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The cost analysis of treatment for patients with newly diagnosed CLL using therapies funded under the drug program B.79 "Treatment of patients with chronic lymphocytic leukaemia (ICD 10: C.91.1)"

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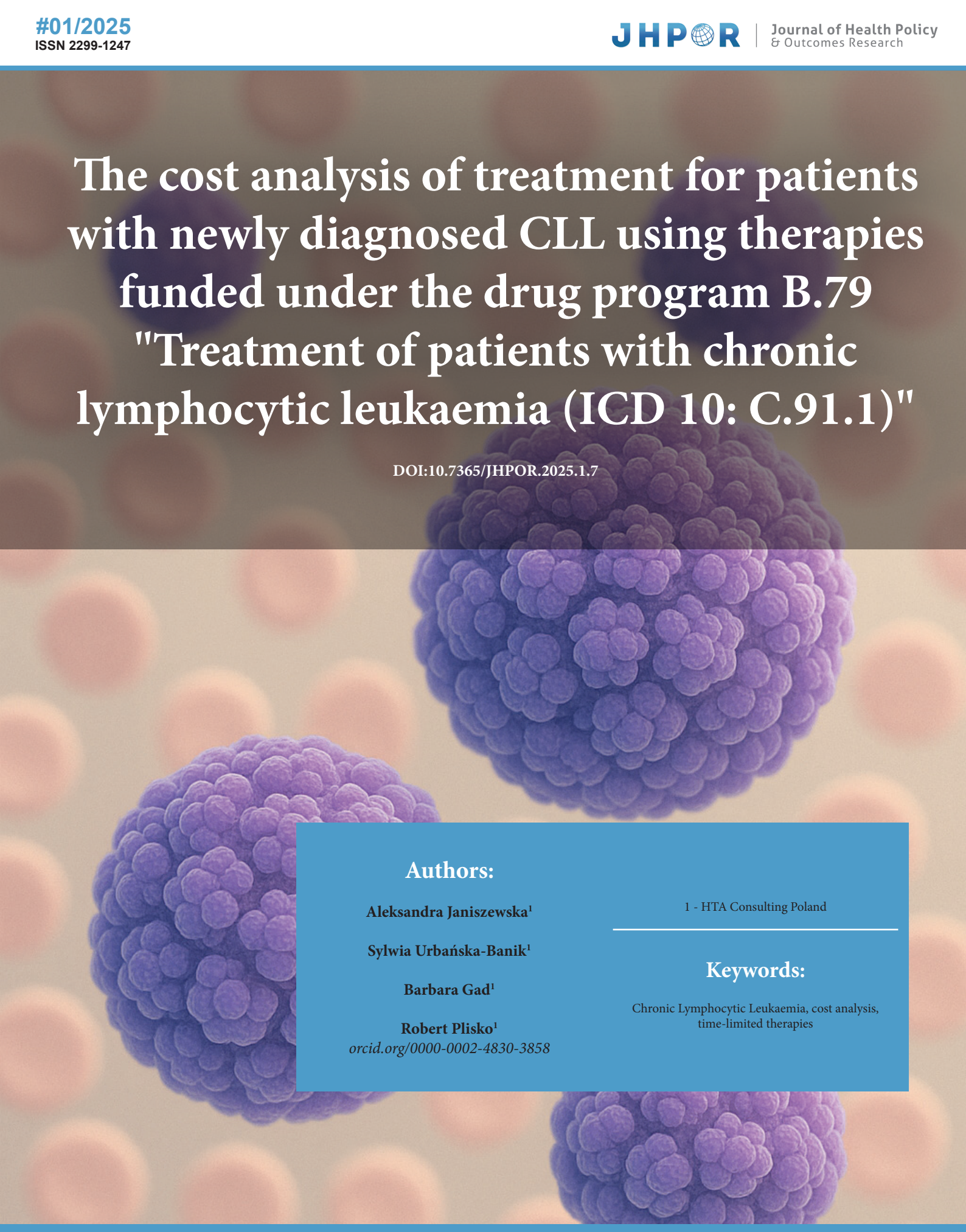

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Abstract

Objective: The aim of this publication is to compare the costs of therapies used in the first-line treatment of chronic lymphocytic leukaemia (CLL) and funded under the B.79 drug program in Poland.

Methods: The cost analysis of treatment was presented in two variants: cost analysis of therapy until disease progression and cost analysis of continuous treatment (without considering therapy discontinuation). For the second variant, estimated costs were presented for a two-year and three-year time horizon. The drug dosing was based on the records of the B.79 drug program.

Results: The average treatment cost for time-limited therapies ranges from PLN 62,611 for OBI + CLB to PLN 238,803 for VEN + IBR. For therapies used continuously until progression, the average treatment cost ranges from PLN 421,178 for IBR to PLN 478,071 for ZAN. The total cost parity between VEN + OBI and therapies requiring continuous treatment until disease progression occurs around the 80th to 91st week, while for IBR + VEN, the total costs equalize around the 119th to 134th week of treatment. After these time points, there is a potential cost saving for the public payer.

Conclusions: The limited duration of treatment allows for cost control within the drug program. Even in the short-term time horizon, the use of time-limited therapies enables savings for the public payer.

Introduction

Chronic lymphocytic leukaemia (CLL) is a cancer of the hematopoietic system belonging to the group of lymphocytic leukaemias.[1] CLL is the most common type of leukaemia diagnosed in the population of North America and Europe.[1,2] According to data from the Polish National Cancer Registry (KRN), lymphocytic leukaemias account for about 60% of leukaemia cases in Poland and are responsible for 46% of leukaemia-related deaths.[3] The incidence of CLL is 4.2/100,000 people per year. Older adults are at the greatest risk for CLL. The median age at diagnosis is 67-72 years, with 70% of CLL patients being over the age of 65.[4]

Over the years 2017-2024, access to reimbursement for new molecular-targeted therapies in the treatment of CLL in Poland has improved. Currently, the foundation of CLL treatment is no longer immunochemotherapy, but newly developed targeted therapies, which are drugs that inhibit signalling through the B cell receptor. CLL is divided into: previously untreated, which occurs in newly diagnosed patients or those who have not received any prior leukaemia treatment, and refractory/relapsed, which applies to patients who have already undergone at least one line of cancer treatment.[4,5]

Currently in Poland patients with CLL have access to therapies funded under the chemotherapy catalogue and the drug program (PL) B.79 "Treatment of patients with chronic lymphocytic leukaemia (ICD 10: C.91.1)".[6] In the first-line treatment of the B.79 drug program, the following treatments are funded: ibrutinib (IBR) , acalabrutinib (ACA) and zanubrutinib (ZAN) as monotherapies, obinutuzumab (OBI) in combination with chlorambucil (CLB), venetoclax (VEN) in combination with obinutuzumab and ibrutinib in combination with venetoclax.[6] Monotherapies are administered continuously until physician decision of discontinuation, while drugs used in combination regimens are administered for a specified duration.

The aim of this publication is to compare the costs of therapies used in the first-line treatment of CLL and funded under the drug program B.79.

Methods

The cost analysis of treatment is presented in two variants: analysis of therapy costs up to disease progression and analysis of the costs of continuous treatment without considering therapy interruption. For the second variant, estimated costs were presented for a two-year and three-year time horizon. The cost analysis was completed in November 2024.

The dosing of drugs used in CLL treatment was based on the records of the drug program B.79.[6] The drugs used in monotherapy are taken every day. Acalabrutinib is administered at dose of 100 mg twice daily. The other two drugs are taken once daily: ibrutinib at dose of 420 mg and zanubrutinib at dose of 320 mg. The treatment with

obinutuzumab in combination with chlorambucil lasts for 6 cycles, with each cycle lasting 28 days. The recommended dose of OBI is 1000 mg on days 1 and 2, day 8, and day 15 of the first cycle, and in subsequent cycles, 1000 mg on the first day of each cycle. The dose of CLB in this regimen is 0.5 mg/kg body weight, administered on days 1 and 15 of each cycle. The venetoclax therapy in combination with obinutuzumab lasts for 12 cycles of 28 days, with OBI being administered until cycle 6. The initial dose of VEN is 20 mg once daily for 7 days. The dose should be gradually increased over a period of 5 weeks until the recommended daily dose of 400 mg is reached, which is then taken once daily until the completion of cycle 12. The recommended dose of OBI is 1000 mg on days 1, 2, 8, and 15 of the first cycle, and on the first day of each cycle from cycles 2 to 6. The last regimen included in the calculations is ibrutinib in combination with venetoclax. The recommended dose of IBR is 420 mg once daily from cycles 1 to 15. The initial dose of VEN is 20 mg once daily for 7 days, with the first dose administered on the first day of the fourth 28-day cycle. The dose should be gradually increased over 5 weeks until the recommended daily dose of 400 mg is reached, which is taken once daily until the completion of cycle 15. The dosing regimens are presented in Table 1.

According to the B.79 drug program[8], OBI + CLB, VEN + OBI, and VEN + IBR regimens continues until disease progression, but no longer than the maximum therapy duration specified in the program. This approach is consistent with labelling of each scheme. Treatment with the remaining regimens lasts until disease progression. In order to conduct a cost analysis of therapy up to disease progression, it was necessary to determine the average duration of therapy for each regimen. Therefore, a search was conducted on the AOTMiT website (Agency for Health Technology Assessment and Tariffing)[7], aimed at finding analyses relevant to the health problem. The documents found were reviewed to assess data regarding the duration of the therapies being compared and to identify potential sources that could help determine this parameter. Recognizing that documents published on the AOTMiT website may not reflect the most current available data, the Internet was further searched for data covering longer observation periods than those included in the aforementioned reports, as well as information from real-world clinical practice. For some regimens, it was not possible to find relevant data. Therefore, the average treatment duration for OBI + CLB and VEN + OBI was determined based on data from previously developed economic models used for the relevant reimbursement applications. For IBR and ZAN, the average treatment duration was assumed to be the same as for ACA—analyses found on the AOTMiT website compared ACA, ZAN, and IBR in the form of cost-minimization analysis [9, 10], and the type of analysis suggests no differences between these therapies. Therefore, assuming the same average treatment duration for these therapies is considered appropriate. For the VEN + IBR regimen, the maximum treatment duration was assumed. The details are presented in Table 2.

Table 1. Dosing regimens

Regime	Substance	Dose per administration	Cycle length [days]	Number of administrations per cycle
IBR	IBR	420 mg	1[a]	1
AKA	AKA	100 mg	1[a]	2
OBI + CLB	OBI	1,000 mg	28	Cycle 1: 3 Cycles 2-6: 1
	CLB	0.5 mg/kg		2
VEN + OBI	VEN	Week 1: 20 mg Week 2: 50 mg Week 3: 100 mg Week 4: 200 mg Week 5+: 400 mg	28	Cycle 1: 7 Cycles 2-12: 28
	OBI	1,000 mg		Cycle 1: 3 Cycles 2-6: 1
ZAN	ZAN	320 mg	1[a]	1
VEN + IBR	IBR	420 mg	28	28
	VEN	Week 13: 20 mg Week 14: 50 mg Week 15: 100 mg Week 16: 200 mg Week 17+: 400 mg		

a) The cycle length in the drug program is longer, but for calculation purposes, 1 day was assumed (the drug is administered daily in oral form).

Table 2. Duration of treatment			
Regime	Maximum treatment time	Average treatment time	Source
IBR	to progression	45.7 months	The assumption was adopted as for ACA
ACA	to progression	45.7 months	Economic analysis for Calquence (acalabrutinib)[8]
OBI + CLB	6 cycles (1 cycle lasts 28 days)	5.28 months	Economic analysis for Venetoclax (Venclyxto)[9]
VEN + OBI	12 cycles (1 cycle lasts 28 days)	10.08 months	Economic analysis for Venetoclax (Venclyxto)[9]
ZAN	to progression	45.7 months	The assumption was adopted as for ACA
VEN + IBR	15 cycles (1 cycle lasts 28 days)	13,8 months	The maximum duration of therapy was assumed

For the estimation of therapy costs, the following cost categories were considered: drug costs used in the B.79 drug program, drug administration costs, and therapy monitoring costs. To determine the unit costs of the drugs, the following data sources were checked: the DGL NHF (National Health Fund) reports on the average cost of accounting for selected active substances used in drug programs and chemotherapy[10], public procurement orders for drug purchases available through the IKAR Pro portal[11], sales data from the NHF reported on the IKAR Pro portal [11], and data on the implementation of the B.79 drug program for the first half of 2024.[11] The actual costs of the analysed active substances were determined as the lowest of the costs reported in the aforementioned data sources. Additionally, it was verified whether the determined drug prices did not exceed the applicable funding limit.[6] The unit costs are presented in Table 3 and the cost per cycle is presented in Table 4.

Table 3. Costs of substances per milligram reimbursed under the B.79 drug program					
Active substance	Price based on tenders	Price based on sales data	Implementation of B.79 drug program	Ministry of Health Announcement	Price used in calculations
IBR	PLN 0.68	PLN0.72	PLN 0.72	PLN 1.96[a]	PLN 0.68
ACA	PLN 1.58	PLN 1.60	PLN 1.63	PLN 4.39	PLN 1.58
OBI	PLN 6.16	PLN 6.16	PLN 6.16	PLN 11.10	PLN 6.16
VEN	PLN 1.24	PLN 1.26	PLN 1.24	PLN 1.96[a]	PLN 1.24
ZAN	PLN 2.57	PLN 1.03	PLN 1.02	PLN 2.57	PLN 1.02
CLB	-	PLN 1.58	-	PLN 1.63	PLN 1.58

a) average from data for available packaging

Table 4. Costs of substances per cycle			
Regime	Active substance	Cycle length	Costs per cycle
IBR	IBR	28 days	PLN 8,001.15
ACA	ACA	28 days	PLN 8,872.15
OBI + CLB	OBI	28 days	Cycle 1: PLN 18,468.00 Cycles 2-6: PLN 6,156.00
	CLB	28 days	PLN 110.78
VEN + OBI	VEN	28 days	Cycle 1: PLN 173.37 Cycle 2: 6 PLN 501.38 Cycles 3-12: PLN 13,869.62
	OBI	28 days	Cycle 1: PLN 18,468.00 Cycles 2-6: PLN 6,156.00
ZAN	ZAN	28 days	PLN 9,146.37
VEN + IBR	VEN	28 days	Cycles 1-3: PLN 0.00 Cycle 4: PLN 3,207.35 Cycles 5-15: PLN 13,869.62
	IBR	28 days	PLN 8,001.15

Most drugs (except for OBI) are in tablet form and are taken orally by patients, and no administration costs are charged. The administration of intravenous drugs is reimbursed under the hospitalization service in a one-day care setting related to the execution of the program, which is settled from the catalogue of services for drug programs. An exception is made for the first cycle of treatment, as the first dose is administered within two days. Therefore, it was assumed that the first administration would occur under the hospitalization service related to the execution of the program. According to Directive No. 175/2023/DGL of the President of the NHF[12], for the therapies OBI + CLB and VEN + OBI, if the total duration of a patient's therapy, as described in the program, lasts less than 12 months, the costs of diagnostic tests performed in the program are settled only once after the completion of the therapy, and the settlement amount is not reduced proportionally to the number of months the patient was treated in the program, except in cases where the patient was excluded from the program or died during the therapy. Therefore, in the case of the OBI + CLB therapy (maximum treatment duration: 6 cycles of 28 days) and VEN + OBI therapy (maximum treatment duration: 12 cycles of 28 days), in the scenario considering the costs of continuous therapy, the full annual cost of treatment monitoring was applied according to the valuation of the diagnostic service for the chronic lymphocytic leukaemia treatment program - 1 year of therapy.

Services available for the implementation of the analysed drug program related to drug administration, diagnosis, and treatment monitoring, along with their point values, were determined based on Directive No. 109/2024/DGL of the President of the NHF.[15] The point valuation was based on data from the NHF Agreement Information Guide[16], based on contracts concluded for the second half of 2024 for the product "Drug Program - Treatment of Patients with Chronic Leukaemia" (product code: 03.0000.379.02). The determined service costs are presented in Table 5.

Table 5. Cost of services available in the B.79 drug program

Service code	Service name	Point value	Cost per point	Cost of service
5.08.07.0000001	Hospitalization related to the execution of the program	486.72	PLN 1.77	PLN 861.49
5.08.07.0000003	One-day hospitalization related to the execution of the program	486.72		PLN 861.49
5.08.08.0000127	Diagnostics in the chronic lymphocytic leukaemia treatment program - 1 year of therapy	4,016.4		PLN 7,109.03
5.08.08.0000128	Diagnostics in the chronic lymphocytic leukaemia treatment program (venetoclax, venetoclax in combination with rituximab, ibrutinib, acalabrutinib) - 2nd and subsequent years of therapy	3,407.4		PLN 6,031.10

Results

Cost analysis of treatment until disease progression

The average cost of treating a patient until disease progression in the first line setting ranges from PLN 62,640 PLN for OBI + CLB to PLN 478,071 for ZAN. The treatment cost for regimens involving VEN is PLN 194,405 for VEN + OBI and PLN 283,803 for VEN + IBR. Table 6 presents the estimated treatment costs, broken down by cost categories, and Figure 1 shows the total treatment costs.

Table 6. Results of the cost analysis until disease progression

Regime	Acquisition cost	Administration cost	Monitoring cost	Total cost
IBR	PLN 397,484	PLN 0	PLN 23,695	PLN 421,178
ACA	PLN 440,754	PLN 0	PLN 23,695	PLN 464,448
OBI + CLB	PLN 48,281	PLN 7,529	PLN 6,801	PLN 62,611
VEN + OBI	PLN 180,16	PLN 7,753	PLN 6,49	PLN 194,405
ZAN	PLN 454,376	PLN 0	PLN 23,695	PLN 478,071
VEN + IBR	PLN 275,790	PLN 0	PLN 8,013	PLN 283,803

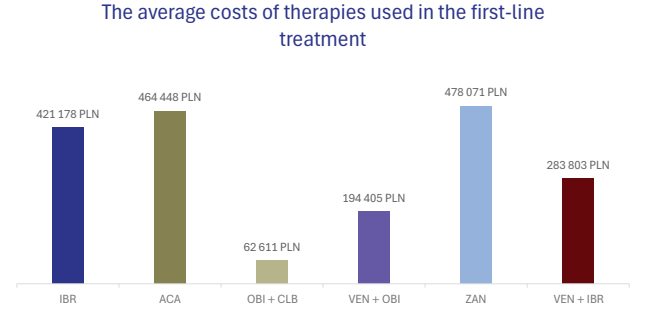

Figure 1. Average therapy cost until disease progression

In the comparison of treatment costs until disease progression in first-line therapy, the least expensive regimens for the public payer are OBI + CLB and VEN + OBI. The ZAN, IBR, and ACA therapies require continuous treatment until disease progression, thus generating higher costs for the payer.

Figure 2 and Figure 3 present, respectively, the drug costs and total costs until disease progression incurred by the public payer for each therapy. Schemes with limited treatment duration are marked with dashed lines, while continuous treatment schemes until treatment interruption are represented by solid lines. Triangular markers indicate the point at which the costs of limited-duration therapies equal those of continuously administered therapies. The analysis indicates that the total cost parity between VEN + OBI and therapies requiring continuous treatment until disease progression occurs around the 80th to 91st week, depending on the therapy used, while for IBR + VEN, the total costs equalize around the 119th to 134th week of treatment. After these time points, there is a potential cost saving for the public payer.

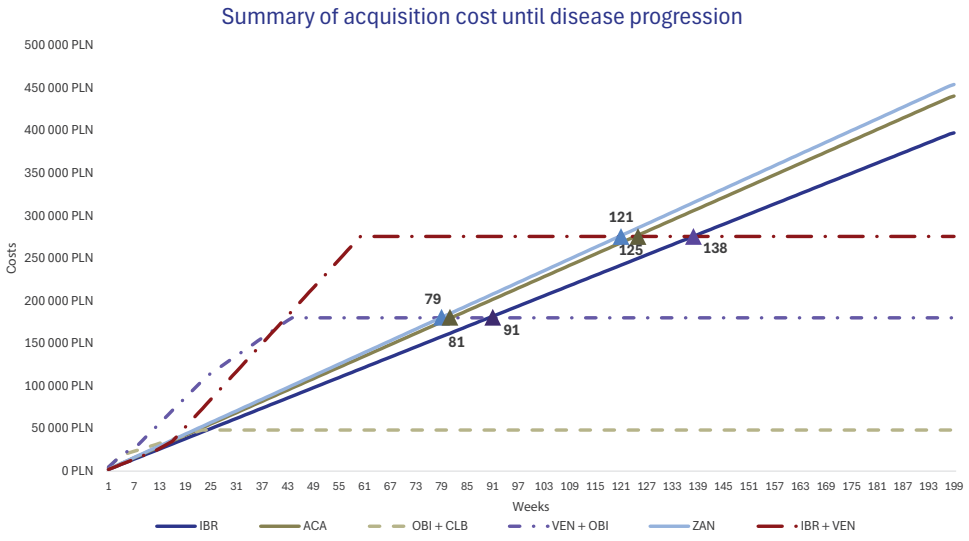

Figure 2. Summary of acquisition cost until disease progression

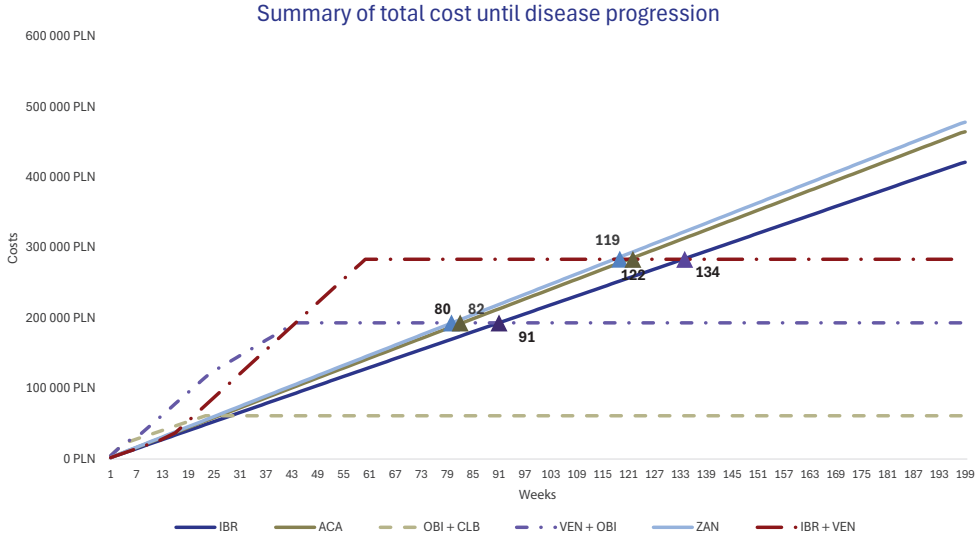

Figure 3. Summary of total cost until disease progression

Analysis of the costs of continuous treatment

In the two-year time horizon, the cost of continuous treatment (without considering therapy discontinuation) ranges from PLN 64,775 for the OBI + CLB regimen to PLN 283,803 for the VEN + IBR regimen. In the three-year time horizon, it ranges from PLN 64,775 for the OBI + CLB regimen to PLN 377,105 for the ZAN therapy. The cost of treatment with regimens containing VEN, due to the limited duration of therapy, is the same in both time horizons: PLN 209,481 for VEN + OBI therapy and PLN 283,803 for VEN + IBR therapy. Table 7 presents the estimated treatment costs, broken down by cost categories, and Figure 4 shows the total treatment costs.

Table 7. Results of the cost analysis for a patient undergoing continuous therapy, two-year time horizon

Regime	Acquisition cost	Administration cost	Monitoring cost	Total cost
Two-year time horizon				
IBR	PLN 208,744	PLN 0	PLN 13,140	PLN 221,884
ACA	PLN 231,468	PLN 0	PLN 13,140	PLN 244,608
OBI + CLB	PLN 49,913	PLN 7,753	PLN 7,109	PLN 64,775
VEN + OBI	PLN 194,619	PLN 7,753	PLN 7,109	PLN 209,481
ZAN	PLN 238,622	PLN 0	PLN 13,140	PLN 251,762
VEN + IBR	PLN 275,790	PLN 0	PLN 8,013	PLN 283,803
Three-year time horizon				
IBR	PLN 313,116	PLN 0	PLN 19,171	PLN 332,287
ACA	PLN 347,202	PLN 0	PLN 19,171	PLN 366,373
OBI + CLB	PLN 49,913	PLN 7,753	PLN 7,109	PLN 64,775
VEN + OBI	PLN 194,619	PLN 7,753	PLN 7,109	PLN 209,481
ZAN	PLN 357,933	PLN 0	PLN 19,171	PLN 377,105
VEN + IBR	PLN 275,790	PLN 0	PLN 8,013	PLN 283,803

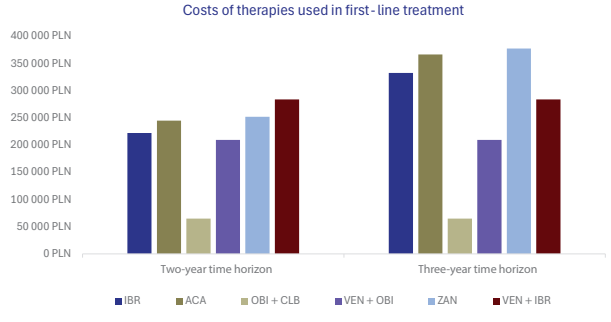

Figure 4. Total treatment costs for a patient undergoing continuous therapy, two-year time horizon

Discussion

Chronic lymphocytic leukaemia (CLL) is an incurable disease with a highly variable clinical course due to its significant biological heterogeneity. Most patients will require the initiation of appropriately selected therapy.[5] It is important to remember that CLL primarily affects older individuals, often with the presence of other comorbidities, which are classified as unfavourable prognostic factors and are associated with shorter overall survival. The presence of comorbid conditions necessitates additional therapies, and the drugs used simultaneously may interact, reduce their effectiveness, and increase the risk of adverse events. In the coming years, the aging process of the population in Poland will continue. By 2060, the number of people aged 65 and older will increase by more than one-third, and the number of people aged 80 and older will double.[13] As the proportion of older individuals in the population rises, the percentage of people with CLL will also increase. The growing number of patients and the costs of modern therapies call for the introduction of strategies aimed at optimizing treatment expenses.

Advances in the understanding of CLL biology have led to the development of modern targeted therapies, such as Bruton's kinase inhibitors and BCL-2 protein inhibitors, which are now the foundation of CLL treatment. As a result, CLL treatment has evolved from traditional chemotherapy to more precise and safer therapeutic strategies, enabling improvements in patients' quality of life and extending their survival. In Poland access to reimbursement for CLL therapies has also significantly improved. Since 2017, new substances have been introduced and indications for already reimbursed drugs have been expanded. Since January 2023, patients have had the opportunity to access a single, consolidated drug program B.79, which combines previously separate programs. The number of patients treated under the drug program has been steadily increasing. According to NFZ data (reported on the IKAR Pro portal[11]), in 2016, only 5 patients were treated under the available CLL-related drug programs—treatment within the program became available in July 2016. By 2023, the number of patients had increased to 4,000, and in the first half of 2024, it was about 3,900.[11] Over 90% of the expenses for reimbursement of services under the B.79 program are related to active substances. In 2023, the value of drug reimbursements amounted to PLN 301.7 million, while the value of services was PLN 16.0 million[11] The projected steady increase in the number of patients requiring CLL treatment in the coming years will lead to higher treatment costs and may pose a significant burden on the healthcare system. In this case, therapies with a limited duration could play an important role in controlling CLL treatment expenses.

Time-limited therapies used in the treatment of CLL, such as VEN + OBI, VEN + IBR, and OBI + CLB, offer numerous benefits both to patients and the healthcare system in Poland. By shortening the duration of treatment, the patient's body is less burdened, leading to a reduction in side effects and a faster return to daily activities. Patients, often burdened with additional diseases, are not tied to long-term therapy and can focus on the treatment of comorbid conditions. The use of venetoclax-based regimens allows for deep remission, which leads to long-term health stabilization, effectively delaying the need for subsequent-line therapies.[14] From the perspective of the healthcare system, time-limited therapies significantly optimize the use of medical resources. Shortening the treatment period reduces the number of follow-up visits, hospitalizations, and tests, alleviating the burden on both doctors and medical facilities.

The main limitation of our study is focus on costs of therapies only without inclusion of effectiveness data. As cost-effectiveness analysis would be great asset for decision makers, treatment schemes included in analysis are already reimbursed in Polish settings. Additionally clinical guidelines for CLL treatment[15] indicates that for the 1st line of treatment targeted therapies should be the first choice. When deciding between time-limited ibrutinib-venetoclax or venetoclax-obinutuzumab versus continuous BTKis, time limited therapy is preferred, as it is associated with reduced toxicity and retreatment would be possible at relapse. Effectiveness of innovative targeted therapies is not a factor influencing the choice of therapy in guidelines, suggesting similar effects of therapies.

Treatment duration data were sourced primarily from economic evaluations submitted to the Polish Agency for Health Technology Assessment and Tariff System (AOTMiT). These evaluations are based on literature reviews and the best available clinical evidence. Although we conducted an additional search to identify most recent data, the most robust and applicable information was found within these reimbursement dossiers.

In the analysis the same time of treatment was assumed for each BTKi treatment. This assumption is supported by PFS data in long term observation. While PFS should not be used directly to estimate treatment duration - given the variety of reasons for therapy discontinuation - it remains a key proxy. Long-term PFS rates support this assumption: at 72 months, 62% of patients remain progression-free with both ibrutinib and acalabrutinib; at 48 months, PFS is 74% for ibrutinib, 76% for acalabrutinib, and 79% for zanubrutinib[16] especially regarding molecular genetic drivers and relevant signaling pathways. Agents focusing on B-cell receptor (in particular Bruton tyrosine kinase [BTK]. These comparable outcomes support the validity of our approach regarding treatment duration. Additionally long PFS rates support the assumption of long time on treatment for these therapies.

Importantly, treatment duration is a crucial driver of overall therapy cost. Therefore, we included sensitivity analyses to account for variations in time horizons, as well as a threshold analysis. Even when a shorter treatment duration for continuous therapies (e.g., 2 years) is assumed - as opposed to the nearly 4-year average used in our base-case - these therapies remain more expensive than the fixed-duration options. The threshold analysis revealed that for the conclusions to change, the treatment duration would need to be as low as: 1.75 years for IBR, 1.56 years for ACA, and 1.52 years for ZAN, compared to VEN+OBI.

Conclusion

Traditionally used therapies without time limitations require long-term administration of drugs until disease progression or the occurrence of intolerance. In contrast, time-limited therapies enable the achievement of a deep treatment response after a relatively short treatment period. Time-limited therapies reduce the overall treatment costs as the medications are used only for a specified period. Under the B.79 drug program, patients in the first line of treatment have access to six therapeutic regimens, half of which require continuous treatment until disease progression. The use of time-limited therapies helps to reduce the payer's expenditures. According to the conducted estimations, regardless of the time horizon assumed, the least expensive available therapies under the B.79 drug program are OBI + CLB and VEN + OBI. Limiting the duration of treatment allows for better control of expenditures within the drug program. Even in the short-term horizon, the use of time-limited therapies leads to savings for the public payer.

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Conflict of interest
The authors of this publication are simultaneously authors of several HTA dossiers prepared for health technologies in Poland. All the authors are working for HTA Consulting company which performs services for pharmaceutical companies in Poland.

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