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MEDICAL DEVICES FOR BLOOD GLUCOSE SELF-MONITORING: COMMODITY AND ECONOMIC ASPECTS

SUMMARY. The relevance of the study lies in the need for scientific substantiation of the effectiveness of the state reimbursement program for medical devices intended for self-monitoring of blood glucose levels under the conditions of healthcare system reform in Ukraine. The program aims to improve accessibility, quality of life, and pharmaceutical care for patients with type 1 diabetes mellitus.

The aim – to examine the commodity characteristics of test strips for self-monitoring of blood glucose levels and to analyze their economic accessibility within the framework of the "Available Medicines" state reimbursement program.

Material and Methods. The research object comprised medical devices included in the reimbursement lists of the National Health Service of Ukraine for the period from August 2023 to March 2025. A comparative commodity analysis, content analysis of regulatory legal acts of the Ministry of Health of Ukraine, and a retrospective analysis of data from NHSU analytical dashboards were conducted. Statistical and analytical methods, along with graphical data interpretation, were applied to summarize the research findings.

Results. It has been established that test strips for blood glucose determination are single-use medical devices that are sensitive to external factors, thus requiring specific storage conditions (temperature 4–30 °C, relative humidity ≤65%). The packaging serves both protective and informational functions: the primary packaging is a hermetically sealed tube containing a desiccant; the secondary packaging consists of a cardboard box with labeling and instructions; and the transport packaging is a corrugated container.

A retrospective analysis revealed an expansion in the range of medical devices subject to reimbursement – from 23 items in 2023 to 43 in 2024, along with an increase in the proportion of fully reimbursed products. According to the National Health Service of Ukraine (NHSU), there has been a growth in the number of redeemed e-prescriptions in 2025, indicating improved physical and financial accessibility of medical devices for patients with type 1 diabetes mellitus.

Conclusions. The conducted study confirmed that the expansion of the reimbursement program enhances the accessibility of test strips for blood glucose self-monitoring, contributes to improving patients' quality of life, supports the prevention of complications, and promotes the rationalization of healthcare system expenditures. It is considered advisable to further improve the assortment policy and state reimbursement mechanisms, taking into account the needs of different age groups of patients.

KEY WORDS: test strips; glucose level; type 1 diabetes mellitus; commodity analysis; pharmaceutical supply; "Affordable Medicines" state program.

Introduction. Under the current conditions of healthcare system reform in Ukraine, particular attention is given to ensuring patients' access to essential medicinal products (MPs) and medical devices (MDs) based on the principle of financial accessibility [1, 2]. One of the key instruments of state policy in this direction is the "Available Medicines" state reimbursement program (AMRP), which enables citizens to obtain vital treatment products free of charge or with partial co-payment [3, 4]. Since 2021, patients with type 1 diabetes mellitus (T1DM) in Ukraine have been provided with insulin preparations through a government reimbursement program [4, 5]. Beginning in August 2023, the program was expanded to include medical devices for self-monitoring of blood glucose levels, which is of particular relevance for individuals suffering from T1DM – a group that numbers over 100,000 patients in Ukraine [6, 7]. Ensuring the supply of test strips (TS) to insulin-dependent Ukrainians plays a crucial role in maintaining their quality of life, preventing complications, and reducing the overall burden of the disease on the healthcare system [8, 9].

However, despite the positive outcomes of introducing MD reimbursement, certain challenges persist. These include issues related to the assortment composition, physical availability of medical devices in pharmacies, the level of co-payment, and the awareness and adherence of patients participating in the AMRP [10]. These factors highlight the relevance of conducting a scientific study aimed at analyzing the assortment policy underlying the formation of

reimbursement lists for MDs and assessing the level of pharmaceutical provision of patients with T1DM with test strips for blood glucose monitoring.

The aim of the study was to examine the commodity characteristics of test strips for self-monitoring of blood glucose levels and to analyze their financial accessibility within the framework of the "Available Medicines" state reimbursement program.

Material and Methods. The object of the study was the range of medical devices (MDs) included in the lists of reimbursable products under the State Guaranteed Medical Services Program, covering the period from August 2023 to March 2025 [11-13].

The research employed a comparative commodity analysis, a retrospective analysis of data from the analytical dashboards of the National Health Service of Ukraine (NHSU), and a content analysis of four orders issued by the Ministry of Health of Ukraine, which regulate the formation of reimbursement registers for MDs.

Additionally, systematization and generalization methods, statistical–analytical approaches, and graphical techniques were used. Statistical data were processed using standard statistical software packages – Statistica (version 12.0, StatSoft, Tulsa, USA) and Microsoft Excel. The study outcomes were arranged in visual charts and supplemented with explanatory text and summarized findings.

Results and Discussion. Patients suffering from type 1 diabetes mellitus (T1DM) require continuous monitoring of blood glucose levels [5, 9]. Elevated glucose levels can be detected within a very short time using test strips, which are easy to use, require no special training, and pose no difficulty for patients [5, 10].

According to the definition [14], a test strip is a thin plastic or paper substrate coated with reagents and intended for *in vitro* diagnostic use as a single-use device. When a drop of blood is applied to the designated area, a chemical reaction occurs within the strip, and the glucometer interprets the result as a numerical value corresponding to the blood glucose concentration [15].

The technology for blood glucose determination using test strips first emerged in the 1960s [16]. The first strips were developed by the Ames Division of Miles Laboratories in the USA and were originally designed for visual assessment of color change [17]. A major breakthrough occurred in the 1980s, when the first portable glucometers appeared, allowing results from the test strips to be read automatically [5].

The advantages and disadvantages of using test strips are presented in Table 1.

Table 1. Advantages and disadvantages of using test strips for blood glucose determination

	Determination	Characteristic
Advantages	Speed	Result within 5–10 seconds
	Convenience	Easy to use at home
	Accuracy	Reliable measurement of blood glucose levels
	Small blood volume	Modern strips require only 0.3–1 μL of blood
	Control	Effective daily health monitoring
Disadvantages	High cost	Each measurement requires a separate strip
	Shelf life	Strips have a limited storage period (6 months) after opening the package
	Sensitivity to external conditions	Temperature, humidity, and light may affect accuracy
	Compatibility	Strips work only with certain glucometer models and are incompatible between brands

Test strips for blood glucose determination are single-use medical devices designed for use with compatible glucometers [16, 18]. Each glucometer model has its own specific test strips optimized for the device's electronics. Automatic coding or manual code entry on the glucometer ensures accurate readings. Some test strips contain built-in chips that transmit calibration data [18]. They can be used at home by patients with type 1 diabetes mellitus (T1DM), as well as by healthcare professionals in clinical settings to monitor treatment effectiveness [18].

A number of requirements apply to test strips for self-monitoring of blood glucose levels, particularly concerning storage and operation conditions [18]. The package must be kept in a cool, dry place at a temperature between 4 °C and 30 °C and a relative humidity not exceeding 65%. Storage in the refrigerator, bathroom, or car is prohibited, as excessive humidity and low temperatures may cause activation or degradation of the enzyme (glucose oxidase or glucose dehydrogenase) and damage the reagent layer, altering electrochemical conductivity and leading to inaccurate or unreliable results. Test strips must also be protected from direct sunlight and heat. Exceeding the recommended temperature or humidity limits can result in measurement errors [19].

Test strips should be used within the manufacturer's specified expiration period, as expired

strips may yield inaccurate results. A newly opened container should be used within six months after its first opening. The reaction zone must not be touched with fingers, and the container must be tightly closed immediately after removing a strip. Testing should be carried out at ambient temperatures between 10 °C and 44 °C. Upon opening a new container, the disposal date should be recorded on the label. Since used test strips are considered biohazardous waste, users must follow medical guidance and local regulations for the proper disposal of medical devices.

The packaging of test strips is multi-component, combined, and functional, serving protective, informational, and labeling purposes. It preserves the activity of enzymatic reagents throughout the product's shelf life-typically 18–24 months in a sealed container and 3–6 months after opening. The primary packaging consists of a hermetically sealed polypropylene or polyethylene tube with a tight-fitting cap that includes a built-in desiccant (such as silica gel) or a sachet with a moisture absorber, ensuring direct protection of the strips from moisture, light, and air exposure. Transferring the strips into another container or leaving the tube open is prohibited. The primary label must indicate the product name, batch number, manufacturing date, expiration date, storage conditions, number of strips, and a barcode.

The secondary packaging consists of a cardboard box containing the instructions for medical use, designed to hold several primary packages (typically one or two tubes of 25 or 50 strips each) and to provide additional protection during transportation. The cardboard packaging includes complete information in Ukrainian about the test strips, in accordance with the Technical Regulation on Medical Devices (Resolution of the Cabinet of Ministers of Ukraine No. 753 of October 2, 2013) [19]. It specifies the type of glucometer compatible with the strips, and displays CE / ISO 13485 conformity marks, confirming the quality and safety of the medical device. It may also contain protective elements, such as a hologram or a QR code for verifying authenticity.

The transport (outer) packaging consists of group containers (corrugated boxes or transport containers) made of cardboard or plastic, which ensure integrity and protection against vibration, moisture, and temperature fluctuations during transportation and storage of secondary packaging.

On the Ukrainian pharmaceutical market, the most widespread test strip brands are Accu-Chek, OneTouch, Gamma, GlucoDr, and Wellion. Their prices range from UAH 400 to 900 per pack of 50 strips, which may be financially burdensome for many patients without a state reimbursement mechanism.

The next stage of this study involved an analysis of the dynamics of the medical device reimbursement program from 2023 to 2025. Figure 1 presents quantitative data obtained from the orders of the Ministry of Health of Ukraine [6, 11-13], illustrating the list of medical devices subject to reimbursement under the State Guaranteed Medical Services Program.

It was found that as of 2023, the reimbursement list included 23 test strip items, available in packages of 10, 25, and 50 units. Among them, two were fully

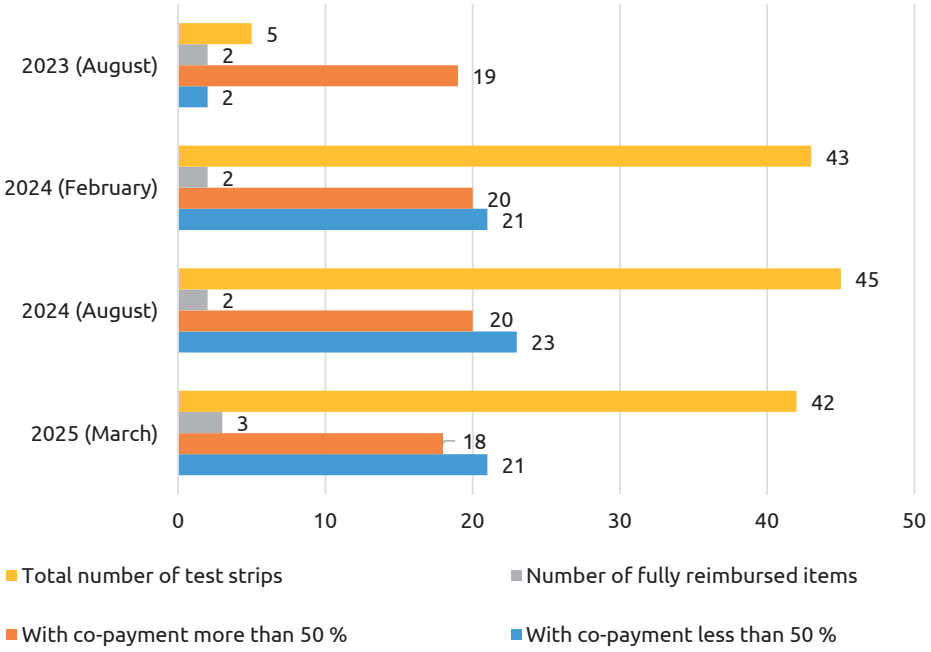

Fig. 1. Dynamics of the development of the "Available Medicines" program.

reimbursed, while 19 required a co-payment exceeding 50%, and two had a co-payment below 50%.

After six months, in February 2024, the AMRP expanded to 43 items (a 1.87-fold increase compared to the previous year). Packages of 100, 150, and 200 strips were added, while the Austrian manufacturer "Med Trust" retained one 10-strip package and five 200-strip packages. The number of fully reimbursed items remained at two. There were 20 items with a co-payment exceeding 50% and 21 with a co-payment below 50%.

The next list, published in August 2024, increased by two additional items compared to the previous one. One 10-strip package and five 200-strip packages remained available. The number of fully reimbursed items stayed at two; 20 items required a co-payment above 50%, and 23 required a co-payment below 50%.

The March 2025 list was revised – 200-strip packages were removed, and only one manufacturer of 10-strip packages remained. The number of fully reimbursed items increased to three, while 18 items required a co-payment over 50%, and 21 required a co-payment under 50%.

Thus, the program continues to expand annually, with an increasing proportion of test strips requiring co-payment below 50%, indicating positive trends in accessibility for patients. The near twofold increase in the total range of test strips between 2023 and 2024 demonstrates improved access to medical devices for patients with type 1 diabetes mellitus (T1DM). Moreover, the inclusion of 100-, 150-, and 200-strip packages in February 2024 significantly broadened the range and allowed patients to obtain larger packages for longer-term use.

In 2025, one new fully reimbursed test strip was added – "2B Ultra" test strips (50 pieces), which had not been represented in 2024. However, the limited number of fully reimbursed products (three as of 2025) remains a significant issue.

The analysis of analytical dashboards published by the NHSU [20] provides a comprehensive overview of the functioning of the electronic prescription system for medical devices within the reimbursement program. The diagram in Figure 2 illustrates the number of issued e-prescriptions for medical devices across different regions of Ukraine from 2023 to 2025. The highest numbers of prescriptions were

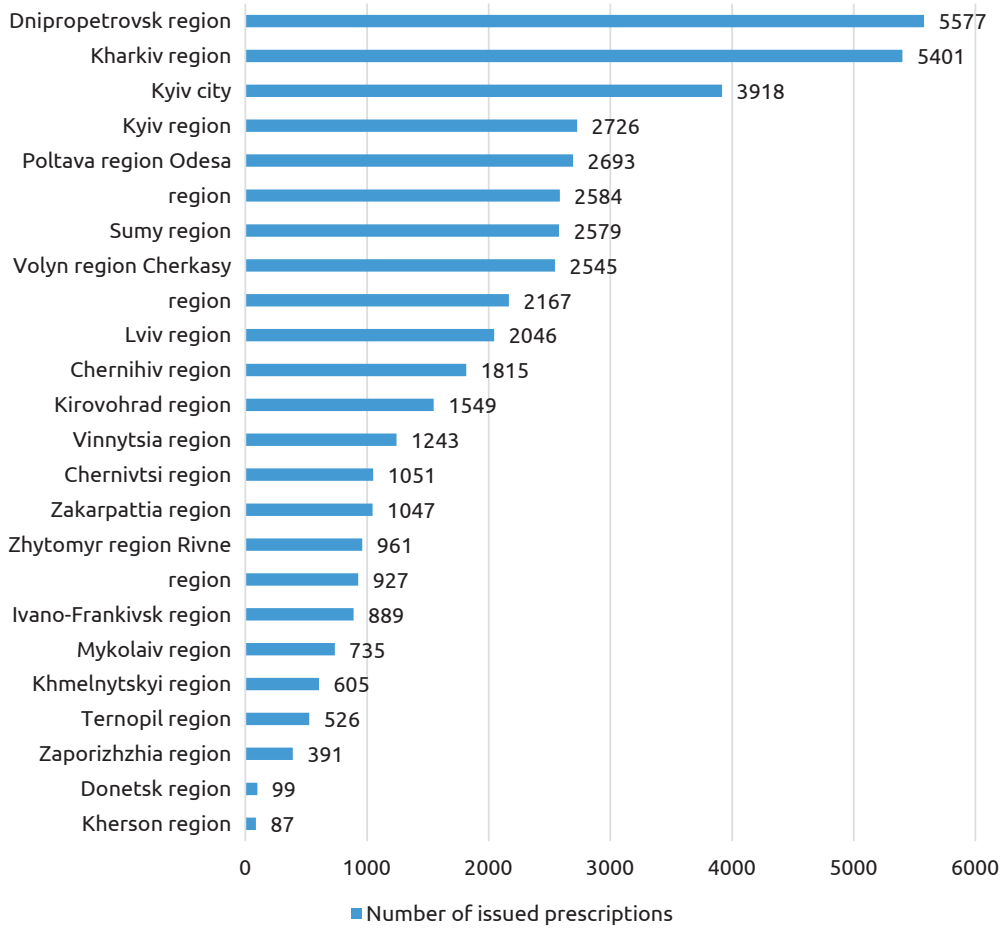

Fig. 2. Distribution of the number of redeemed prescriptions for medical devices by region.

recorded in the Dnipropetrovsk region (5,577), followed by the Kharkiv region (5,401) and Kyiv city (3,918).

Among the regions with average indicators were Kyiv (2,726), Poltava (2,693), Odesa (2,584), Sumy (2,579), Volyn (2,545), Cherkasy (2,167), and Lviv (2,046) regions [20]. The lowest numbers of electronic prescriptions were recorded in Kherson (87), Donetsk (99), and Zaporizhzhia (391) regions, which may be attributed both to objective factors, such as the security situation, and to a low level of program implementation in certain territories.

Overall, the diagram clearly demonstrates an uneven distribution of electronic prescription issuance across the regions, indicating differences in the accessibility of medical devices (MDs), the activity of healthcare institutions, as well as the awareness levels of patients and physicians regarding the mechanisms of the reimbursement program.

The results of the distribution of redeemed electronic prescriptions by co-payment level (Fig. 3) reveal significant disparities in the degree of financial burden placed on patients when obtaining MDs under the reimbursement program [20].

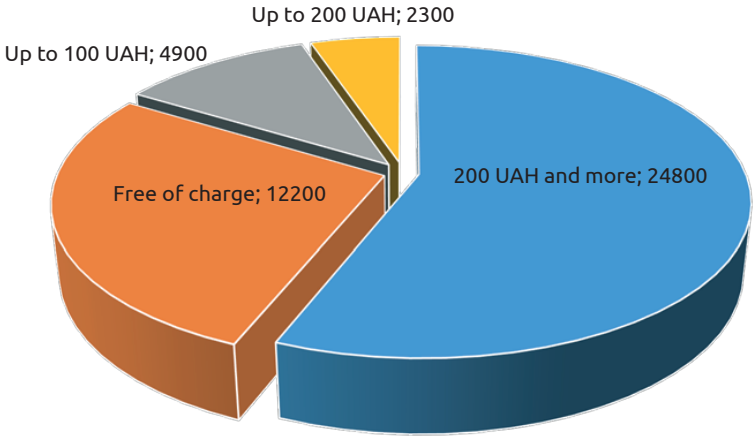

Fig. 3. Distribution of the number of redeemed prescriptions by the patient's co-payment per package.

The largest share corresponds to prescriptions with a co-payment exceeding 200 UAH – 24.8 thousand cases. This indicates a significant proportion of medical devices (MDs) with high costs, which are partially reimbursed by the state but still require substantial out-of-pocket expenses from patients.

A total of 12.2 thousand prescriptions were fully reimbursed, demonstrating a positive trend in ensuring access to MDs for certain categories of the population without additional financial burden [33]. In 4.9 thousand cases, the co-payment was up to 100 UAH, and in 2.3 thousand cases, it was up to 200 UAH. These categories represent smaller proportions compared with others, indicating an uneven distribution of financial burden among patients.

The change in the number of redeemed electronic prescriptions for MDs [20] between October 2023 and March 2025 (Fig. 4) illustrates a clear upward trend, with a gradual increase throughout the study period and peak values recorded at the beginning of 2025.

In October 2023, the number of redeemed prescriptions amounted to only 0.7 thousand, which can be attributed to the initial stage of program implementation or limited awareness among patients and healthcare professionals. Beginning in November 2023, the number of prescriptions increased to 1.8 thousand, after which the indicator stabilized within the range of 1.6–1.9 thousand until September 2024.

From October 2024, a significant increase in the number of redeemed prescriptions for medical devices (MDs) was observed: 2.7 thousand in October, 3.0 thousand in November, 3.3 thousand in December, and 3.8 thousand in January 2025. The highest level was recorded in February 2025, reaching 4.8 thousand prescriptions. This sharp rise is likely related to the intensified implementation of the reimbursement program and/or the expansion of the list of available MDs.

By March 2025, the number of redeemed prescriptions remained at 4.8 thousand, confirming the steady upward trend.

The annual dynamics of redeemed electronic prescriptions for MDs across different age groups during 2023–2024 (Fig. 5) allow for an analysis of which age categories most actively use the reimbursement program mechanisms [20].

The analysis of the age structure of program participants in 2023–2024 revealed uneven growth trends among different age groups [20]. The most significant increase was observed among individuals aged 40–64 years – from 1,089 redeemed prescriptions

in 2023 to 11,187 in 2024. This indicates a high demand for medical devices in this population segment and reflects the effectiveness of the reimbursement program for this age group.

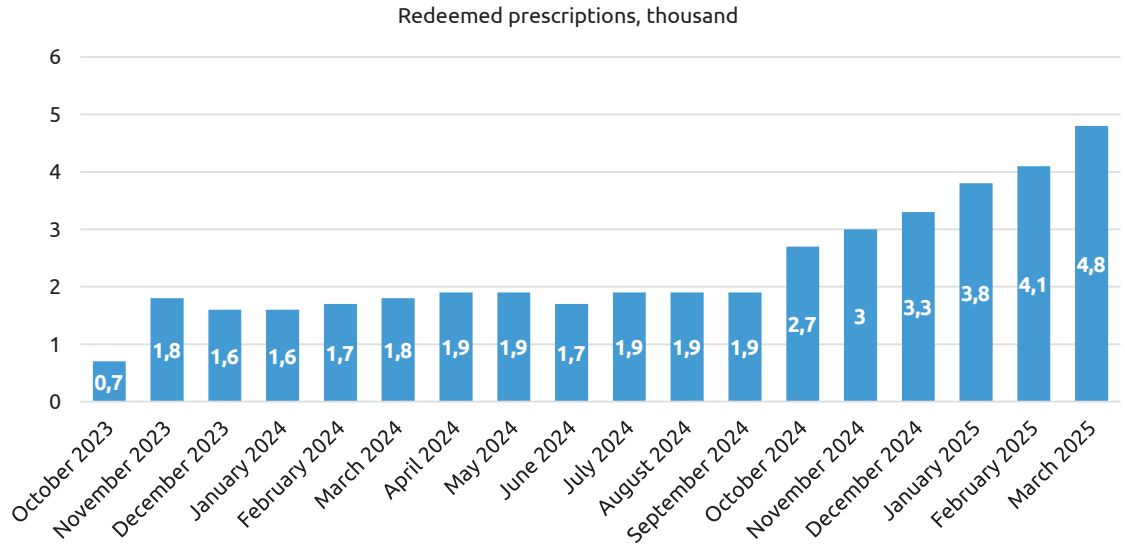

Fig. 4. Distribution of the number of redeemed prescriptions for medical devices.

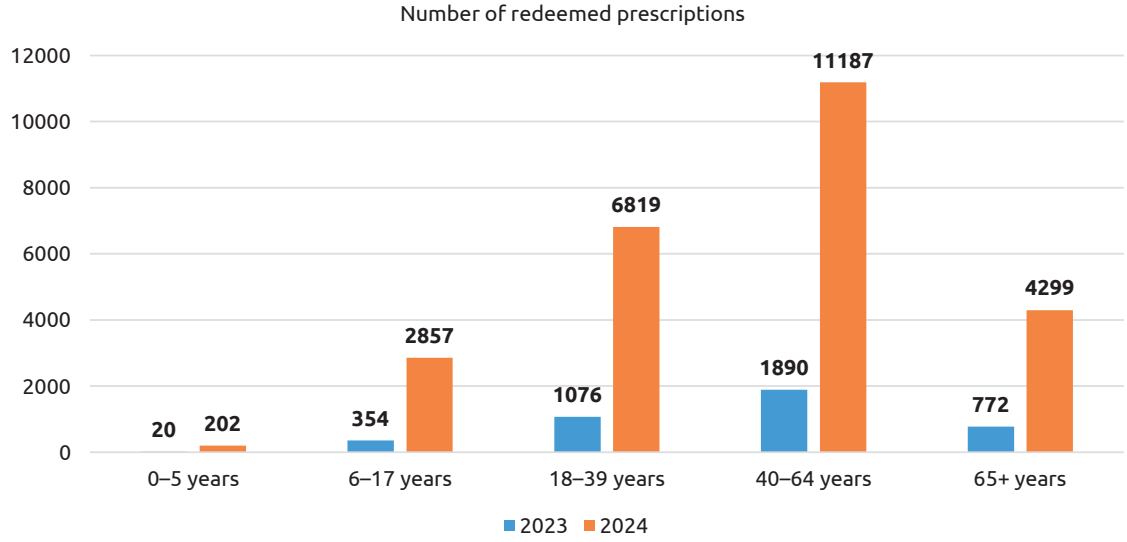

Fig. 5. Dynamics of the number of redeemed prescriptions for medical devices from 2023 to 2024 by age categories.

Substantial growth was also noted among individuals aged 18-39 years, where the number of redeemed prescriptions rose from 1,076 to 6,819, suggesting greater awareness and engagement of the younger working-age population in the program.

Among people aged 65 years and older, the increase was moderate – from 772 redeemed prescriptions to 4,299, which may indicate difficulties in program accessibility or lower adaptability of its mechanisms to the needs of older adults.

In the 6-17-year age group, there was also modest growth, from 354 to 2,857 prescriptions. Meanwhile, the involvement of children under 5 years remained minimal, with an increase of only 2,024 prescriptions, reflecting a low level of coverage for this category, likely due to a limited list of medical devices suited to their specific needs.

The total number of redeemed prescriptions nationwide amounted to 44.16 thousand, although there remains significant regional variation in distribution.

The highest indicators were recorded in the Dnipropetrovsk region – 5,577 prescriptions, Kharkiv region – 5,401 prescriptions, and Kyiv city – 3,918 prescriptions. These regions are the leaders in program implementation, which may be attributed to high population density, well-developed healthcare infrastructure, and the active participation of pharmacy institutions [20].

Relatively high values were also observed in the Poltava (2,693), Kyiv (2,726), Sumy (2,579), Odesa (2,584), and Cherkasy (2,167) regions. The lowest figures were recorded in the Kherson region (87), Donetsk region (99), Zaporizhzhia region (391), and Ternopil region (526) [33]. The Luhansk region reported zero prescriptions, which is likely due to objective factors such as the security situation, temporary occupation, or the lack of technical capability to implement the program.

The analysis of the map reveals a significant territorial disparity in the implementation of the reimbursement program. The highest activity is concentrated in the central, northeastern, and southern regions with well-developed medical infrastructure. The lowest coverage is observed in border and war-affected regions, highlighting the need for additional support and improved mechanisms to ensure access to reimbursement in these areas [33].

Thus, the provision of medical devices (MDs) is a critical component of pharmaceutical care, particularly in the management of chronic diseases such as type 1 diabetes mellitus (T1DM). Ensuring their broad physical accessibility should remain a priority of state healthcare policy. Overall, the dynamics indicate a strengthening of the AMRP in 2025 and an expansion of its scale compared with the initial stages of implementation.

The reimbursement of medicinal products (MPs) and medical devices (MDs) represents an essential component of the healthcare and pharmaceutical systems in many countries [21-23]. This process may be financed either by the state or by private insurance companies. For instance, the populations of the United States and Canada primarily rely on private insurance providers, whereas England operates under a public compulsory health insurance system [23]. Ukraine, like most European countries, can be classified as having a mixed reimbursement model [21, 22].

In the Republic of Poland, the Act of May 12, 2011 "On the Reimbursement of Medicinal Products, Foodstuffs for Particular Nutritional Uses, and Medical Devices" introduced the practice of full or partial reimbursement of the cost of MPs and MDs for patients. Since then, the lists of reimbursable products have been updated every two months. However, as of November 1, 2023, legislative changes were implemented, establishing quarterly updates instead [21].

In Ukraine, no medical devices were included in the reimbursement list as of February 2023. In contrast, at that time, the Republic of Poland included 544 medical device names and 89 food products for special medical purposes (including dietary products) eligible for reimbursement [21].

Ukrainian pharmacoeconomists have calculated the cost of diabetes self-monitoring, specifically the annual expenses for test strips and glucometers incurred by patients with type 1 and type 2 diabetes mellitus [5]. It was found that self-monitoring of type 1 diabetes mellitus requires the highest yearly expenditure on test strips, ranging from UAH 5,986.00 to 15,622.00. Furthermore, the total annual cost of self-monitoring, including both glucometers and test strips, was estimated to be UAH 6,318.00–15,997.00 for patients with type 1 diabetes mellitus and UAH 4,821.50–12,091.50 for those with type 2 diabetes mellitus [5]. These findings open promising prospects for further research, including the analysis of reimbursement program effectiveness in other EU countries with the aim of adapting best practices to the Ukrainian context; the evaluation of the impact of the "Available Medicines" program on the dynamics of diabetes complications based on clinical and socioeconomic indicators; the assessment of patient satisfaction with the quality of medical devices included in the reimbursement program; and the development of methodological approaches to forming lists of medical devices for reimbursement, taking into account evidence-based medicine and comprehensive pharmacoeconomic evaluation.

Conclusions. 1. A commodity analysis of test strips for blood glucose determination was conducted, covering their physicochemical, technological, and operational characteristics, as well as storage, packaging, and labeling requirements in accordance with the technical regulation on medical devices.

2. A retrospective analysis of the reimbursement registries of medical devices and the NHSU dashboards revealed an expansion of the assortment from 23 items in 2023 to 43 items in 2024, along with an increase in the share of fully reimbursed products.

3. Electronic prescription data indicate the intensification of the reimbursement program in 2025 and an increase in patient coverage, particularly among the 40–64 age group.

4. The development of the test strip reimbursement program enhances the availability of medical devices for patients with type 1 diabetes mellitus, contributing to improved self-monitoring, reduced risk of complications, and optimization of healthcare system expenditures.

5. Further research should focus on the analysis of state reimbursement effectiveness, patient satisfaction levels, and the improvement of assortment policy within the framework of the "Available Medicines" program.

Perspectives for further research. Further research should be aimed at evaluating the long-term effectiveness of the "Available Medicines" state reimbursement program for medical devices

used in blood glucose self-monitoring. It is advisable to analyze the program's impact on reducing diabetes complications, improving treatment adherence, and optimizing healthcare expenditures. Comparative studies with EU countries could help identify best practices for enhancing reimbursement mechanisms in Ukraine. In addition, future investigations should assess patient satisfaction, accessibility, and awareness levels, as well as develop evidence-based approaches to expanding the list of reimbursed medical devices according to patient needs and age-specific characteristics.

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Authors' contribution:

O. O. Pokotylo – development of the research idea and design, data analysis and interpretation, article editing;

M. B. Demchuk – formulation of the research concept, synthesis of conclusions;

L. I. Budniak – literature review, manuscript writing;

R. Yu. Basaraba – discussion of the research results;

A. I. Dub – conducting the study, participation in manuscript preparation.

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МЕДИЧНІ ВИРОБИ ДЛЯ САМОКОНТРОЛЮ ГЛЮКОЗИ В КРОВІ: ТОВАРОЗНАВЧІ ТА ЕКОНОМІЧНІ АСПЕКТИ

РЕЗЮМЕ. Актуальність роботи полягає у необхідності наукового обґрунтування ефективності державної програми реімбурсації медичних виробів для самоконтролю рівня глюкози в крові в умовах реформування системи охорони здоров'я України, що спрямована на підвищення доступності, якості життя та фармацевтичного забезпечення пацієнтів із цукровим діабетом 1-го типу.

Мета – дослідити товарознавчі характеристики тест-смужок для самоконтролю рівня глюкози в крові та проаналізувати їхню економічну доступність у межах програми державного відшкодування «Доступні ліки».

Матеріал і методи. Об'єктом дослідження стали медичні вироби, включені до Переліків відшкодування Національної служби здоров'я України за період з серпня 2023 р. по березень 2025 р. Використано порівняльний товарознавчий аналіз, контент-аналіз нормативно-правових актів МОЗ України, а також ретроспективний аналіз даних аналітичних дашбордів НСЗУ. Для узагальнення результатів застосовано статистично-аналітичні методи та графічну інтерпретацію отриманих даних.

Результати. Встановлено, що тест-смужки для визначення рівня глюкози у крові є одноразовими медичними виробами, чутливими до впливу зовнішніх факторів, тому потребують спеціальних умов зберігання (температура 4–30 °С, вологість ≤ 65 %). Пакування виконує захисну та інформаційну функції: первинне – герметичний тубус із сорбентом; вторинне – картонна коробка з маркуванням і інструкцією; транспортне – гофрокороб. Ретроспективний аналіз показав розширення асортименту медичних виробів, що підлягають реімбурсації: з 23 позицій у 2023 р. до 43 у 2024 р. та підвищення частки безоплатних позицій. За даними НСЗУ, встановлено зростання кількості по-

гашених е-рецептів у 2025 р., що свідчить про підвищення як фізичної, так і фінансової доступності медичних виробів для пацієнтів із цукровим діабетом 1-го типу.

Висновки. Проведене дослідження підтвердило, що розширення програми реімбурсації підвищує доступність тест-смужок для самоконтролю глюкози в крові, сприяє покращенню якості життя пацієнтів, профілактиці ускладнень та раціоналізації витрат системи охорони здоров'я. Доцільним є подальше вдосконалення асортиментної політики та механізмів державного відшкодування з урахуванням потреб різних вікових груп пацієнтів.

КЛЮЧОВІ СЛОВА: тест-смужки; рівень глюкози; цукровий діабет 1-го типу, товарознавчий аналіз, фармацевтичне забезпечення, програма «Доступні ліки».

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