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Analysis of actual results of drug supply implementation within framework of High-Cost Nosologies Program

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The accessibility and pharmaceutical care coverage are linked to political, economic and managerial decisions. That fact necessitates the evaluation of the state programs results in the field of the drug provision.

The aim of the work was to assess the quantitative results of the implementation of the High-Cost Nosologies program in the Russian Federation from 2008 to 2023 to determine further vectors of its improvement.

Materials and methods. The regulatory base of the work was made up of the Russian Federation legislation in the field of the drug provision. The open sources were used as the research information base for the data collection and analysis: reports of federal and regional executive authorities, materials of specialized conferences, results of published studies.

Results. The drug coverage under the High-Cost Nosologies (VZN) program is provided for 14 nosologies, 11 of which are classified as orphan diseases. Since its implementation, the HCNs program has been expanded twice by including new nosologies in 2019 and 2020. As of 01 October 2023, the number of patients in the Federal Register of VZN was 263 721 people, which was 13.58 times greater compared to 2008. The drug provision is carried out according to the list of 47 INNs. The amount of funding for the program increased from RUB 32 bn in 2008 to RUB 87.96 bn in 2023. The most resource-intensive nosologies include hemophilia, multiple sclerosis and oncohematology.

Conclusion. The main quantitative characteristics of the implementation of the VZN program and the identified vectors for its further improvement have been analyzed in this study. The results obtained can be used to conduct analytical studies, including the ones within nosologies and nosological groups included in the program, in order to optimize a pharmaceutical care. The focus of improving the implementation of the HCNs program is related to the improvement of the legal framework, a patient treatment paradigm and approaches to its financing.

Keywords: drug provision; list of expensive drugs; High-Cost Nosologies Program; evaluation of medical technologies

Abbreviations: VZN – high-cost nosologies; SRP – State Reimbursement Program; MNs – malignant neoplasms; MP – drug provision; FR – federal register; INN – international nonproprietary name; ODs – orphan diseases; VED – list of vital and essential drugs; MS – multiple sclerosis; BOL – budgetary obligations limit; SCs – state contracts.

Анализ фактических результатов реализации лекарственного обеспечения в рамках программы высокозатратных нозологий

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Доступность и охват фармацевтической помощью связаны с принятием политических, экономических и управленческих решений, что обуславливает необходимость оценки результатов государственных программ в сфере лекарственного обеспечения.

Цель. Оценка количественных результатов реализации программы высокозатратных нозологий в Российской Федерации с 2008 по 2023 гг. для определения дальнейших векторов ее совершенствования.

Материалы и методы. Нормативную базу работы составило законодательство Российской Федерации в сфере лекарственного обеспечения. В качестве информационной базы исследования для сбора и анализа данных использовали открытые источники: отчеты федеральных и региональных органов исполнительной власти, материалы профильных конференций, результаты опубликованных исследований.

Результаты. Лекарственное обеспечение в рамках программы высокозатратных нозологий (ВЗН) осуществляется по 14 нозологиям, 11 из которых отнесены к категории орфанных. С момента реализации программа ВЗН расширялась 2 раза за счет включения новых нозологий в 2019 и 2020 гг. По состоянию на 01 октября 2023 года численность пациентов в Федеральном регистре ВЗН составляла 263 721 человек, что в 13,58 раз выше в сравнении с 2008 г. Лекарственное обеспечение осуществляется по перечню из 47 МНН. Объем финансирования программы увеличился с 32 млрд руб. в 2008 г. до 87,96 млрд руб. в 2023 г. К наиболее ресурсоёмким нозологиям относятся гемофилия, рассеянный склероз и онкогематология.

Заключение. В настоящем исследовании проведен анализ основных количественных характеристик реализации программы ВЗН, определены векторы дальнейшего ее совершенствования. Полученные результаты могут быть использованы для проведения аналитических исследований, в том числе внутри нозологий и нозологических групп, включенных в программу, с целью оптимизации фармацевтической помощи. Фокус совершенствования реализации программы ВЗН связан с совершенствованием правового поля, парадигмы лечения пациентов и подходов к её финансированию.

Ключевые слова: лекарственное обеспечение; перечень дорогостоящих лекарственных препаратов; программа высокозатратных нозологий; оценка медицинских технологий

Список сокращений: ВЗН – программа высокозатратных нозологий; ДЛО – программа дополнительного лекарственного обеспечения; ЗНО – злокачественные новообразования; ЛО – лекарственное обеспечение; ЛП – лекарственный препарат; ФР – федеральный регистр; МНН – международное непатентованное наименование; ОЗ – орфанные заболевания; перечень ЖНВЛП – перечень жизненно-необходимых и важнейших лекарственных препаратов; РС – рассеянный склероз; ЛБО – лимит бюджетных обязательств; ГК – государственные контракты.

INTRODUCTION

In the system of the sustainable development, a human capital occupies a central place, and its preservation and growth is a priority task of the social and economic policy of the state [1–3]. One of the qualitative characteristics of the human resource of the state is the population health, the loss of which is measured by the size of the economic burden caused by morbidity, a temporary loss of working capacity, the level of disability and mortality, especially a premature mortality among the economically active population [4–6]. The system of health protection measures is aimed at ensuring the quality and accessibility of a medical care, including a drug provision (DP) [7, 8]. The effectiveness of the health care system is determined by a combined assessment of three components: social, medical and economic. Herewith, social and medical components of the industry efficiency assessment are predominant [9]. From the point of view of the legislation, medicines are a structural element of both the provision of a medical care and a tool for ensuring social guarantees by the state [10, 11]. I.e., the sphere of circulation of medicines and DP can be considered as a mechanism for regulating the achievement of sustainable development goals for the preservation and increase of the human capital [12].

From the position of a medical and social significance and improvement of patients' quality of life, the state program of treatment with expensive drugs "High-Cost Nosologies Program (VZN)". is the most indicative[1] [13], since its creation became a start not only for the treatment of certain categories of citizens with life-threatening and disabling diseases in outpatient settings, but also served as a beginning for the use of additional sources of funding for the drug therapy of the most resource-intensive nosologies.

The VZN program has been implemented in the Russian Federation for 15 years. The basis for its launch in 2008 was Federal Law No. 132-FZ dated 17 July 2007. Before its adoption in 2007, by the decision of the Government of the Russian Federation and in accordance with Order No. 159 of the Ministry of Health and Social Development of the Russian Federation (abolished

[1] Zhuleva Yu. [Quality of life of patients receiving treatment in the 7VZN program]. Forum of the All-Russian Union of Patients. Moscow, 2018. Available from: https://forum-vsp.ru/media/5cjjitck/vserossiiskiiforumzhulevkachestvozhiznipacientovpoluchayushihlecheniepoprogramme7nozologii-rassh.pdf. Russian

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on 21 May 2012) dated 09.03.2007, drugs for the delegation of powers on the DP of VZN to the federal level were made: the procedure for forming a list of patients in need of the expensive drug therapy was developed, a list of 7 diseases was defined, a list of patients was formed, and their number was determined[2]. The program included malignant neoplasms of lymphoid, hematopoietic and related tissues (oncohematology) (ICD 10 codes C 82, 83. 0, 83.1, 83.3, 83.4, 83.8, 83.9, 84, 84.5, 85, 88.0, 90.0, 91.1, 92.1), multiple sclerosis (MS) (ICD-10 Code G 35.0), hemophilia (ICD-10 Code D 66.0, D 67.0, D 68. 0,), pituitary nanism (ICD-10 Code E 23.0), cystic fibrosis (ICD-10 Code E 84.0), Gaucher disease (ICD-10 Code E 75.5) and conditions after organ and tissue transplantations (transplantation)[3]. In 2008, the number of patients in the program amounted to 19 416[4,5], and the amount of the allocated funding was RUB 32 bn [14, 15]. The patients were treated according to the list of 18 INNs.

During the implementation period, the VZN program has been expanded twice. In 2019, 5 orphan diseases (ODs) were included: hemolytic uremic syndrome, juvenile arthritis with a systemic onset, mucopolysaccharidosis type I, mucopolysaccharidosis type II, mucopolysaccharidosis type VI. In 2020, a financial provision of 2 more ODs (aplastic anemia unspecified, hereditary deficiency of factors II (fibrinogen), VII (labile) X (Stuart-Prower)) were transferred from the regional level to the federal one. Thus, at the moment, 14 nosologies are included in the VZN program, 11 of which have been classified as rare[6,7].

Within the framework of the VZN program, the advantages of DP include guaranteed financing from the federal budget, including the provision of the organizational costs for storage and logistics, a centralized procurement of the drugs on a separate list, a personalized registration of patients in the VZN federal register (VZN FR), incl. the availability of algorithms for the provision of newly identified and already included in the VZN FR patients, a protection of the application for the planned period, monitoring of balances and the possibility of their redistribution. However, despite the significant advantages of the VZN program, a number of problematic issues remains. According to the All-Russian Union of Patients, the most pressing issues of the VZN program implementation include the availability of innovative medicines, preservation and optimization of the treatment regimens, as well as an allocation of a commensurate amount of funding for the program[8,9] [13].

Positive medical and social results of the VZN program implementation indicate the need for a further improvement of its main tools. For the process of strategic goal setting of state programs, first, it is necessary to assess the actual results and current tools of their implementation[10].

In this regard, the aim of this study was to assess the actual results of the High-Cost Nosologies program implementation for a further identification of potential vectors for its development. In the course of the work, the following problems were solved:

– an analysis of normative legal acts (NLAs) regulating the VZN program implementation was conducted;

– a systematic search and a data review to determine the key parameters of the VZN program implementation was conducted;

– an actual results analysis of the VZN program implementation according to the selected key parameters was carried out.

THE AIM of the work was to assess the quantitative results of the implementation of the High-Cost Nosologies program in the Russian Federation from 2008 to 2023 to determine further vectors of its improvement.

[2] Order of the Ministry of Health and Social Developmentof Russian Federation dated 03 September 2007 No. 159 “On measures to ensure certain categories of citizens with necessary medicines”. Russian

[3] Order of the Ministry of Health and Social Development of the Russian Federation dated 4 April 2008 No. 162n “On the procedure for maintaining the Federal Register of patients with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, myeloid leukemia, multiple sclerosis, as well as after organ and (or) tissue transplantation”. Russian

[4] Vlasov YaV. [Diagnostics and dynamics of the number of patients, receiving treatment under the “7 nosologies” Program]. All-Russian forum “10 years of the 7 nosologies program”. Available from: https://forum-vsp.ru/10-let/. Russian

[5] Report “Analysis of procurement procedures for the 14 VZN program”; in 2017–2021. All-Russian Union of Patients. Available from: https://vspru.ru/media/1440603/19072021-predsedatelyu-pravitelstva-rossiiskoifederacii-mv-mishustinu-o-dop-finansirovanii-vzn.pdf. Russian

[6] Federal Law dated 3 August 2018 No. 299-FZ “On Amendments to the Federal Law “On the Fundamentals of Protecting the Health of Citizens in the Russian Federation”. Russian

[7] Federal Law dated 27 December 2019 No. 452-FZ “On Amendments to the Federal Law “On the Fundamentals of Protecting the Health of Citizens in the Russian Federation”. Russian

[8] Vlasov YaV. [Diagnostics and dynamics of the number of patients, receiving treatment under the “7 nosologies” Program]; 2018. Russian

[9] Report “Analysis of procurement procedures for the 14 VZN program”; in 2017–2021. Russian

[10] Federal Law dated 28 June 2014 No. 172-FZ (as amended on February 17, 2023) “On Strategic Planning in the Russian Federation”. Russian

MATERIALS AND METHODS

The study was conducted at the Department of Regulatory Relations in the field of circulation of drugs and medical devices of Sechenov University in the period from 15 January 2023 to 10 November 2023. A set of research methods was used to solve the set tasks: a literature review; data excerpts from the reporting forms of federal and regional executive authorities in the field of healthcare; a content analysis of regulatory documents governing a drug supply to patients with rare and life-threatening diseases. The regulatory base of the study was the legislation of the Russian Federation regulating relations in the field of DP[11,12,13]. The search for normative legal acts was carried out in the Electronic Periodical Reference Book "GARANT System". As sources of information for determining the key parameters of the VZN program implementation, the data from the reports of the Accounts Chamber of the Russian Federation[14], the reports of the Federal Treasury of the Russian Federation on the budget execution for 2008–2021[15], were used. There were also reports on the implementation of the performance indicators of Federal Centre for the Planning and Organization of Drug Provision to Citizens[16], regional reports on the VZN program implementation 14[17]. The search for published research results on this topic was carried out in the e-library.ru [15–17]. The materials of the All-Russian Patients Union[18,19] posted on the Internet were studied, as well as the Reports of experts at specialized industry events[20,21]. The information from the Unified Information System in Procurement Procurement (UIS Procurement) was analyzed. Previously unpublished proprietary data were also used in the study.

To analyze the actual results of the VZN program implementation, a database was created in the MS Excel 2019 format with the following parameters: the information on the dynamics of the number of patients included in the VZN FR, the number of patients included in the application for the drug provision, the amount of financial support and budget execution of the VZN program, the structure of the number of patients included in the VZN FR, the dynamics of the number of patients by nosologies, the number of patients receiving DP by nosologies, the structure of patients' DP within the VZN program by ICD-10 and the share structure of drug purchases in the relevant INNs within nosologies. The results were interpreted and analyzed using StatTech Software v. 4.1.1 (StatTech LLC, Russia).

RESULTS AND DISCUSSION

Regulation of drug supply for patients with rare and life-threatening diseases: background and current status

The transformation of the pharmaceutical market under the influence of the economic and political situation in the Russian Federation in the late 80's-early 90's led to fundamental changes in the institutional environment for the regulation of DP [18, 19]. RSFSR

[11] Federal Law dated 21 November 2011 No. 323-FZ (as amended on 13 June 2023) "On the fundamentals of protecting the health of citizens in the Russian Federation". Russian

[12] Decree of the Government of the Russian Federation dated 26 November 2018 No. 1416 (as amended on 15 February 2023) "On the procedure for organizing the provision of medicines to persons with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, hemolytic-uremic syndrome, juvenile arthritis with systemic onset, mucopolysaccharidosis types I, II and VI, unspecified aplastic anemia, hereditary deficiency of factors II (fibrinogen), VII (labile), X (Stuart-Prower), persons after organ transplantation and (or) fabrics (with changes and additions)". Russian

[13] Decree of the Government of the Russian Federation dated 28 August 2014 No. 871 (as amended on 3 December 2020) "On approval of the Rules for the formation of lists of medicines for medical use and the minimum range of medicines necessary for the provision of medical care". Russian

[14] Katrenko VS. Report on the results of the expert-analytical event. [Analysis of the effectiveness of the use of public funds allocated for the implementation of the state's obligations to provide medicines to certain categories of citizens in 2011–2012]. Accounts Chamber of the Russian Federation. Available from: https://ach.gov.ru/upload/iblock/f00/fj405se3rz3in7sdmx1f9153sxx6bm96.pdf. Russian

[15] Federal Treasury official website of the Treasury of Russia. Reporting on budget execution. Available from: https://roskazna.gov.ru/ispolneniebyudzhetov/. Russian

[16] Reports on the implementation of performance indicators of the Federal Centre for the Planning and Organization of Drug Provision to Citizens. Available from: https://fcpilo.minzdrav.gov.ru/?page_id=4029. Russian

[17] Ministry of Health of the Udmurt Republic. Reports on the implementation of the 14 VZN program. Available from: https://mzur.ru/activity/support/14vznreports/. Russian

[18] Vlasov YaV. [Diagnostics and dynamics of the number of patients, receiving treatment under the "7 nosologies" Program]; 2018. Russian

[19] Report "Analysis of procurement procedures for the 14 VZN program" in 2017–2021. Russian

[20] Maksimkina EA. [Drug provision for patients suffering from rare (orphan) diseases, as part of the implementation of the program of High-Cost Nosologies (VZN) and the activities of the Circle of Good Foundation. Materials of the Round Table on the topic: "Results and prospects for the development of the organization of medical and social care for patients suffering from rare (orphan) diseases in the Russian Federation"]. State Duma Committee on Health Protection. Available from: http://komitet2-2.km.duma.gov.ru/Novosti-Komiteta/item/28214556/. Russian

[21] Shulyak S. The VZN program through the eyes of analysts. All-Russian forum "10 years of the 7 nosologies program". Available from: https://forum-vsp.ru/10-let/. Russian

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Government Resolution No. 68[22] dated 26 December 1991 classified vital and essential drugs as priority products, and the RSFSR was instructed to form a list of such drugs. Within the framework of this decree, the State Program for the improvement of DP and development of the pharmaceutical industry in the RSFSR (Program) was also approved. First, it was planned to expand the list of privileged categories of citizens with chronic diseases, who receive drugs free of charge. These provisions were enshrined in the Resolution of the Government of the Russian Federation No. 890 dated 30 June 1994 "On State Support for the Development of the Medical Industry and Improvement of the Provision of the Population and Health Care Institutions with Medicines and Medical Devices". In addition, the program laid down the principles of the state regulation of prices for vital and essential drugs (VEDs).

In 1995, Federal Law No. 181-FZ dated 24 November 1995 "On Social Protection of Disabled Persons in the Russian Federation" was adopted, according to which "a qualified medical care for disabled persons, including a drug provision, is provided free of charge or on preferential terms", in accordance with the norms of the law established in the legislation. The adoption of this law was the beginning of the State Reimbursement Program (SRP) implementation. In accordance with Federal Law of No. 178-FZ "On State Social Assistance" dated 17 July 1999, the state social assistance is also guaranteed to certain categories of citizens in the form of a set of social services, which includes medicines as vital goods. Despite the adopted legal acts, due to the shortage of funding, the actual State Reimbursement Program implementation started only in 2005. For the same reason, since 2007, at the level of the RF Government, it was decided to divide the federal budget funds allocated for SRP of privileged categories of citizens, into two streams[23]:

– federal budget funds to finance the centralized purchase of medicines approved by the RF Government Order No. 1328-r dated 02 October 2007 "On the list of medicines to be centrally purchased at the expense of the federal budget";

– federal budget funds in the form of subventions and transfers to constituent entities of the Russian Federation for the implementation of the authority to provide medical treatment to certain categories of citizens who have retained the right to receive medicines.

According to the current legislation, the DP is carried out in accordance with the "standards of medical care in the amount not less than that stipulated by the VEDs list"[24]. The first VEDs list was formed in 1992 in the context of the economic crisis, which required the state to take measures to ensure not only the affordability of medicines, especially for unprotected segments of the population and privileged categories of citizens, but also measures to develop the local pharmaceutical industry. Based on the regulatory legal acts of those years, it can be concluded that the formation of the VEDs list was based on three principles of improving VEDs: production, the principle of realizing the rights of citizens to the social assistance and the principle of the state regulation of prices for drugs that are included in the list. The regulatory legal framework governing the formation of the VEDs list has been developed over 20 years and continues to be improved to this day. During this period, in the regulatory field, there was a qualitative transition from the methodological recommendations of the Formulary Committee on the formation of the VEDs list to the level of the Government Decree, which approved the order and procedure for the formation of several lists within the system of medical treatment of the population [20]. In 2014, Government Resolution No. 871 established uniform principles for the formation of lists of drugs for medical use: the order and procedure for their formation, criteria for the inclusion of medicines in each of the lists, integral scales on which the information about the benefits of the proposed drug for the inclusion is assessed. The VEDs list has become the basis for the formation of the list of expensive drugs[25]. The criteria for the formation of the VEDs program and the list of expensive drugs are not enshrined in the legal framework, therefore, within the framework of this study it was expedient to determine their essential characteristics (Table 1).

[22] Decree of the Government of the RSFSR dated 26 December 1991 No. 68 "On urgent measures to provide the population and health care institutions of the RSFSR with medicines in 1992 and the development of the pharmaceutical industry in 1992–1995" (together with the "State Program of the RSFSR for improving the supply of medicines and developing the pharmaceutical industry in 1992–1995"). Russian

[23] Katrenko VS. Report on the results of the expert-analytical event. [Analysis of the effectiveness of the use of public funds allocated for the implementation of the state's obligations to provide medicines to certain categories of citizens in 2011–2012]. Russian

[24] Federal Law dated 21 November 2011 No. 323-FZ (as amended on 13 June 2023) "On the fundamentals of protecting the health of citizens in the Russian Federation". Russian

[25] Decree of the Government of the Russian Federation dated 28 August 2014 No. 871 (as amended on 3 December 2020) "On approval of the Rules for the formation of lists of drugs for medical use and the minimum range of medicines necessary for the provision of medical care". Russian

Table 1 – Essential characteristics of High-Cost Nosologies program parameters and high cost drugs list

Parameter	Parameter characteristics	Short description
Criteria for the inclusion of nosologies in VZN program	Medical Aspect: – life-threatening, rare (orphan) disease; – availability of pathogenetic therapy; – identifiable patient cohort. Financial aspect: – significant burden on the budget of the Russian Federation subject; – possibility of savings in case of centralization of procurement; – possibility of redistribution of medicines.	The order and procedure for the inclusion of nosologies in the VZN program is not regulated. The decision on the inclusion in the list of diseases related to VZN is made at the level of the Government of the Russian Federation (Clause 21, Article 14, Chapter 3; Clause 21 introduced by Federal Law No. 112-FZ dated 26 April 2016; ed. by Federal Laws No. 299-FZ dated 03 August 2018, and No. 452-FZ dated 27 December 2019; Clause 7, Article 44; Chapter 10, Article 44, Chapter 5 of the Federal Law No 323-FZ dated 21 November 2011 (edited 28 April 2023) "On the basis of health protection of citizens in the Russian Federation"); In accordance with Art. 104 of the Constitution of the Russian Federation, the President of the Russian Federation, the Federation Council, the Government of the Russian Federation, the legislative bodies of the constituent entities of the Russian Federation, and deputies of the State Duma may initiate the legislation on its expansion.
Source of funding	Federal budget funds: – in respect of adults aged 18 and over – at the expense of budgetary appropriations provided for in the federal budget to the authorized federal executive body; – in respect of children aged 0 to 18 – at the expense of budgetary appropriations provided for in the federal budget to the authorized federal executive body, for the needs of the Circle of Goodness Foundation for the Support of Children with Severe Life Threatening and Chronic Diseases, including rare (orphan) diseases.	Starting from 2021, the procurement of drugs on the list of high cost drugs is carried out by the Federal Centre for the Planning and Organization of Drug Provision to Citizens.
Contingent and drug therapy record keeping tools	The VZN Federal Register	The procedure for maintaining the VZN FR is stipulated by Decree of the Government of the Russian Federation No. 1416[26] dated 26 November 2018. Clause 7, Art. 44, No. 323-FZ. The categories of citizens entitled to preferential treatment are specified.
Moment of entitlement to preferential treatment	Entering data about patients in the VZN Federal Register	Clause 8, Article 44, Chapter 5 of Federal Law No. 323-FZ dated 21 November 2011 (ed. 28 April 2023) "On the Fundamentals of Health Protection of Citizens in the Russian Federation".
Nature of procurement	Centralized procurement	In accordance with Resolution of the Government of the Russian Federation No. 1025 dated 26 June 2021 "On Amendments to Certain Acts of the Government" of the Federal Centre for the Planning and Organization of Drug Provision to Citizens performs the functions of organizing and conducting the procurement of drugs for medical use at the expense of the federal budget.
Criteria for inclusion of a drug in the high cost drugs list	– the drug must be included in the VEDs list; – the drug is used for the pathogenetic treatment of a disease which is classified as a high-cost nosology; – the drug must not increase the amount of budgetary allocations provided for in the federal budget for the relevant fiscal year and planning period	The rules and procedure for forming lists of medicines for medical use are regulated by Decree of the Government of the Russian Federation No. 871n dated 28 August 2014: the drug proposed for the inclusion in this list must be registered in the territory of the Russian Federation, included in the VEDs list and have the advantages compared to their counterparts already on this list.

Note: * – adopted due to the expansion of the high-cost technology program beginning in 2019.

[26] Decree of the Government of the Russian Federation dated 26 November 2018 No. 1416 (as amended on 15 February 2023). Russian

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Table 2 – Dynamics of the number of patients that are included in the VZN program for 2010 and from 2018 to 2023, in the context of nosology

Nosology	The annual number of patients included in VZN FR (absolute value, %)						
	2010	2018	2019	2020	2021	2022*	2023*
MNPs of lymphoid, hematopoietic and related tissues	30 754 (42.89%)	85 335 (47.13%)	88 327 (46.43%)	99 886 (46.33%)	109 026 (45.60%)	108 833 (44.49%)	115 698 (43.87%)
MS	25 048 (34.94%)	63 455 (35.05%)	66 493 (34.95%)	75 114 (34.84%)	83 884 (35.08%)	87 287 (35.69%)	95 316 (36.14%)
Transplantation	5 060 (7.06%)	13 810 (7.63%)	15 077 (7.92%)	17 474 (8.10%)	19 706 (8.24%)	20 246 (8.28%)	22 659 (8.59%)
Hemophilia	6 069 (8.46%)	9 434 (5.21%)	9 413 (4.95%)	10 302 (4.78%)	11 139 (4.66%)	11 684 (4.78%)	12 125 (4.60%)
Pituitary anism	2 704 (3.77%)	5 142 (2.84%)	4 914 (2.58%)	6 460 (3.00%)	6 918 (2.89%)	7 411 (3.03%)	8 259 (3.13%)
CF	1 906 (2.66%)	3 496 (1.93%)	3 651 (1.92%)	3 920 (1.82%)	4 246 (1.78%)	4 429 (1.81%)	4 511 (1.71%)
Juvenile arthritis with a systemic onset	–	2 (0.001%)	1 346 (0.71%)	1 414 (0.66%)	1 666 (0.70%)	1 811 (0.74%)	1 927 (0.73%)
Aplastic anemia unspecified	–	–	–	–	1 057 (0.44%)	1 280 (0.52%)	1 483 (0.56%)
Hemolytic uremic syndrome	–	6 (0.003%)	398 (0.21%)	380 (0.18%)	463 (0.19%)	538 (0.22%)	600 (0.23%)
GD	156 (0.22%)	364 (0.20%)	361 (0.19%)	398 (0.18%)	438 (0.18%)	457 (0.19%)	474 (0.18%)
Hereditary deficiency of factors II (fibrinogen), VII (labile), X (Stuart-Prower)	–	–	–	–	253 (0.11%)	313 (0.13%)	374 (0.14%)
Mucopolysaccharidosis type I	–	1 (0.001%)	11 (0.06%)	123 (0.06%)	139 (0.06%)	112 (0.05%)	94 (0.04%)
Mucopolysaccharidosis, type II	–	8 (0.004%)	98 (0.05%)	98 (0.05%)	104 (0.04%)	143 (0.06%)	146 (0.06%)
Mucopolysaccharidosis type VI	–	–	53 (0.03%)	47 (0.02%)	51 (0.02%)	54 (0.02%)	55 (0.02%)
Total	71 697	181 053	190 250	215 615	239 090	244 600	263 721

Note: * – for 2022 and 2023, the data on the number of patients in the VZN FR are given as of October of the respective year. MNPs – malignant neoplasms; MS – multiple sclerosis; GD – Gaucher disease; CF –- cystic fibrosis.

Table 3 – Number of patients without combined pathologies* included in the VZN FR as of 1 October 2023, in the context of nosological groups and ages

Nosology	Number of patients without combined pathologies included in the VZN FR in 2023, absolute value			Proportion of patients without co-morbidities included in the the VZN FR, by age, %	
	Children under 18 years	Adults	Total	Children under 18 years	Adults
MNPs of lymphoid, hematopoietic and related tissues	367	115 275	115 642	0.32%	99.68%
MS	897	93 899	94 796	0.95%	99.05%
Transplantation	2 254	20 412	22 666	9.94%	90.06%
Hemophilia	3 888	8 049	11 937	32.57%	67.43%
Pituitary nanism	6 035	2 493	8 528	70.77%	29.23%
Cystic fibrosis	3 091	1 273	4 364	70.83%	29.17%
Juvenile arthritis with a systemic onset	1 354	598	1 952	69.36%	30.64%
Aplastic anemia unspecified	185	1 354	1 539	12.02%	87.98%
Hemolytic-uremic syndrome	338	209	547	61.79%	38.21%
Gaucher disease	114	346	460	24.78%	75.22%
Hereditary deficiency of factors II (fibrinogen), VII (labile), X (Stuart-Prower)	209	219	428	48.83%	51.17%
Mucopolysaccharidosis, type I	69	18	87	79.31%	20.69%
Mucopolysaccharidosis type II	111	25	136	81.62%	18.38%
Mucopolysaccharidosis, type VI	34	24	58	58.62%	41.38%
Total without combined nosologies	18 946	244 194	263 140	7.20%	92.80%

Note: As of 1 October 2023, 581 patients with combined nosologies were included in the VZN FR. MNPs – malignant neoplasms; MS – multiple sclerosis.

Table 4 – Dynamics of the declared need to meet the requirements for the drug coverage from 2021 to 2023 in the context of nosology

Nosology	2021		2022		2023	
	Expenses, RUB bn	Share, %	Expenses, RUB bn	Share, %	Expenses, RUB bn	Share, %
Hemophilia	20.556	28.07%	23.744	26.99%	25.455	28.94%
MS	17.763	24.26%	24.254	27.57%	24.185	27.50%
MNPs of lymphoid, hematopoietic and related tissues	17.638	24.09%	20.542	23.35%	18.092	20.57%
Hemolytic-uremic syndrome	4.530	6.19%	5.707	6.49%	6.178	7.02%
Mucopolysaccharidosis type II	3.663	5.00%	3.849	4.38%	3.728	4.24%
Transplantation	2.016	2.75%	2.493	2.83%	2.303	2.62%
JRA	1.878	2.56%	1.768	2.01%	2.047	2.33%
CF	1.543	2.11%	1.529	1.74%	1.502	1.71%
GD	1.377	1.88%	1.518	1.73%	1.501	1.71%
Mucopolysaccharidosis type VI	1.375	1.88%	1.518	1.73%	1.405	1.60%
Mucopolysaccharidosis type I	0.565	0.77%	0.694	0.79%	0.737	0.84%
Pituitary anemia	0.183	0.25%	0.188	0.21%	0.206	0.23%
Aplastic anemia unspecified	0.125	0.17%	0.107	0.12%	0.110	0.13%
Hereditary deficiency of factors II (fibrinogen), VII (labile), X (Stuart-Prower)	0.008	0.01%	0.05	0.06%	0.51	0.58%
Total	73.22	100%	87.96	100%	87.96	100%

Note: The summary table was compiled by the authors based on the data from the unified procurement information system; MNPs – malignant neoplasms; MS – multiple sclerosis; JRA – juvenile rheumatoid arthritis; GD – Gaucher disease; CF – cystic fibrosis.

Table 5 – Ranking of nosologies of the HCNs program, taking into account the number and structure of patients and the amount of financial support in 2023

Nosology	Range			
	by the number of patients in the HCNs FR	by the number of patients in the application	by the amount of financial support in the total program costs	by the share of adult patients
MNPs of lymphoid, hematopoietic and related tissues (oncohematology)	1	2	3	1
MS	2	1	2	2
Transplantation	3	3	6	3
Hemophilia	4	4	1	6
Hypophyseal anism	5	5	13	11
CF	6	6	8	12
Juvenile arthritis with a systemic onset	7	7	7	10
Aplastic anemia unspecified	8	8	14	4
Hemolytic-uremic syndrome	9	10	4	9
GD	10	9	9	5
Hereditary deficiency of factors II (fibrinogen), VII (labile), X (Stuart-Prower)	11	11	12	7
Mucopolysaccharidosis, type I	13	13	5	14
Mucopolysaccharidosis, type II	12	12	11	13
Mucopolysaccharidosis, type VI	14	14	10	8

Note: MNPs – malignant neoplasms; MS – multiple sclerosis; GD – Gaucher disease; CF – cystic fibrosis.

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Table 6 – Dynamics of expenditures per 1 beneficiary in the context of nosologies at the level of the constituent entity of the Russian Federation in 2020–2022 (using the example of data on the 14 VZN program implementation in the Republic of Udmurtia)

Nosology	Expenditures per beneficiary, RUB								
	2020			2021			2022		
	Average amount of expenditures	Minimum amount of expenditures	Maximum amount of expenditures	Average amount of expenditures	Minimum amount of expenditures	Maximum amount of expenditures	Average amount of expenditures	Minimum amount of expenditures	Maximum amount of expenditures
Hemolytic uremic syndrome	5 188 601.70	3 003 927.30	7 373 276.10	6 554 023.20	–	6 554 023.20	12 925 990.20	10 377 203.40	18 023 563.80
Mucopolysaccharidosis type II	19 074 627.00	–	19 074 627.00	19 837 612.08	–	19 837 612.08	17 930 149.38	–	17 930 149.38
Juvenile arthritis with a systemic onset	1 026 797.57	57 978.26	6 102 939.00	645 821.25	44 995.32	1 109 625.00	1 314 600.04	674 929.80	1 362 201.60
Oncohematology	443 160.00	12 097.80	476 511.04	461 462.99	12 359.70	486 045.63	575 726.35	182 482.20	586 470.73
CF	327 345.73	272 308.28	412 959.55	350 164.76	331 320.00	381 572.68	458 371.64	397 584.00	500 455.38
Hemophilia	2 134 154.71	192 959.28	2 179 298.79	2 591 382.42	2 020 806.12	2 803 310.76	2 470 798.90	1 787 210.30	2 812 593.20
MS	274 685.31	196 215.04	278 975.57	287 755.52	196 105.88	292 636.50	295 409.96	166 676.68	302 094.54
Pituitary nanism	46 467.77	–	46 467.77	43 006.16	–	43 006.16	31 293.55	–	31 293.55
GD	2 153 779.20		2 153 779.20	2 183 328.00	–	2 183 328.00	2 363 904.00	–	2 363 904.00
Organ and/or tissue transplantation	1 505.05	7 638.58	1 590.67	1 389.29	6 150.21	1 488.38	1 268.24	74 039.21	1 301.68

Note: MS – multiple sclerosis; ; GD – Gaucher disease; CF – cystic fibrosis. Data are adapted by the authors from the source[27].

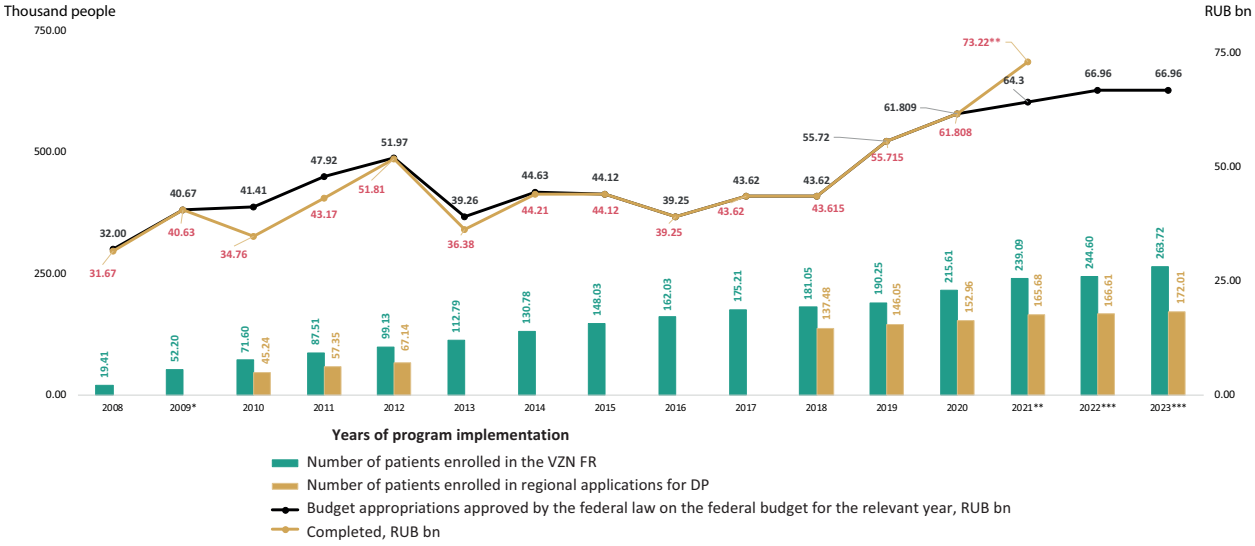

Figure 1 – Dynamics of the number of patients in the VZN program, the amount of budget allocations from the federal budget of the program and its budget execution from 2008 to 2023

Note: * – for 2009 and 2014, data on budget allocations approved by the Consolidated Budget List with account of changes; ** – for 2021 with account of additional RUB 8.90 bn allocated by Federal Centre for the Planning and Organization of Drug Provision to Citizens; *** – for 2022 and 2023, data on the number of patients in the VZN FR are given as of October of the respective year. The figure presented here was compiled by the authors based on data[28,29,30,31] and their own results.

[27] Ministry of Health of the Udmurt Republic. Reports on the implementation of the 14 VZN program. Russian
[28] Federal Treasury official website of the Treasury of Russia. Reporting on budget execution. Russian
[29] Katrenko VS. Report on the results of the expert-analytical event. [Analysis of the effectiveness of the use of public funds allocated for the implementation of the state's obligations to provide medicines to certain categories of citizens in 2011–2012]. Russian
[30] Reports on the implementation of performance indicators of the Federal Centre for the Planning and Organization of Drug Provision to Citizens. Russian
[31] Ministry of Health of the Udmurt Republic. Reports on the implementation of the 14 VZN program. Russian

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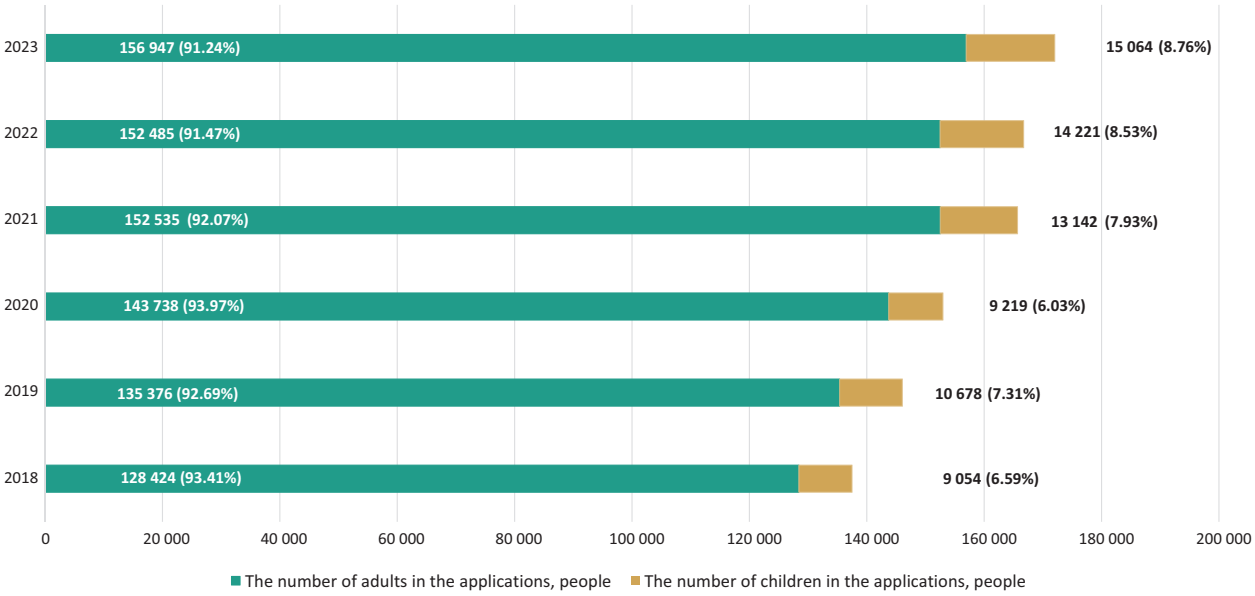

Figure 2 – Numbers of adults and children in absolute values and percentages in the DP application in 2018 and after the inclusion of new nosologies in the program

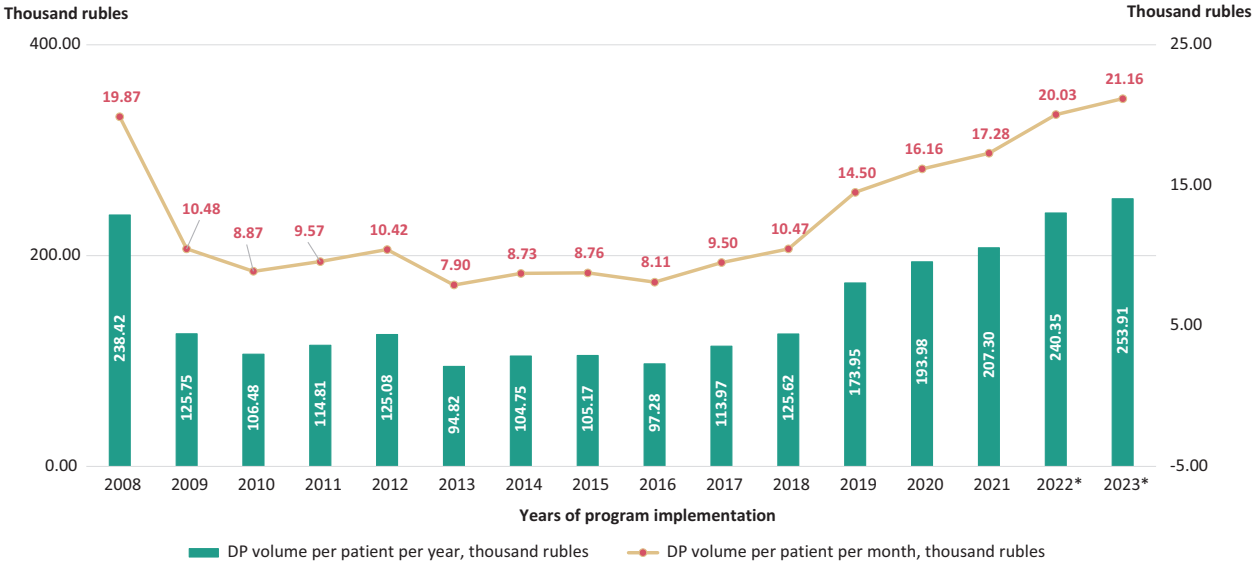

Figure 3 – The volume of drug supply per patient from 2011 to 2023

Note: * – including funds from the Circle of Goodness Foundation; ** the volume of treatment per patient is calculated in 2023 prices, taking into account the discount rate of 13.9% [20].

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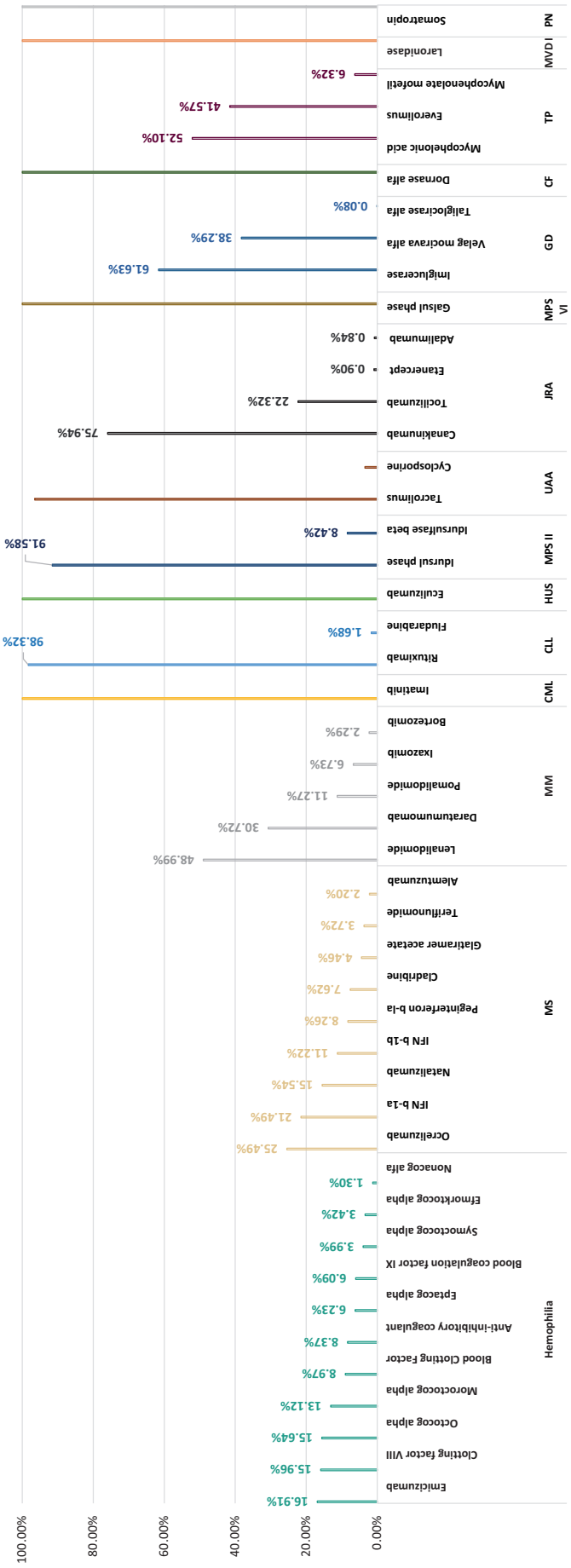

Figure 4 – Share structure of expenditures on patient care in the context of the VZN program in terms of ICD-10 and shares in procurement within the respective INNs in each nosology in 2021–2022

Note: MS – multiple sclerosis; MM – multiple myeloma; CML – chronic myeloid leukemia; CLL – chronic lympholeukemia; HUS – hemolytic uremic syndrome; MPS II – mucopolysaccharidosis type II; UAA – unspecified aplastic anemia; JRA – juvenile rheumatoid arthritis with a systemic onset; MPS IV – mucopolysaccharidosis type IV; GD – Gaucher disease; CF – cystic fibrosis; TP – transplantation; MPS I – mucopolysaccharidosis type I; PN – pituitary nanism. The information is adapted from the source[32].

[32] Orphan zone: how and why the state program "14 VZN" shares wards with the state fund "Circle of Good". Available from: https://vademec.ru/article/orfan-zona_kak_i_pochemu_gosprogramma_-14_vzn_delitsya_podopechnymi_s_gosfondom_-krug_dobra/

Number of patients and volume of budget allocations for drug provision to patients with rare and life-threatening diseases within the framework of the High-Cost Nosologies program 14

In 2008, the volume of budget funds allocated for the treatment of 19.41 thousand patients amounted to RUB 32 bn[33] [14]. By 2021, the volume of financing increased twofold – up to RUB 64.3 bn, and the total number of patients in the VZN FR reached 239.09 thousand people. By 1 October 2022, there were already 244.60 thousand people in the VZN FR, by 1 October 2023 their number increased to 263.72 thousand people (+9.33%), taking into account combined nosologies[34]. From 2022 to 2024, RUB 66.96 bn are annually budgeted to finance the VZN program 14[35]. The dynamics of the number of patients, the volume of budget allocations from the federal budget and the budget execution of the VZN program are shown in Figure 1.

14 VZN program in the context of nosology: population dynamics, age distribution of patients

The cumulative average annual growth rate in the number of patients for the 7 nosologies that had been initially included in the VZN program between 2010 and 2023, was 10.54% and ranged from 6.85% for pituitary dwarfism to 12.22% for transplantation. The major nosologies that accounted for the increase in patients, included hematologic oncology and MS, accounting for more than 80% of the patients in the VZN FR. The cumulative average annual growth rate of the ODs patient population was 8.16% from 2010 to 2023. In 2022, hemophilia (41.39%), hypophysial nanism (26.25%) and cystic fibrosis (15.69%) accounted for 83.32% of the total population of patients with ODs. In 2023, more than 80% (82.85%) of patients with ODs were patients with these rare pathologies. The ratio of orphan and non-orphan diseases in 2022 was 11.54 and 88.46%, in 2023 – 11.39 and 88.61%, respectively, which indicates that this trend will continue in the current year. Table 2 shows the dynamics of the number of patients in the context of nosologies, which are included in the VZN FR.

In 2018, the number of children included in the VZN FR was 9.05 thousand people, or 6.59%. Due to the inclusion of nosologies with a high prevalence rate in the paediatric population in 2019 and 2020, their share in 2023 increased to 15.06 thousand people (8.76%). The increase in the number of children amounted to 6.01 thousand people in absolute terms and +66.38% in percentage terms.

As of 1 October 2023, the total number of children without combined pathologies included in the VZN FR, amounted to 18.94 thousand people, the share of patients with ODs of which amounted to 81.43%, or 15 428 people. Among adults, on the contrary, the share of patients without combined pathologies included in the VZN FR with non-orphan diseases is 94%. Most nosologies are characterized by a high proportion of adult patients receiving DP at the expense of the federal budget. Table 3 shows the number of patients without combined pathologies included in the VZN FR in 2023 in the context of nosological groups and age of beneficiaries.

The numbers of adults and children in absolute values and percentages in the DP application in 2018 and after the inclusion of new nosologies in the program are shown in Figure 2.

From 2018 to 2023, the ratio of adults to children in the program averaged 92.41% (144 924±11 184) and 7.59% (11 897±2 598), respectively.

Considering the age structure of patients included in the DP application, the nosological groups included in the DP program can be classified as follows:

– nosologies with the proportion of adult patients receiving therapy from 10 to 20% of the total number of patients receiving the treatment for mucopolysaccharidosis type II (1);

– nosologies with the proportion of adult patients receiving therapy from 20 to 40% of the total number of patients receiving the treatment for hypophyseal nanism, mucopolysaccharidosis type I, cystic fibrosis juvenile arthritis with a systemic onset (4);

– nosologies with a share of adult patients receiving therapy, from 40 to 70% of the total number of patients, on the preferential treatment – hemophilia, mucopolysaccharidosis type VI, hereditary deficiency of factors II (fibrinogen), VII (labile), X (Stuart–Prower) (3);

– nosologies with a share of adult patients exceeding 70% of the total number of patients receiving DP – MS, oncohematology, Gaucher disease, aplastic anemia unspecified, transplantation (6).

[33] Maksimkina EA. [Drug provision for patients suffering from rare (orphan) diseases, as part of the implementation of the program of High-Cost Nosologies (VZN) and the activities of the Circle of Good Foundation. Materials of the Round Table on the topic: "Results and prospects for the development of the organization of medical and social care for patients suffering from rare (orphan) diseases in the Russian Federation"]. Russian

[34] Ibid.

[35] Federal Treasury official website of the Treasury of Russia. Reporting on budget execution. Russian

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The need for a DP and the structure of centralized procurement in the context of 14 VZN program

Until 2021, the Ministry of Health of the Russian Federation carried out centralized procurement of medicines under the VZN program at the expense of the federal budget on the basis of regional requests. By the order of the Government of the Russian Federation from 2021, this function is assigned to Federal Centre for the Planning and Organization of Drug Provision to Citizens[36]. The budget obligation limits (BOLs) for 2021 amounted to RUB 64.31 bn, RUB 7.129 bn was transferred to Federal Centre for the Planning and Organization of Drug Provision to Citizens and RUB 8.90 bn was additionally allocated. For 2022, BOLs increased to RUB 66.96 bn Federal Centre for the Planning and Organization of Drug Provision to Citizens concluded 147 state contracts (SCs) for the amount of RUB 58.68 bn and 6 additional agreements under multi-year SCs from 2021 for the supply of drugs for 3 INNs in 2022 for the amount of RUB 8.28 bn In order to ensure the uninterrupted treatment of patients suffering from VZN, in the fourth quarter of 2021, Federal Centre for the Planning and Organization of Drug Provision to Citizens procured medicines at the expense of funds and according to the needs for 2022. As in 2022, for the uninterrupted treatment and formation of the carry-over stock of drugs for 2023, in the second quarter of 2022 Federal Centre for the Planning and Organization of Drug Provision to Citizens procured medicines at the expense of funds of 2023 according to the part of the approved needs of 2022. The BOLs for 2023 amounted to RUB 87.96 bn, including BOLs for the provision of the adult population – RUB 66.96 bn and for the provision of children within the framework of the delegation of powers to the Circle of Goodness Foundation – RUB 21 bn[37,38]. Advanced procurement, on the one hand, is due to the shortage of funds allocated for the implementation of the VZN program, on the other hand, it is due to the introduction of the practice of purchasing treatment through Federal Centre for the Planning and Organization of Drug Provision to Citizens within the framework of long-term contracts. Starting from 1 January 2023, DP for children with disabilities is financed from the funds received from the increased tax rate and allocated to the Circle of Goodness Fund. The release of federal budget resources is primarily at the expense of nosologies with high numbers of children, which include hypophyseal nanism, hemophilia, cystic fibrosis, hereditary deficiency of blood factors.

For the period from 2008 to 2023, the increase in the number of persons participating in the VZN program amounted to 244.31 thousand people (+1258%); at the same time, the volume of allocated BOLs per patient per month remained practically unchanged: in 2023 prices, the increase amounted to +6.10% or RUB 1.29 thousand. The median cost per 1 patient per month for the analyzed period amounted to 10 446.12 [Q1 8 846.29; Q3 16 442.29], per year – 125 353.46 [Q1 106 155.47; Q3 197 307.47] (Figure 3).

Three nosologies are among the most financially intensive in the VZN program: hemophilia, MS and oncohematology. In 2023, the cost of an the DP application for patients with hemophilia amounted to RUB 25.45 bn, MS – RUB 24.18 bn, oncohematology – RUB 18.09 bn, or 77% of the total cost of the application (Table 4).

In 2022, 6 nosologies accounted for more than 98% of ICD-10 diagnoses among patients with hematologic oncohematology receiving DP in the context of the VZN program: Diffuse non-Hodgkin lymphoma (C83), 30.85%; lymphoid leukemia [lympholeukemia] (C91), 20.45%; multiple myeloma and malignant plasma cell neoplasms (C90), 19.30%; myeloid leukemia [myeloleukemia] (C92) – 12.20%; other and unspecified types of non-Hodgkin's lymphoma (C85) – 8.02%; follicular [nodular] non-Hodgkin's lymphoma (C82) – 7.48%. Of the hemophilia patients, 60.34% had hemophilia A, 11.11% had hemophilia B, and 27.59% were patients with Willebrandt's disease. Among those who had undergone a transplantation, 63.58% of patients were with a kidney transplantation, 20.14% with a liver transplantation, and 8.25% – with a heart transplantation. All of them received treatment at the expense of the federal budget. The total amount of financing of procurement in 2021–2022, incl. the budget allocated for 2022–2024, amounted to RUB 138.91 bn. More than 45% of funds were spent on the procurement of the drugs for oncohematology – lenalidomide (9.02%) and daratumumab (5.67%), MS – ocrelizumab (6.92%) and natalizumab (4.22%), hemophilia – emicizumab (4.62%), clotting factor VIII (4.36%), octocog alpha (4.27%), and a hemolytic-uremic syndrome – eculizumab (6.16%)[39]. Figure 4 shows the share structure of expenditures on the treatment of

[36] Order of the Government of the Russian Federation dated 28 October 2020 No. 2798-r "On the creation of the federal government institution "Federal Center for Planning and Organization of Drug Provision for Citizens"".

[37] Reports on the implementation of performance indicators of the Federal Centre for the Planning and Organization of Drug Provision to Citizens. Russian

[38] Maksimkina EA. [Drug provision for patients suffering from rare (orphan) diseases, as part of the implementation of the program of High-Cost Nosologies (VZN) and the activities of the Circle of Good Foundation. Materials of the Round Table on the topic: "Results and prospects for the development of the organization of medical and social care for patients suffering from rare (orphan) diseases in the Russian Federation"]. Russian

[39] Federal Treasury official website of the Treasury of Russia. Reporting on budget execution. Russian

patients in the context of the VZN program in terms of ICD-10 and the share of procurement within the respective INNs in each nosology in 2021–2022.

In terms of the number of patients included in the HCNs FR, the number of patients in the application for DP, and the amount of the necessary funding, the most resource-consuming nosologies are: MS, hemophilia, and oncohematology. Table 5 shows the ranking of nosologies included in the HCNs program according to 4 parameters: the number of patients included in the HCNs FR and the application for DP; the amount of financing for DP; the share of adult patients in the morbidity structure.

Guided by the norms of Government Decree No. 1416, Federal Centre for the Planning and Organization of Drug Provision to Citizens conducts an application campaign to organize the purchase of drugs according to the list of the expensive drugs, based on the needs of the constituent entities of the Russian Federation. At the constituent entity level, the application is formed on the basis of clinical recommendations. Herewith, the current standards of medical care, the average course dose and the monthly actual need of a patient in drugs, in accordance with the data of the regional segment of the VZN FR and the need to form a stock for 15 months (1 year plus a carryover balance for 3 months), have been taken into account. Thus, the need for DP is determined by taking into account the projected balances. The application coordinated with Federal Centre for the Planning and Organization of Drug Provision to Citizens supervisors, chief freelance specialists on the profile and experts of federal centers, is defended and approved by the commission of the Ministry of Health of Russia.

The main factors affecting the amount of funding to meet the needs for treatment and the average cost per patient are the composition of nosologies in the subject, a direct number of patients and the therapy scheme used to treat a particular patient. For example, according to the reports of the VZN program implementation 14 in the Republic of Udmurtia in 2020 was provided to 1,161 beneficiaries, the number of serviced prescriptions was 6,550 units, the average cost of 1 prescription – RUB 90 135.52, and the average amount spent per 1 beneficiary – RUB 511 601.11. According to the data for 2021, there were 1 166 beneficiaries on provision, the number of prescriptions served was RUB 5 701, the average cost of 1 prescription increased to RUB 114 321.52, and the average amount spent per 1 beneficiary increased to RUB 57 076.64. In 2022, 1 165 patients received DP, the total number of prescriptions issued amounted to 5 432, the average cost of 1 prescription reached RUB 131 950.35, the average amount spent per 1 beneficiary – RUB 616 828.15. Table 6 shows the dynamics of expenditures per 1 beneficiary in the context of nosology at the level of the constituent entity of the Russian Federation in 2020–2022, using the example of the data on the VZN program implementation in the Republic of Udmurtia[40].

Survey results and their discussion

In 2008, within the framework of the VZN program, the treatment was provided for 7 nosologies according to the list of 18 INNs; at present, the treatment is provided for 14 nosologies according to the list of 47 INNs. The number of patients in the VZN FR as of 01 October 2023, amounted to 263 721 patients. Compared to 2008, their number increased by 13.58 times, which cannot be said about the program financing. The data of earlier analytical studies of the VZN program implementation [22] and the results of the present study show a relative stability of the procurement structure by the main nosological segments. The most resource-intensive nosologies in the VZN program, before and after its expansion, include oncohematology, MS and hemophilia. In this regard, in order to make management decisions, it is necessary to analyze the VZN program implementation within nosologies and nosological groups. It is obvious that the trends of growth in the number of patients in the VZN program and, accordingly, the growth of expenditures on the purchase of medicines will continue in the future. This is due to the increase in the overall life expectancy, as well as to the improvement of diagnostic methods and approaches to the treatment of patients, including the use of innovative therapy schemes. Experts and the patient community have noted the positive results of the state program implementation from the clinical point of view and from the point of view of improving the quality of life of patients, which determines the need for a further VZN program implementation. The increase in the number of beneficiaries, the expansion of the VZN list and the drugs list for their treatment requires revision of not only the amount of funding, but also of other institutional mechanisms to improve the program effectiveness.

Certain difficulties in expanding the list of expensive drugs are associated with the unified rules for the formation of drugs lists for medical use. Since the list includes drugs for the treatment of diseases with high medical and social significance, it is necessary to develop criteria that take into account the specifics of nosologies included in the VZN program and new technologies for their therapy. In many foreign countries, the process of forming reimbursable lists is preceded by the so-called "horizon scanning" stage [23–25]. In this case, horizon

[40] Ministry of Health of the Udmurt Republic. Reports on the implementation of the 14 VZN program. Russian

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scanning means not only the process of a systematic identification of new and emerging technologies, but also the development of new and/or adaptation of existing tools for their subsequent evaluation. The following definition of horizon scanning is used in foreign literature – "early awareness and alert" (EAA), which, in the Russian-language version, can be considered as a system of an early detection and alert (SEDA). SEDA aims to search for and identify promising health technologies or new opportunities for the use of medical technologies already used in clinical practice; to assess or predict their impact on health, the health care system and/or society as a whole; and to further disseminate the results obtained. The implementation of SEDA will make it possible to predict the epidemiological and economic consequences of the use of new drugs within the framework of the VZN program [26].

After the market launch of drugs, studies of their efficacy and safety continue. They include the purpose of expanding the indications for use in new patient groups and lines of therapy. The updated pool of data on drugs, taking into account the data of real clinical practice, should be used for the optimization of patient therapy: the identification of target groups (subgroups) of patients, where the use of drugs brings the greatest clinical and economic effect.

In the absence of a system for monitoring the VZN program implementation, taking into account the outcomes of the treatment, risk sharing agreements not related to the results of the treatment can be used as available innovative methods of payment: price-volume agreements, payment at the expense of funds [27–29]. At present, Federal Centre for the Planning and Organization of Drug Provision to Citizens is already actively using the tool of long-term contacts (price-volume agreements) with manufacturers of original molecules. Financing of children's DP under VZN program implementation 14 at the expense of the Fund "Circle of Good" also refers to new forms of financing. The introduction of various mechanisms of "risk sharing agreements" will make it possible to further optimize the use of budget funds to improve the treatment of patients.

Study limitations

Within the framework of this study, only the main qualitative and quantitative indicators of the VZN program implementation as a whole have been studied. The analysis in nosological segments of the program taking into account regional peculiarities, has not been conducted. Clinical and economic efficiency in the conditions of real clinical practice of drugs that had already been included in the program was not assessed. These areas are promising for a further analysis and forecasting of the need for the expansion and financial support of the VZN program.

CONCLUSION

The present study has identified the main quantitative characteristics of the DP implementation according to the VZN program. The results obtained can be used for further analytical studies, including the ones within nosologies and nosological groups included in the program. The main vectors for improving the VZN program implementation include: the improvement of the legal framework, the drug therapy optimization, the application of new forms of financing the program.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTION

Oksana I. Ivakhnenko – study design, collection and critical analysis of scientific literature and regulatory legal documents, collection and analysis of data, interpretation of results, writing, editing and design of the article, final approval of the manuscript; Vasily V. Ryazhenov – critical analysis of scientific and methodological literature, making remarks of intellectual content, editing of the article; Elena A. Maksimkina – collection of scientific and methodological literature, critical analysis of scientific and methodological literature, making remarks of intellectual content, editing of the article; Victor S. Fisenko – collection and critical analysis of scientific literature and normative legal documents, making remarks of intellectual content, editing of the article; Oleg V. Savoskin – collection, analysis and interpretation of data, editing of the article; Maria M. Kuznetsova – collection and critical analysis of scientific literature and normative legal documents, making remarks of intellectual content, editing of the article. All the authors confirm their authorship compliance with the ICMJE international criteria (all authors made a significant contribution to the conceptualization, research and preparation of the article, read and approved the final version before publication).

REFERENCES

1. Miladinov G. Socioeconomic development and life expectancy relationship: evidence from the EU accession candidate countries. Genus. 2020;76(2). DOI: 10.1186/s41118-019-0071-0
2. Collin ME, Weil DN. The effect of increasing human capital investment on economic growth and poverty: A simulation exercise (September 25, 2018). World Bank Policy Research Working Paper No. 8590.
3. Romanova AS. Human capital in the system of sustainable development. Proceedings BSTU. Economics and Management. 2015;7(180):310–5. Russian
4. Bezrukov NS, Polyanskaya EV. [Economic assessment of public health losses as a factor in the development of human capital]. Bulletin of the Pacific State University. 2009;1(12):57–64. Russian
5. Shafi R, Fatima S. Relationship between GDP, life expectancy, and growth rate of G7 countries. Int J Sci. 2019;8(06):74–9. DOI: 10.18483/ijSci.2085
6. Ivakhnenko OI, Avksentyeva MV, Maksimova LV. Methods for estimating indirect costs in health technology assessment. Medical technologies. Evaluation and selection. 2013;1(11):29–35. Russian
7. Avksentyeva MV, Gerasimova KV, Zheleznyakova IA, Zuev AV, Ivakhnenko OI, Ignatieva VI, Lazareva ML, Lemeshko VA, Lukyantseva DV, Melnikova LS, Musina NZ, Sura MV, Sukhorukikh OA, Fedyaev DV. [System of medical care in the Russian Federation: information bulletin]. Omelyanovsky VV, editor. Moscow: Academic Scientific Publishing, Production, Printing and Book Distribution Center “Science”; 2019. 181 p. Russian
8. Tsomartova FV. Health Protection in the Focus of Medical Legislation. Journal of Russian Law. 2021;25(8):156–60. DOI: 10.12737/jrl.2021.106. Russian
9. Shamanina EA, Polozova DV. Main principles of social and economic policy efficiency evaluation in the health system of the Russian Federation. Vestnik Akademii. 2019;(4):96–104. Russian
10. Tsomartova FV. State guarantees of availability of drugs in Russia and abroad. Journal of Foreign Legislation and Comparative Law. 2018;4(71):161–70. DOI: 10.12737/art.2018.4.21. Russian
11. Bessarab NS. Right to medical aid and medical support. Izvestiya Tula State University. Economic and legal sciences. 2019;(2):90–4. Russian
12. Kazarina ON. On the implementation of economic policy in the field of preferential drug provision of the population in the territory of the Russian Federation. Vestnik RUK. 2023;1(51):38–43. Russian
13. Vorobyev PA, Krasnova LS, Vorobyev AP, Zykova AB, Zhulyov YuA, Zozulya NI. Epidemiology, economics and quality of life of patients with hemophilia in Russia for 2007–2017: Results of standardization use in therapy. Problems of standardization in healthcare.2018;9-10:15–34. Russian
14. Telnova EA, Zagoruychenko AA. About the state of preferred medicinal provision. Bulletin of Semashko National Research Institute of Public Health. 2021;(2):72–81. DOI: 10.25742/NRIPH.2021.02.009. Russian
15. Telnova EA. Extensive drug coverage – ONLS program is 10 years. Vestnik of Roszdravnadzor. 2016;(5):143–7. Russian
16. Reykhtman TV, Moshkova LV. The approaches to maintain the availability of pharmaceutical assistance to certain categories of citizens of the Russian Federation. Research Result. Medicine and Pharmacy Series. 2014;1(2):26–37. DOI: 10.18413/2313-8955-2014-1-2-26-37. Russian
17. Tolkushin AG, Fedorov AA, Zhulev UA, Pogudina NL, Ermolaeva TN. Directions of development of the program of drug provision for expensive diseases. Health care of the Russian Federation. 2019;63(5):237–44. DOI: 10.18821/0044-197X-2019-63-5-237-244. Russian
18. Zatravkin SN, Vishlenkova EA, Ignatiev VG. The Russian pharmaceutical branch in 1990s. Report 1. From the Soviet to the market. Problems of Social Hygiene, Public Health and History of Medicine. 2022;30(1) 160–6. DOI: 10.32687/0869-866X-2022-30-1-160-166. Russian
19. Zatravkin SN, Vishlenkova EA, Ignatiev VG. The Russian pharmaceutical branch in 1990s. Report II. The optics of external observers. Problems of Social Hygiene, Public Health and History of Medicine. 2022;30(2):322–8. DOI: 10.32687/0869-866X-2022-30-2-322-328. Russian
20. Omelyanovskiy VV, Maksimkina EA, Ivakhnenko OI, Avxentyeva MV, Sura MV, Khachatryan GR. Improvements to the formation of lists of drugs for medical use: analysis of changes in the Government Decree no. 871. FARMAKOEKONOMIKA. Modern Pharmacoeconomics and Pharmacoepidemiology. 2020;13(2):113–23. DOI: 10.17749/2070-4909/farmakoekonomika.2020.032. Russian
21. Voronov DS, Ramenskaya LA. Evaluation of the cost of capital and the discount rate based on the Russian financial statistics. Journal of New Economy. 2023;24(1):50–80. DOI: 10.29141/2658-5081-2023-24-1-3. Russian
22. Trofimova EO, Denisova MN, Utomova AS. Structural changes and import substitution processes in the VZN segment in 2008-2018. Remedium. 2019;(6):14–9. DOI: 10.21518/1561-5936-2019-6-14-19. Russian
23. Grössmann N, Wolf S, Rosian K, Wild C. Pre-reimbursement: early assessment for coverage decisions. Wien Med Wochenschr. 2019;169(11-12):254–62. DOI: 10.1007/s10354-019-0683-1
24. Eriksson I, von Euler M, Malmström RE, Godman B, Wettermark B. Did we see it Coming? An evaluation of the swedish early awareness and alert system. Appl Health Econ Health Policy. 2019;17:93–101. DOI: 10.1007/s40258-018-0434-2
25. Simpson S, Cook A, Miles K. Patient and public involvement in early awareness and alert activities: An example from the United Kingdom. Int J Technol Assess Health Care. 2018;34(1):10–7. DOI: 10.1017/S0266462317004421
26. Gutierrez-Ibarluzea I, Simpson S, Benguria-Arrate G; Members of EuroScan International Network. Early awareness and alert systems: an overview of EuroScan methods. Int J Technol Assess Health Care. 2012;28(3):301–7. DOI: 10.1017/S0266462312000360
27. Wenzl M, Chapman S. Performance-based managed entry agreements for new medicines in OECD countries and EU member states: How they work and possible improvements going forward. OECD Health Working Papers. 2019;(115). DOI: 10.1787/6e5e4c0f-en
28. Rotar AM, Preda A, Löblová O, Benkovic V, Zawodnik S, Gulacsi L, Niewada M, Boncz I, Petrova G, Dimitrova M, Klazinga N. Rationalizing the introduction and use of pharmaceutical products: The role of managed entry agreements in Central and Eastern European countries. Health Policy. 2018;122(3):230–6. DOI: 10.1016/j.healthpol.2018.01.006

ОРИГИНАЛЬНАЯ СТАТЬЯ
DOI: 10.19163/2307-9266-2024-12-1-15-31

29. Zampirolli Dias C, Godman B, Gargano LP, Azevedo PS, Garcia MM, Souza Cazarim M, Pantuzza LLN, Ribeiro-Junior NG, Pereira AL, Borin MC, de Figueiredo Zuppo I, Iunes R, Pippo T, Hauegen RC, Vassalo C, Laba TL, Simoens S, Márquez S, Gomez C, Voncina L, Selke GW, Garattini L, Kwon HY, Gulbinovic J, Lipinska A, Pomorski M, McClure L, Fürst J, Gambogi R, Ortiz CH, Canuto Santos VC, Araújo DV, Araujo VE, Acurcio FA, Alvares-Teodoro J, Guerra-Junior AA. Integrative Review of Managed Entry Agreements: Chances and Limitations. Pharmacoeconomics. 2020;38(11):1165–85. DOI: 10.1007/s40273-020-00943-1

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