of conflicts of interest for authors and reviewers.
3) Brief information (structured, 1 page).
4) Resume (structured, 2-3 pages).
5) List of abbreviations and acronyms.
6) Table of Contents.
7) Chapter 1. Introduction:
purpose of the report;
research questions (PICO formula – Patient, Intervention, Comparison, Outcomes).
8) Chapter 2. Background:
description of the problem, including the use of epidemiological
data (morbidity, prevalence, etc.);
current situation in Kazakhstan (in the world);
description of the technology.
9) Chapter3. Clinical review: methods and results:
clinical effectiveness search strategy;
clinical review methods, including PICO and data;
results:
safety;
clinical effectiveness (efficacy).
10) Chapter 4. Economic review: methods and results:
economic effectiveness search strategy;
economic methods;
results:
published economic estimates;
economic calculations with account of Kazakhstan's data.

11) Chapter 5. Significance for the healthcare system:
psychological, social and ethical aspects;
organizational and professional implications;
economic implications: resource implications, budget impact analysis, etc.
12) Chapter 6. Discussion:
summary of the results and discussion of their relevance;
limitations of research and generalization of results
13) Chapter 7. Conclusions:
Appendix;
literature;
search strategies;tables and figures.

The volume of the report depends on the complexity of the technology under consideration.

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