ORIGINAL ARTICLE

Medycyna Ogólna i Nauki o Zdrowiu 2022, Tom 28, Nr 2, 149–156
www.monz.pl

A preliminary model for assessing real costs incurred by a healthcare entity in connection with the implementation of an oncological drug programme

Wstępny model oceny kosztów rzeczywistych ponoszonych przez podmiot leczniczy w związku z realizacją onkologicznego programu lekowego

Krystyna Futyma[1,A-D], **Andrzej Śliwczyński**[1,E-F]

[1] *Academy of Humanities and Economics, Łódź, Poland*
A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of article

Futyma K, Śliwczyński A. A preliminary model for assessing real costs incurred by a healthcare entity in connection with the implementation of an oncological drug program. Med Og Nauk Zdr. 2022; 28(2): 149–156. doi: 10.26444/monz/150619

Abstract

Introduction and Objective. Modern drug therapies are made available on the basis of specific legal and economic solutions. In Poland, a model for financing modern therapies by the public payer in the form of a drug programme has been developed. The basic principles of such a strictly defined therapeutic procedure, apart from ensuring maximum safety and clinical effectiveness, is the need to define a budget that can be used for these usually expensive drugs. The aim of the study was to identify and analyse the actual costs related to the treatment process of a patient within the framework of an oncological drug programme, incurred by a healthcare entity.

Materials and method. The oncological drug programme B.50 'Treatment of patients with ovarian cancer, fallopian tube cancer or peritoneal cancer', implemented in an oncology centre in 2018–2021, was selected for the analysis. On average, 19 patients were treated annually.

Results. The lump-sum method of financing healthcare benefits under the drug programme, adopted by the public payer, does not cover the actual costs of treatment. Providing patients with all necessary medical services at every stage of the treatment process, which are not financed by the payer under the drug programme, creates a real risk of indebtedness to the healthcare entity.

Conclusions. The chronic nature and therapeutic process of many diseases generate additional costs for the treatment of complications. Without the valuation of benefits adequate to the actual costs of treatment, a significant increase in the availability of innovative therapies to patients may become impossible.

Key words

drug programs, financing, ovarian cancer

Streszczenie

Wprowadzenie i cel pracy. Nowoczesne terapie lekowe udostępniane są na podstawie szczególnych rozwiązań prawno-ekonomicznych. W Polsce został opracowany model finansowania nowoczesnych terapii przez płatnika publicznego w formie programu lekowego. Podstawowymi założeniami tak ściśle określonej procedury terapeutycznej, poza zapewnieniem maksymalnego bezpieczeństwa i efektywności klinicznej, jest potrzeba ustalenia budżetu, który może być wykorzystany dla tych z reguły kosztownych leków. Celem pracy była identyfikacja i analiza rzeczywistych kosztów związanych z procesem leczenia pacjenta w ramach onkologicznego programu lekowego, ponoszonych przez podmiot leczniczy.

Materiał i metody. Do analizy wybrano onkologiczny program lekowy B.50 „Leczenie chorych na raka jajnika, raka jajowodu lub raka otrzewnej", zrealizowany w ośrodku onkologicznym w latach 2018–2021. Leczeniem średniorocznie objętych było 19 pacjentek.

Wyniki. Przyjęty przez płatnika publicznego ryczałtowy sposób finansowania świadczeń medycznych w ramach programu lekowego nie pokrywa rzeczywistych kosztów leczenia. Zapewnienie pacjentom wszystkich niezbędnych na każdym etapie procesu leczenia usług medycznych, które nie są finansowane przez płatnika w ramach programu lekowego, stwarza realne ryzyko zadłużania podmiotu leczniczego.

Wnioski. Przewlekły charakter i długotrwały proces terapeutyczny wielu chorób generuje dodatkowe koszty leczenia powikłań. Bez dokonania wyceny świadczeń adekwatnej do rzeczywistych kosztów leczenia istotne zwiększenie pacjentom dostępu do innowacyjnych terapii może stać się niewykonalne.

Słowa kluczowe

programy lekowe, finansowanie, rak jajnika

Address for correspondence: Krystyna Futyma, Academy of Humanities and Economics, Łódź, Poland
E-mail: dyrektor@poliklinika.net

Received: 20.05.2022; accepted: 02.06.2022; first published: 09.06.2022

INTRODUCTION

Modern drug therapies are made available on the basis of specific legal and economic solutions, which differ in individual countries in the European Union (EU) and worldwide. In the countries of the EU, including Poland, a new therapy may be used after authorisation by the European Medicines Agency (EMA), and may also be the subject of an application for reimbursement from public funds. Quick and State-subsidised access to modern drug therapies is a difficult task. The barriers here are primarily the availability of drug therapy (including the proces of its approval for use by the appropriate central institution), the price of the drug (which affects the cost of patients' therapy), and the associated costs, i.a. costs of monitoring effectiveness and safety. In addition to clinical criteria, such as (most important) patient safety and clinical effectiveness, economic and organisational conditions are also considered. In Poland, a model for financing modern therapies by the public payer – the National Health Fund (NFZ) was developed in the form of a strictly defined procedure of a drug programme. The basis for qualifying a therapy for reimbursement is its assessment by the Agency for Health Technology Assessment and Tariff System (AOTMiT) and a recommendation issued by the President of AOTMiT for the Minister of Heath, based on the position of the Transparency Council. The scope of the assessed scientific evidence was developed by AOTMiT and is publicly available on the website [1]. The path of proceeding adopted in Polish regulations is similar to the solutions adopted in other countries [2]. The rules of financing a therapy with new drugs, including the description of a drug programme, are announced [3] by the Minister of Health every two months. The description of a drug programme consists of three modules:

- healthcare beneficiaries (patients) – rules (criteria) of qualification for therapy;
- therapy – drug dosage schedule;
- monitoring – diagnostic tests performed under the programme.

The basic principles of such a strictly defined therapeutic procedure, apart from ensuring maximum safety and clinical effectiveness, is the need to define a budget that can be used for these usually expensive drugs. This budget is specified in the plan and successively in the contracts of the healthcare entity (hospital) with the public payer in Poland – the National Health Fund [4]. Matters related to covering individual drugs with public funding are dealt with in accordance with the provisions of the Reimbursement Act [5], with the principles of making reimbursement decisions being based on, i.a., the assessment of:

- clinical and practical effectiveness;
- safe use;
- relation between health benefits and risk of use;
- ratio of costs to the achieved health effects, taking into account the amount of the cost-effectiveness threshold of a quality-adjusted life year.

The reimbursement of a medicinal product is made by way of an administrative decision issued by the Minister of Health, based on an application submitted by the marketing authorisation holder (drug manufacturer, its representative or importer). After formal and legal assessment of the application, the content of the drug programme is agreed with the applicant, after which the application, together with the agreed drug programme, is sent for evaluation by AOTMiT. The President of AOTMiT, taking into account the position of the Transparency Council, the quality of available scientific evidence and the credibility of comparisons and the results of the analyses carried out, issues a recommendation on reimbursement of the drug applied-for in a given indication. In the next stage, the Economic Commission conducts negotiations with the entities responsible for the negotiations on the determination of the official selling price, the level of payment and the indications at which the drug is to be reimbursed. At the same time, when determining the official selling price of a drug, the Minister of Health is responsible for balancing the interests of beneficiaries and marketing authorisation holders, taking into account the financial capacity of the public payer [1].

In recent years, the availability of modern drugs reimbursed by the public payer has significantly increased in Poland. In 2012–2018, the number of drug programmes and the active substances available within them doubled in Poland. In 2012, 44 drug programmes were conducted in Poland, including 12 oncologica programmes. In 2020, there were 92 drug programmes, 32 of which were related to the treatment of cancer patients. At the end of 2021, 105 drug programmes were conducted, including 37 oncological. However, the phenomenon of limited availability of innovative drugs to patients in accordance with the current clinical guidelines and European standards is still pointed out. In the coming years, we can expect the introduction of many innovative therapies to the market, the financing of which from public funds in Poland will constitute a significant challenge for the public payer [6].

OBJECTIVE

The aim of the study was to identify and analyse the actual costs related to the treatment process of a patient as part of an oncological drug programme, incurred by the healthcare entity – the programme implementer.

MATERIALS AND METHOD

In order to estimate the real costs incurred by the healthcare entity for the implementation of a drug programme, the drug programme B.50 'Treatment of patients with ovarian cancer, fallopian tube cancer or peritoneal cancer' (ICD-10: C56, C57, C48)' was selected. This is a combination of previous programmemes in this indication functioning until the end of April 2021, i.e. B.50 – 'Treatment of advanced ovarian cancer, fallopian tube cancer or primary peritoneal cancer (ICD-10 C56, C57, C48)' and B.80 – 'Maintenance treatment with olaparib in patients with platinum-sensitive relapsed advanced ovarian cancer, fallopian tube cancer or primary peritoneal cancer (ICD-10 C56, C57, C48)', and a new indication of treatment with olaparib in patients with newly-diagnosed ovarian cancer. The new shape of the B.50 drug programme was given in the announcement of the Minister of Health of 21 April 2021 [7]. The choice of this programme was dictated by its cost-intensive nature (oncology programme) and the small population of patients

treated within it, which makes it easier to calculate the actual treatment costs per patient. The study used cost and revenue data in the ovarian cancer drug programme implemented at the Warmian-Masurian Cancer Center of the Ministry of the Interior and Administration's Hospital in Olsztyn. Data from the implementation of this drug programme in 2018–2021 were used for the analysis. For this purpose, for each year covered by the analysis, all expenses incurred by the healtcare entity related to a patient's participation in the drug programme dedicated to ovarian cancer were summed-up, in particular costs resulting from the obligatory diagnostic tests indicated in the description of a given drug programme, costs of hospitalisation, costs of drug therapy used and monitoring costs. The analysis covered all treatment modes provided for in the 'description of the drug programme', i.e. inpatient mode (stay in the ward), one-day mode, and outpatient mode. The actual cost of a patient-day for each cost centre was determined, which includes direct and indirect costs such as: personnel costs (doctors, nurses, medical secretaries, healthcare assistants), heating, energy, water, insurance, maintenance and repair of equipment, catering services, cleaning and washing, costs of acquisition and maintenance and depreciation of fixed assets, costs of support units (pharmacies, cytotoxic drug laboratories, admissions rooms, etc.), administrative costs (e.g. accounting, statistics, as well as billing and public procurement departments), costs of maintenance departments, management costs. The determined costs of a patient's stay were contrasted with the revenue obtained from the National Health Fund in accordance with the evaluation of the stay benefits adopted by the payer. In revenue from this in the year 2021, the quality coefficient of 1.025 used by the National Health Fund was taken into account in accordance with the order of the President of the National Health Fund of 27 January 2021 [8]. In order to standardise the financial values, they were converted based on the purchasing power parity (PPP) for 2019, and presented in the 'USD-inter' currency (always having the value '1' taking into account 'PPP'). For 2019, the value of 'USD 1 PPP' was PLN 1.787 [9].

RESULTS

In 2018–2021, on an annual average basis, 19 patients participated in the drug programme dedicated to ovarian cancer. The patients were treated in all three modes.

Table 1. Number of patients treated in the B.50/B.80 programme in the years 2018–2021

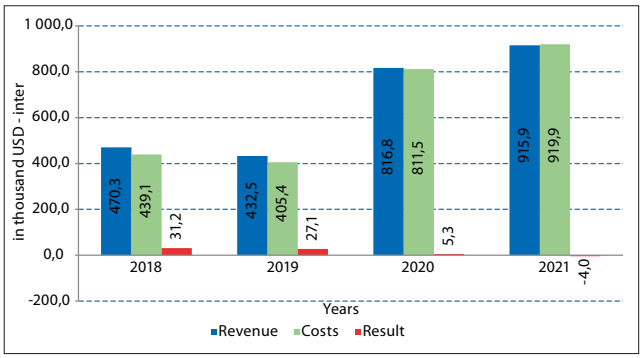
YEAR	Number of patients	Number of patient-days [10] of hospitalisation	Number of patient-days[10] one-day stay	Number of outpatient stays	Total
2021	18	37	42	75	154
2020	16	22	57	55	134
2019	21	5	129	10	144
2018	22	47	148	1	196

Between 2018–2021, the National Health Fund, under the adopted tariffs, paid for benefits related to the implementation of the drug programme in the following ways:

a) hospitalisation in the inpatient mode related to the implementation of the programme – per patient-day: USD-inter 272.367 (additionally in 2021, after taking into account the quality coefficient 1.025, the payment was USD-inter 276.262);
b) hospitalisation in the one-day mode related to the implementation of the programme – per patient-day: USD-inter 272.367 (in 2021, due to quality coefficients, the hospital received USD-inter 276.262);
c) outpatient admission of a patient related to the implementation of the programme USD-inter 60.526 (in 2021, after taking into account the quality coefficient USD-inter 62.037).

In the analysed period of 2018–2021, the average cost of a patient-day in hospitalisation increased from USD-inter 302.054 to USD-inter 408.523, i.e. by 35.25%; the cost of a patient-day in the one-day mode increased from the level of USD-inter 77.230 to USD-inter 211.802, respectively, i.e. by 274.25%; while the cost of an outpatient admission increased from the level of USD-inter 47.118 to USD-inter 58.383, which is 123.91% of the base value (costs of admitting a patient to the programme in the outpatient mode in 2018). The above data show that the payment for hospitalisation of a patient related to the treatment of a patient in the given drug programme is underestimated. Throughout the analysed period, the revenue received from the National Health Fund did not cover the full costs of a patient›s stay in the ward and the necessary medical procedures. The cost of a patient-day of stay in a hospital ward is the difference between the total cost of a cost centre and the cost of drugs, medical devices and medical procedures.

Figure 1. Balance comparison of revenue and costs together with the result from the implementation of the B.50 programme in 2018–2021 in thousand USD-inter



Years	Revenue	Costs	Result
2018	470,3	439,1	31,2
2019	432,5	405,4	27,1
2020	816,8	811,5	5,3
2021	915,9	919,9	-4

As shown in Figure 1, the value of revenue in 2021 reached 194% of the 2018 revenue; however, the costs of 2021 increased to 209.5% of the cost level in 2018. As a result of the faster pace of growth of costs than revenue, despite obtaining an additional payment for the application of the quality coefficient, activities related to the implementation of the drug programme in the analysed indication, in 2021, closed with a negative financial result. In 2020, revenue and costs

Table 2. Summary of revenue and the cost of a stay in the B.50/B.80 drug programme in 2018–2021 (in USD-inter)

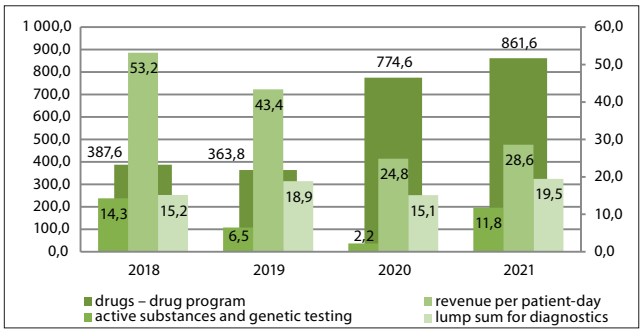
YEAR	Stay in a ward			One-day stay			Outpatient mode		
	Revenue	Cost	% of costs covered	Revenue	Cost	% of costs covered	Revenue	Cost	% of costs covered
2021	276.262	408.523	67.6%	276.262	211.802	130.4%	62.037	58.383	106.3%
2020	272.367	374.203	72.8%	272.367	150.672	180.8%	60.526	62.496	96.8%
2019	272.367	321.388	84.7%	272.367	84.398	322.7%	60.526	51.494	117.5%
2018	272.367	302.054	90.2%	272.367	77.230	352.7%	60.526	47.118	128.5%

Table 3. Summary of the lump sum for diagnostics in the B.50 / B.80 programme in the years 2018–2021

No.	Name of a healthcare benefit	Year				
		2018	2019	2020	01–04.2021	From 05.2021
1	Diagnostics in the programme of maintenance treatment with olaparib in patients with platinum-sensitive relapsed advanced ovarian cancer, fallopian tube cancer or primary peritoneal cancer	x	1,704.53	1,704.53	1,704.53	x
2	Diagnostics in the programme of treatment of patients with advanced ovarian cancer – 1st year of therapy	2,049.80	2,049.80	2,049.80	2,049.80	x
3	Diagnostics in the programme of treatment of patients with advanced ovarian cancer – 2nd and subsequent year	344.15	344.15	344.15	344.15	x
4	Diagnostics in the programme of treatment of patients with ovarian cancer, fallopian tube cancer or peritoneal cancer – bevacizumab (1st and subsequent year of therapy), olaparib (1st year of therapy)	x	x	x	x	2,396.42
5	Diagnostics in the programme of treatment of patients with ovarian cancer, fallopian tube cancer or peritoneal cancer – 2nd and subsequent year of therapy with olaparib	x	x	x	x	1,538.0

doubled compared to 2019. This is related to the admission to reimbursement of new high-cost molecules in the analysed indication, with a relatively constant number of patients treated in the given drug programme.

Figure 2. Summary of revenue components in the B.50/B80 drug programme in 2018–2021 in thousand USD-inter

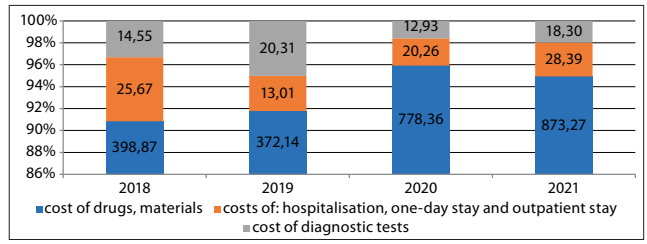


Years	Drugs – drug programme	Active substances and genetic testing	Revenue per patient-day	Lump sum for diagnostics
2018	387,6	14,3	53,2	15,2
2019	363,8	6,5	43,4	18,9
2020	774,6	2,2	24,8	15,1
2021	861,6	11,8	28,6	19,5

As shown in Figure 2, the value of drugs in the drug programme has an upward trend (in 2018, USD-inter 387.6 thousand; in 2021, USD-inter 861.6 thousand). In 2020, the value of drugs administered doubled compared with 2019. The growing trend continues (2019: 363.8; 2020: 774.6). The lump sum for diagnostics varies over time and remained at low values throughout the analysed period (2018: 15.2; 2021: 19.5). The change in the total amount of the lump sum for diagnostics depends on the number of patients in the programme in a given period and the year of therapy.

The value of revenue from hospitalisation patient-days tends to decrease. It is related to the introduction of the outpatient mode to a greater extent than the hospitalisation of a patient in order to administer a drug in connection with the introduction of the tablet form of drugs.

Figure 3. Summary of cost components in the B.50/B80 drug programme in 2018–2021 in thousand USD-inter

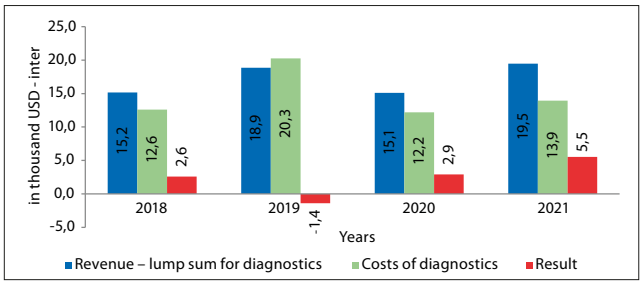


Years	Costs of drugs, materials	Costs of: hospitalisation, one-day stay and outpatient stay	Cost of diagnostic tests
2018	398,87	25,67	14,55
2019	372,14	13,01	20,31
2020	778,36	20,26	12,93
2021	873,27	28,39	18,3

In the analysed period, in the structure of costs related to the implementation of the drug programme, drugs have the largest share (2018: 90.8%; 2019: 91.8%; 2020: 95.9%; 2021: 94.9%), and their level noticeably increased from 2020. The share of the costs of stays ranges from 5.8% – 2.3% of the structure. The level of costs of stays related to the implementation of the drug programme depends on the mode of providing healthcare benefits, which is related to the route of administration of the drug. In 2018, when the share of costs of stays in the cost structure was the highest and amounted to 5.8%, 195 patient-days were completed, including 47 hospitalisations and 1 outpatient

stay. In 2020, when the share of costs of stays in the total cost structure was the lowest and amounted to 2.3%, 79 patient-days were completed, including 22 hospitalisations and 55 outpatient stays. In 2021, the share of costs of stays in the cost structure was 3.1%. In 2021, 79 patient-days were completed, including 37 in the form of hospitalisation and 75 outpatient stays. However, the increase in the outpatient mode did not compensate for the increase in costs caused by the increased number of hospitalisations (by 10) compared with the previous year.

Figure 4. Summary of costs and revenue from the lump sum for diagnostics of patients with ovarian cancer in 2018–2021



Years	Revenue – lump sum for diagnostics	Costs of diagnostics	Result
2018	15,2	12,6	2,6
2019	18,9	20,3	-1,4
2020	15,1	12,2	2,9
2021	19,5	13,9	5,5

With the exception of 2019, in the remaining years of the analysed period, the lump sum for diagnostics covered the costs of diagnostics. As can be seen in Figure 4, the costs of diagnostics were covered in individual years at the level of: 2018: 120.6%; 2019: 93%; 2020: 123.8%; 2021: 140.3%. The increase in the coverage of costs in this respect observed in 2021 is related to the increase by the payer of the lump sum for diagnostics in the drug programme in question.

DISCUSSION

Access to treatment with the use of innovative, high-cost drug technologies is possible under drug programmemes; however, only well-defined disease entities are covered by this form of treatment. In order to determine whether a given programme is profitable, it is necessary to determine the cost-effectiveness of treatment, i.e. social readiness to pay for obtaining an additional unit of result: years of life (QALY), years of life adjusted by its quality, or the number of years without progression – in oncology. In order to maximise the result within a limited budget, it is necessary to calculate not the average, but the incremental cost-effectiveness ratios. The incremental cost and the incremental result show how much the cost and the result increase when a marginally better therapeutic option is selected for a given patient [11]. A detailed description of each of the drug programmemes available in Poland is published as an Appendix to an announcement of the Minister of Health. In addition to the criteria for including a patient in treatment and the criteria for excluding a patient from the programme, the description includes a drug dosage schedule the route of drug administration, as well as a list of diagnostic tests performed when qualifying a patient to the programme and necessary to monitor the treatment process. The provision of healthcare benefits in the field of drug programmemes is possible in the following three modes:

1) outpatient stay;
2) one-day stay – only if the therapy goal is not achieved during the outpatient mode);
3) hospitalisation – only if the therapy goal is not achieved during outpatient or one-day stay modes.

The payer‘s expectation is that in the event that the goal of the therapy can be achieved equally in each of the above-mentioned modes, the outpatient mode is the dominant one. However, as a rule, in the case of intravenous administration of the drug to the patient, the hospitalisation mode is used to take into account the patient‘s safety. In the case of subcutaneous therapies, a one-day stay is used. In contrast, for oral therapies, dispensing a drug for home use to the patient takes place in the outpatient mode.

The decision to qualify a patient for a given programme is made by a doctor from a centre that has a contract for the implementation of a specific programme, based on the detailed inclusion criteria described in the programme [12]. Due to the cost-effectiveness criterion used in the reimbursement process, high-cost treatment methods are intended for patients who are likely to gain the greatest clinical benefits from therapy, and patients for whom the use of other therapeutic options is usually less effective. Therefore, drug programmemes constitute a compromise between the patients› needs in terms of modern treatment methods and the payer›s capabilities [13].

The costs of implementing drug programmemes incurred by healthcare providers are covered by the public payer on the basis of a contract concluded between a healthcare provider and a regional branch of the National Health Fund in accordance with the provisions of the order on lying down the terms and conditions for concluding and implementing contracts regarding hospital treatment in respect of drug programmemes [14]. The financing of treatment in drug programmemes covers the cost of drugs reimbursed to hospitals in accordance with a purchase invoice and, separately, the cost of services provided – outpatient visits, one-day stays and/or hospitalisation, as well as diagnostic tests performed.

Outpatient visits and hospitalisation are financed in accordance with the valuation from the catalogue of benefits for each benefit provided, while diagnostic tests are financed in the form of an annual lump sum, the value of which varies in different drug programmemes. In theory, the pricing of these benefits should reflect the real costs incurred by hospitals, but usually this is not the case. Thus, the burden on the budgets of medical centres is the cost assessment of drug programmemes inadequate to the actual expenses incurred by these entities. The problem of underestimating the valuation of stay procedures (hospitalisation in a hospital ward) in correlation to high personnel costs and costs of patient diagnostics under drug programmemes\ has been raised by healthcare providers for many years. However, the value of a single reference point in both drug and chemotherapy programmemes has remained the same for five

years. Equally difficult to meet are the increasing bureaucratic requirements imposed by the payer, overburdening the medical and administrative staff of hospitals. According to the provisions of the Act on Health Care Services Financed from Public Funds, Article 188c, paragraph 1 [15], the President of the National Health Fund is obliged to run and maintain an electronic System for Monitoring Therapeutic Programmemes\ (SMPT), made available to healthcare providers by the Fund›s regional branches through a web application. This system enables the Fund to process data on the fulfilment by beneficiaries of the criteria for inclusion in a drug programme, qualification of beneficiaries to a drug programme, monitoring the course of therapy and assessing its effectiveness, the date and reason for excluding from a drug programme, and assessing the effectiveness of a drug programme, as well as a therapy used, including the method of administration and dosage of a drug. Treatment data reported in SMPT are cross-checked by the National Health Fund by comparing them with the data reported for a given period by the healthcare provider. Supplementing all the required data for each patient in SMPT, and their compliance with the data reported by the hospital, is a condition for the National Health Fund to settle the costs of the drug used under the drug programme and the costs of related healthcare benefits. In the case of lack of data in the system or their inconsistency, payment for the healthcare benefits provided is suspended. This situation creates a lot of controversy on the part of healthcare providers because inconsistencies or unintentional errors found during verification by the payer often result from system imperfections, and not from incorrect or untimely reporting. This results in the lack of settlement of costs incurred by the hospital, and this, in turn, may deepen the problems of the financed hospitals and cause further restrictions in access to healthcare benefits. [16].

The need to repeatedly complete the data on the therapy used within drug programmemes also raises concerns in the medical communit, as it imposes an additional workload on doctors and, above all, takes time which should be devoted to patients. This problem was highlighted with the COVID-19 pandemic, which resulted in significant temporary shortages of medical personnel because of isolation due to infections. In order to enable the continuation of therapy by patients in the face of a significant reduction in staff, as well as to support the functioning of healthcare entities implementing drug programmemes, the legislator changed the regulations and introduced a simplification of the settlement of the costs of programme implementation for the duration of the epidemic. According to the amended provision, the only condition for the settlement of costs related to the implementation of drug programmemes is the correct reporting of these data by the healthcare provider to the payer (NFZ) [17]. It remains to be hoped that the above rule will apply permanently, also after the epidemic has ceased, which will be for the benefit of all parties involved in the implementation of drug programmeme. \

Accounting for drugs under risk sharing instruments is also problematic. This requires the additional involvement of accounting services in tracking the number of administrations in order to subsequently request corrective invoices from the drug supplier. In each case, it causes a time shift in settlements, disrupting the proportionality of costs to revenue, as well as financial liquidity. The negative determinant is the settlement of the price of the drug per milligram administered to the patient, when the substance remaining after the administration cannot be used or settled with the payer. The costs of drugs are settled on the basis of the price in accordance with a purchase invoice, and only the amount of the drug that has been administered or dispensed to the patient, in amounts consistent with the dosing specified in the decription of the drug programme, is settled. Unused parts of the drug are not subject to settlement and constitute a loss for the healthcare provider, who is additionally forced to bear the costs of disposal of the unused drug. The costs of diagnostic tests performed during the qualification and implementation of the drug programme are settled by the service provider as a lump sum, specified separately for each drug programme in the lump sum catalogue (described in an Appendix to an order of the President of the National Health Fund). This lump sum covers the average cost of diagnostic tests resulting directly from the description of the drug programme. In addition, it is not without significance that the lump sums in some items do not even cover a part of the costs necessary to perform a full diagnostics in individual diseases. Other tests performed in a given beneficiary covered by a given drug programme, related to monitoring the safety of the therapy and often necessary due to coexisting diseases, are not financed with a lump sum. This is largely due to the fact that the description of a drug programme does not reflect the general situation in practice, in particular the presence of coexisting diseases, as new drugs are registered and admitted to trading on the basis of the results of clinical trials in which carefully selected patients participate. This creates enormous problems in the implementation of drug programmemes and generates additional costs of treatment of complications. [18]. This leads to further losses on the part of drug programme implementers who, faced with the dilemma of discontinuing therapy and excluding the patient from the programme because of complications due to coexisting diseases, take up the challenge of treating complications in order to regain the possibility of continuing drug therapy. After all, it is quite obvious that in this situation, in addition to obtaining the greatest possible health benefit by the patient, there is a real risk of losing the effects of the expenditure incurred by the public payer on the current drug therapy. These effects will be lost when the therapy is discontinued.

In the case of using some drugs containing active substances for which their generic or biosimilar equivalents have been reimbursed, the National Health Fund from 1 November 2018 introduced the so-called catalogue of correction coefficients, i.e. a catalogue of coefficients increasing the value of the lump sum for diagnostics and the value of healthcare benefits when making settlements for patients treated with active substances listed in the catalogue. The increase in the value of individual benefits varies depending on the drug programme and the therapy used. The corrective mechanism, increasing the valuation, covers all modes of providing healthcare benefits in the field of drug programmes, while the necessary condition for applying a higher valuation is the cost of the drug, which cannot exceed the upper value specified in the catalogue. The cost threshold allowing for the application of the coefficient varies over time, which is to the disadvantage of healthcare providers [12]. This is because in the case of accounting for the administration of an active substance divided into several component items, e.g. due to different purchase invoices, each indicated billing item of the drug must meet the cost condition. Diagnostics increased by a correction coefficient is calculated only for those months

for which the required substance was previously reported, taking into account the expected tariff, i.e. the price per drug unit, which is lower than indicated in the catalogue of coefficients. Due to the volatility of the cost thresholds, in practice there is little possibility to apply the correction coefficient. In addition, the reimbursement value (tariff) is calculated on the day of administering the drug and not its purchase, which may result in a situation in which the facility bought the drug at a higher price, and as a result of the reduction of the reimbursement limit indicated in the next announcement of the Minister of Health, it will be obliged to adjust the tariff below the purchase value [19].

Another problem is the underestimation of the financing needs of drug programmemes and their limitation. Due to the increased availability of immunotherapy treatment in drug programmemes, the structure of patients is fundamentally changing, and therefore there are overlimits. The quarterly system of settling overlimits in drug programmemes used by the payer, forces healthcare providers to wait several months for payment for the healthcare benefits provided, and in most cases, it allows to obtain payment only for the drugs administered, and not for hospitalisation or diagnostics of a patient. In this case, a healthcare provider often has to wait for payment until the end of the year. Financial and accounting data confirm that in most drug programmemes the hospital's burden related to the costs of drugs and diagnostics alone is higher than the financing provided by the National Health Fund, which directly means a loss for the hospital and creates a real risk of indebtedness of the centre.

Covering by the reimbursement, from mid-2018, of biosimilar drugs in oncological therapies resulted in a reduction in the annual costs of therapy, which contributed to significant savings for the public payer. According to experts' calculations, the introduction of biosimilar drugs resulted in savings for the National Health Fund at the level of PLN 150–300 million per year, assuming 25–50 percent decline in the real price for the National Health Fund [18]. It is to be hoped that the significant reduction in the costs of therapy associated with this opens the field not only for the reimbursement of subsequent molecules, which will result in the expansion of the treated patient population, but also will allow for the development of a new financing model and an increase in the valuation of healthcare benefits. It should also be mentioned that, apart from the inadequate valuation of the costs of implementing drug programmemes in relation to the actual expenses incurred by medical centres, an important reason for insufficient access to therapy in terms of the number of patients is the shortage of specialist healthcare personnel. \

The development of drug technologies means that every year the main medical agencies – the European EMA and the American FDA – register several dozen new drugs, one-third of which are intended for the treatment of cancer. The activities of many clinical environments and patient organisations contribute to the coverage of further innovative molecules. This is clear proof that the public payer notices and recognises the needs in this regard. The number of patients treated in drug programmemes in Poland increases slightly from year-to-year, and increasing the number of patients treated will be very difficult without introducing the necessary changes in the financing of procedures related to the implementation of drug programmemes [12], and making the valuation of services adequate to the actual costs of treatment incurred by healthcare entities.

CONCLUSIONS

1. The introduction of a special path of financing innovative drug therapies results from the high costs of these drugs with a very limited budget for their reimbursement.
2. New drug technologies require more detailed monitoring, therefore a patient, in order to be able to receive a specific drug, must meet restrictive criteria for inclusion in a drug programme, which are very often narrowed in relation to the drug registration indications and recommendations of scientific societies, and thus clinical practice in other European Union countries.
3. The availability of innovative drugs in Poland is systematically increasing; however, the phenomenon of limited availability of innovative drugs to patients in accordance with the current clinical guidelines and European standards is still raised.
4. The cost of treatment under drug programmemes is increasing, which results, i.a., from introducing more and more advanced technologies to the market.
5. In the coming years, we can expect the introduction of many innovative therapies to the market, the financing of which from public funds in Poland will constitute a significant challenge for the public payer.
6. The chronic nature and therapeutic process of many diseases generate additional costs of treatment of complications.
7. The lump-sum method of financing healthcare benefits related to a patient's hospitalisation in a drug programme and diagnostic services, adopted by the public payer, does not cover the actual costs of these benefits and services incurred by the healthcare entity.
8. Providing patients with all necessary medical services at every stage of the treatment process, which are not financed by the payer under the adopted drug programme reimbursement system, creates a real risk of indebtedness of the centre.
9. Without the valuation of services adequate to the actual costs of treatment incurred by healthcare entities, a significant increase in the availability of innovative therapies to patients, and thus improvement of the effectiveness and efficiency of anticancer treatment, may become impossible.

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