

Analysis of the implementation of the drug program: "TREATMENT OF CHRONIC SPONTANEOUS URTICARIA (ICD-10 L 50.1)" in 2020–2023

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Abstract

Introduction

The B.107 drug program: „TREATMENT OF CHRONIC SPONTANEOUS URTICARIA” became operational in January 2020. The purpose of this paper is to summarize the four years of operation of the B.107 program compared to other drug programs.

Methods

Statistical analysis was carried out on the basis of annual data published by the Council of the Polish National Health Fund (NHF) in the report on the activities of the NHF in Q4 of 2020, 2021, 2022, 2023.

Conclusions

The B.107 drug program is the optimal access path for patients with chronic spontaneous urticaria.

Key findings are as follows:

- The number of patients covered by the B.107 program increased from 225 in 2020 to 1,067 in 2023.
- The number of healthcare providers implementing the program has increased, which demonstrates the growing interest and commitment of medical facilities to CSU treatment.
- The B.107 program is characterized by relatively low costs compared to other drug programs.
- Expenditures on the program increased from PLN 3,501,506 in 2020 to PLN 17,221,837 in 2023, reflecting the growing demand for omalizumab treatment.
- The ability to issue the drug for home use after proper instruction by medical personnel increases patient comfort, reducing the need for frequent visits to medical facilities.

- The uneven distribution of healthcare providers across provinces, such as the Lubuskie Province, where no center has chosen to implement the program, shows the need for further actions to increase the availability of this treatment in underserved regions.
- Further monitoring and optimization of the B.107 program will be necessary to meet the growing needs of patients and the challenges of the healthcare system.
- Introducing additional centers that implement the program and ensuring continuity of funding will be key to the program’s continued success.
- The development of new therapies and drugs may contribute to even better control of CSU symptoms and improvement of patients’ quality of life.

Summary

The B.107 drug program: „TREATMENT OF CHRONIC SPONTANEOUS URTICARIA” has been operational since January 2020. The purpose of this paper is to summarize the four years of operation of the B.107 program compared to other drug programs. Statistical analysis was carried out on the basis of annual data published by the NHF Council in the reports on the activities of the NHF in Q4 of 2020, 2021, 2022, and 2023.

Between 2020 and 2023, there was a significant increase in the number of patients covered by the program, from 225 in 2020 to 1,067 in 2023. The program is implemented by allergists, dermatologists and pediatricians at 48 centers in Poland. Omalizumab, which is the only drug used in the program, can be issued to patients for home use after proper instruction by medical personnel, making the therapy more accessible and comfortable for patients. Expenditures on the B.107 program increased from PLN 3,501,506 in 2020 to PLN 17,221,837 in 2023, reflecting the growing demand for omalizumab treatment. The B.107 program is relatively small in terms of patient population and costs generated but plays a key role in providing access to modern therapies for patients with chronic spontaneous urticaria.

Analysis of the NHF’s financial data indicates that the program is growing rapidly, which is a positive indicator of its effectiveness and acceptance in the medical community. Despite the challenges associated with the uneven distribution of healthcare providers across provinces, the B.107 program significantly improves the quality of life for CSU patients, ensuring that they have access to effective treatment consistent with clinical guidelines and global standards.

Introduction

Chronic spontaneous urticaria (CSU) is a disease characterized by recurrent episodes of urticarial wheals and/or angioedema that persist for at least six weeks. The definition formulated by the EAACI/GA(2)LEN/EDF/WAO (European Academy of Allergy and Clinical Immunology, Global Allergy and Asthma European Network, European Dermatology Forum, World Allergy Organization) in 2013 emphasizes that CSU can be caused spontaneously or induced by various factors.^[1]

CSU significantly affects patients' quality of life, causing not only physical discomfort but also psychological problems such as stress and anxiety. Therefore, effective treatment of this disease is crucial to improve patients' well-being.^[2]

The B.107 drug program: „TREATMENT OF CHRONIC SPONTANEOUS URTICARIA” was introduced in January 2020 as a response to the growing demand for effective therapies for patients with CSU. The program is a guaranteed benefit, which means that treatment is provided with the use of innovative, expensive active substances that are not funded under other guaranteed benefits. Treatment is provided for selected disease entities and covers a strictly defined group of patients.^[3]

The content of each drug program is published as an appendix to the notice of the Minister of Health on the list of reimbursable drugs, foodstuffs intended for particular nutritional uses, and medical devices. The program description includes:

- patient eligibility criteria for the treatment;
- criteria for exclusion from the program;
- drug dosage regimen;
- method of drug administration;
- a list of diagnostic tests performed when qualifying a patient for the program and necessary for monitoring the treatment.^[4]

The B.107 program is implemented by allergists, dermatologists and pediatricians, which ensures that patients have access to specialized medical care. Omalizumab, the only drug used in this program, can be issued to patients for home use after proper instruction by medical personnel, making the therapy more comfortable and accessible.^[5]

The aim of this paper is to summarize the four years of operation of the B.107 program in comparison with other drug programs, taking into account the statistical analysis of data published by the NHF Council in the reports on the activities of the NHF in Q4 of 2020, 2021, 2022 and 2023.

Material and methods

An analysis was conducted for data from 2020–2023 published by the NHF Council in the reports on the activities of the NHF in Q4 of the years: 2020, 2021, 2022, and 2023, regarding all drug programs, with particular emphasis on the B.107 drug program: „TREATMENT OF CHRONIC SPONTANEOUS URTICARIA.”

The following were analyzed:

- Number of settled billing units in individual hospital scopes (drug programs) for B.107
- Number of patients in the drug program
- Contract values for program implementation
- Number of healthcare providers implementing the program
- Number of patients who were issued the drug to take home for self-injections

Results

1. Expenditures on healthcare in Poland in 2020–2023

Preliminary estimates of healthcare expenditures in 2023 indicate a volume of PLN 241.6 billion (accounting for 7.1% of GDP). This means that they are higher than in 2022 by approximately PLN 45.4 billion. The increase relates to public expenditure, while a decrease is observed for private expenditure. Public expenditure in 2023 was PLN 197.8 billion, 53.2 billion higher than in 2022, and accounted for 5.8% of GDP. On the other hand, current private expenditures (including household expenditures) decreased by nearly PLN 7.8 billion and amounted to approximately PLN 43.8 billion in 2023.^[6]

2. Expenditures on drug programs

Between 2020 and 2023, the NHF’s expenditures on drug programs have been reported to almost double from about PLN 5 billion in 2020 to more than PLN 10 billion in 2023.^[7]

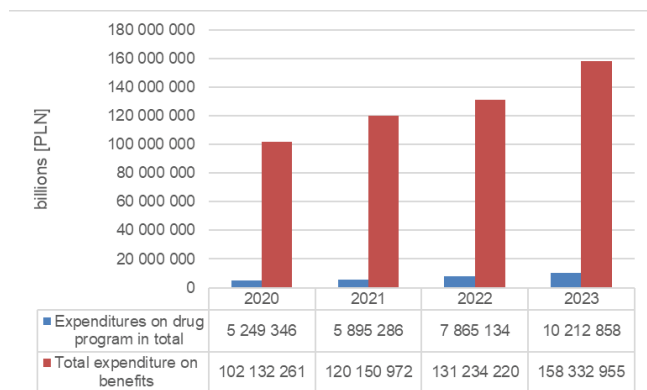


Table 1. Expenditures on healthcare benefits and drug programs in 2020–2023

3. Number of drug programs

By the end of December 2023, 118 NHF drug programs were in operation. In 2023, the number of drug programs funded by NHF increased by 22.^[8]

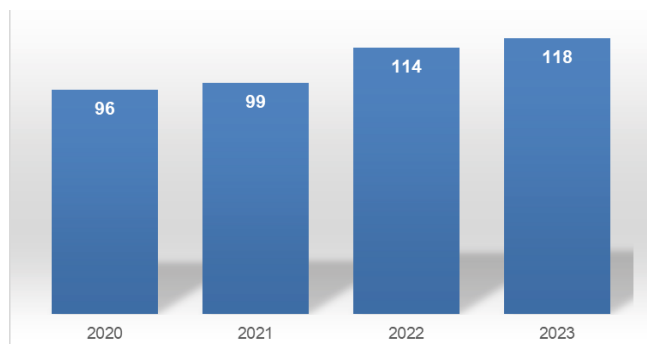


Figure 1. Number of NHF drug programs in 2020–2023.

4. Number of patients in drug programs in 2020–2023.

Over the course of four years, the number of patients treated in drug programs has increased by more than 89,000 patients.^[9]

The largest number of patients in 2023 were treated in the following drug programs:

- B.70. Treatment of patients with retinal diseases – 51,281 patients;
- B.29. Treatment of patients with multiple sclerosis – 23,528 patients;
- B.33. Treatment of patients with active rheumatoid arthritis and juvenile idiopathic arthritis – 16,693 patients;
- B.9. Treatment of patients with breast cancer – 16,101 patients;
- B.6. Treatment of non-small-cell or small-cell lung cancer – 10,304 patients
- B.1. Treatment of patients with chronic hepatitis B – 9,239 patients
- B.28. Treatment of focal dystonia and hemifacial spasm – 8,940 patients
- B.36. Treatment of patients with active ankylosing spondylitis (AS) – 6,519 patients
- B.19. Treatment of short-stature children with somatotropin hypopituitarism – 6,478 patients
- B.71 Interferon-free treatment of patients with chronic hepatitis C – 6,282 patients

Based on the number of patients, the drug program is ranked 39th in the ranking of drug programs with 1,067 patients

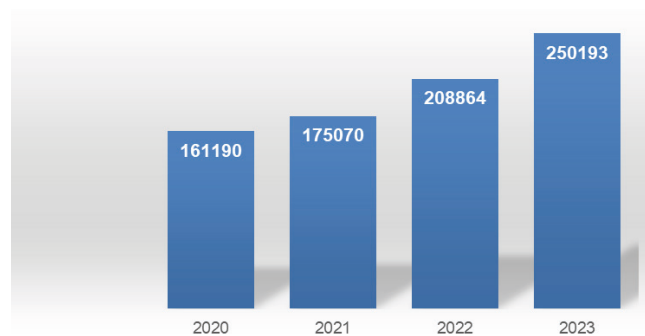


Figure 2. Number of patients covered by treatment in NHF drug programs in 2020–2023.

5. Number of healthcare providers implementing drug programs

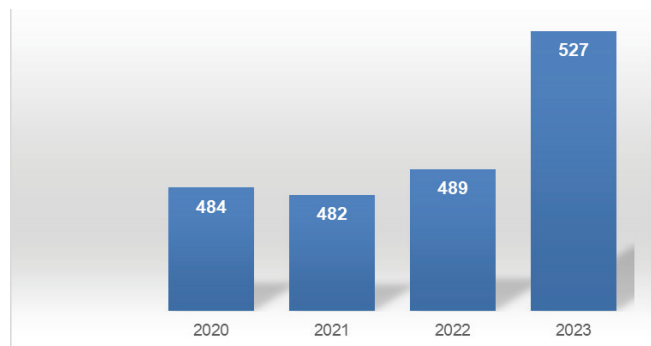


Figure 3. Number of healthcare providers implementing drug programs in Poland in 2020–2023.

Over the course of four years, the number of healthcare providers implementing drug programs in Poland increased by 43 medical facilities.^[10]

6. Billing units – the B.107 drug program in 2020–2023

Name of the benefit	Number of settled billing units			
	2020	2021	2022	2023
ONE-DAY HOSPITALIZATION ASSOCIATED WITH THE IMPLEMENTATION OF THE MEDICAL PROGRAM	450	1,544	2,826	3,218
OUTPATIENT ADMISSIONS ASSOCIATED WITH THE IMPLEMENTATION OF THE PROGRAM	340	1,336	2,268	3,498
DIAGNOSIS IN THE TREATMENT PROGRAM FOR PATIENTS WITH CHRONIC SPONTANEOUS URTICARIA	75	231	425	587

Table 3. Costs of benefits under the B.107 drug program in 2020–2023

Name of the benefit	Costs of benefits [PLN]			
	2020	2021	2022	2023
ONE-DAY HOSPITALIZATION ASSOCIATED WITH THE IMPLEMENTATION OF THE MEDICAL PROGRAM	219,024	751,496	1,666,669	2,341,219
OUTPATIENT ADMISSIONS ASSOCIATED WITH THE IMPLEMENTATION OF THE PROGRAM	36,774	144,502	297,240	565,557
DIAGNOSIS IN THE TREATMENT PROGRAM FOR PATIENTS WITH CHRONIC SPONTANEOUS URTICARIA	28,267	86,753	193,123	328,934

Between 2020 and 2023, the B.107 drug program saw rapid development. In 2020, there were 450 one-day hospitalizations associated with the implementation of the program for a total amount of PLN 219,024, while after four years the number of such benefits increased to 3,218 for a total amount of PLN 2,341,219. At the same time, in 2020, 340 outpatient admissions associated with the implementation of the program were settled for a total amount of PLN 36,774, and in 2023, 3,498 such benefits were provided for a total amount of PLN 565,557.

An analogous increase is observed for the benefit: diagnosis in the drug program. Thus, in 2020, 75 benefits were provided in this area for the amount of 28,267, and in 2023, there were 587 such benefits for the amount of PLN 328,934.

7. Volume of B.107 contracts and degree of their implementation (contract value vs. performance)

In the period 2020–2023, the funds allocated by the NHF for the implementation of the drug program increased significantly. In 2020, the NHF allocated PLN 506,868 to operate the program, then in 2021, the amount increased

Table 4. Volume of B.107 contracts and degree of their implementation in 2020–2023

Name of benefit	Value [PLN]				Contracts [PLN]				Implementation			
	2020	2021	2022	2023	2020	2021	2022	2023	2020	2021	2022	2023
Pharmaceutical program - treatment of patients with chronic spontaneous urticaria	284 065	982 750	2 157 032	3 235 710	506 868	990 728	2 233 804	3 288 649	56%	99%	97%	98%
Medications in the pharmaceutical program - treatment of patients with chronic spontaneous urticaria	2 818 824	7 790 554	13 568 897	18 736 369	3 501 506	6 211 538	13 065 237	17 221 837	81%	125%	104%	109%

to PLN 990,728, in 2022 to PLN 2,233,804, and in 2023 to PLN 3,288,649. The NHF allocated PLN 3,501,506 for medications used in the program in 2020, then the figure rose to PLN 6,211,538 in 2021, to PLN 13,065,237 in 2022, and to PLN 17,221,837 in 2023.

These figures translate into the percentage values of implementation for program operation of 56% in 2020, 99% in 2021, 97% in 2022, and 98% in 2023.

The percentage values of implementation for the medication in the B.107 program were 81% in 2020, 125% in 2021, 104% in 2022, and 109% in 2023.

8. Number of patients – B.107

Table 5. Number of patients covered by the B.107 program between 2020–2023

Provincial branch	OMALIZUMABUM - P - PARENTERAL - 1 MG			
	2020	2021	2022	2023
Dolnośląskie	17	49	85	133
Kujawsko-Pomorskie	3	19	41	62
Lubelskie	11	23	38	45
Lubuskie	0	0	0	0
Łódzkie	68	135	170	192
Małopolskie	13	35	50	54
Mazowieckie	45	85	124	167
Opolskie	11	11	16	19
Podkarpackie	2	9	34	77
Podlaskie	3	7	8	26
Pomorskie	1	9	21	31
Śląskie	19	41	72	82
Świętokrzyskie	10	21	39	64
Warmińsko-Mazurskie	2	4	21	31
Wielkopolskie	19	37	63	66
Zachodniopomorskie	2	8	10	19
total	225	492	790	1,067

Over the period 2020–2023, a substantial increase can be seen in the number of patients covered by the B.107 drug program in every province except Lubuskie. In Lubuskie province, no center has chosen to be part of the B.107 drug program, resulting in no report of treatment in its territory. Consistently, the number of patients was 225 in 2020, rising to 492 in 2021, 790 in 2022, and 1067 in 2023. The highest number of patients covered by the B.107 drug program was recorded in the Łódzkie Province.

9. Volume of contracts, agreements, and completion of the B.107 drug program in 2020–2023

In the period 2020–2023, the amount of money allocated by the NHF for the B.107 drug program increased in every province except Lubuskie (no contracting) and Pomorskie. Consistently, in 2020 the funds allocated to contracts totaled PLN 3,501,506, the figure rose to PLN 6,211,538 in 2021, to PLN 13,065,237 in 2022, and to PLN 17,221,837 in 2023.

These figures translate into percentage values of implementation equal to 81% for 2020, 125% for 2021, 104% for 2022, and 109% for 2023.

The highest percentage values of implementation in 2020 were observed in the Warmińsko-Mazurskie Province, in 2021 in the Pomorskie Province, in 2022 in the Wielkopolskie Province, and in 2023 in the Kujawsko-Pomorskie Province.

Table 6. Volume of contracts, agreements, and completion of the B.107 drug program divided by provincial branches in 2020–2023

Provincial branch	Executed value of contracts				Contracts				% of completion			
	2020	2021	2022	2023	2020	2021	2022	2023	2020	2021	2022	2023
dolnośląski	252 014 zł	572 747 zł	1 359 293 zł	2 374 946 zł	239 344 zł	487 797 zł	1 287 958 zł	2 174 417 zł	105%	117%	106%	109%
kujawsko-pomorski	15 556 zł	256 387 zł	833 350 zł	1 310 969 zł	89 378 zł	49 633 zł	792 784 zł	1 133 914 zł	17%	517%	105%	116%
lubelski	87 116 zł	515 772 zł	721 168 zł	935 356 zł	87 766 zł	496 905 zł	691 120 zł	870 338 zł	99%	104%	104%	107%
lubuski	0 zł	0 zł	0 zł	0 zł	0 zł	0 zł	0 zł	0 zł				
łódzki	952 053 zł	2 527 882 zł	3 023 079 zł	3 452 046 zł	974 500 zł	1 800 411 zł	3 025 687 zł	3 244 216 zł	98%	140%	100%	106%
małopolski	77 782 zł	407 820 zł	708 056 zł	859 358 zł	98 059 zł	309 916 zł	679 325 zł	813 421 zł	79%	132%	104%	106%
mazowiecki	567 809 zł	1 224 968 zł	2 410 450 zł	3 115 903 zł	598 544 zł	1 178 161 zł	2 342 929 zł	2 853 780 zł	95%	104%	103%	109%
opolski	94 894 zł	281 875 zł	301 579 zł	404 834 zł	146 379 zł	246 032 zł	293 730 zł	385 516 zł	65%	115%	103%	105%
podkarpacki	26 446 zł	113 960 zł	547 796 zł	1 236 423 zł	86 192 zł	95 122 zł	507 665 zł	1 125 839 zł	31%	120%	108%	110%
podlaski	12 445 zł	128 943 zł	72 825 zł	208 993 zł	77 572 zł	104 869 zł	70 334 zł	193 414 zł	16%	123%	104%	108%
pomorski	0 zł	112 450 zł	367 140 zł	360 989 zł	59 890 zł	54 286 zł	354 258 zł	333 865 zł	0%	207%	104%	108%
śląski	211 567 zł	497 780 zł	1 072 282 zł	1 395 726 zł	432 690 zł	396 976 zł	1 022 282 zł	1 304 954 zł	49%	125%	105%	107%
świętokrzyski	132 230 zł	343 348 zł	523 058 zł	860 819 zł	132 182 zł	273 866 zł	524 151 zł	809 448 zł	100%	125%	100%	106%
warmińsko-mazurski	34 224 zł	44 980 zł	257 872 zł	511 523 zł	26 296 zł	62 500 zł	263 138 zł	473 186 zł	130%	72%	98%	108%
wielkopolski	308 017 zł	626 723 zł	1 196 119 zł	1 372 342 zł	386 629 zł	524 329 zł	1 033 124 zł	1 204 615 zł	80%	120%	116%	114%
zachodniopomorski	46 669 zł	134 940 zł	174 829 zł	336 143 zł	66 085 zł	130 735 zł	176 754 zł	300 916 zł	71%	103%	99%	112%
total	2 818 824 zł	7 790 554 zł	13 568 897 zł	18 736 369 zł	3 501 506 zł	6 211 538 zł	13 065 237 zł	17 221 837 zł	81%	125%	104%	109%

Discussion

The B.107 drug program, introduced in early 2020, represents a significant step forward in treating chronic spontaneous urticaria (CSU). Its introduction was a response to the growing need for effective and accessible therapies for patients suffering from this troublesome disease. Chronic spontaneous urticaria, characterized by recurrent episodes of urticarial wheals and/or angioedema, significantly affects patients' quality of life, causing physical and psychological discomfort.

One of the key aspects of the B.107 program is its effectiveness. Omalizumab, the only drug used in this program, has shown high effectiveness in controlling CSU symptoms.^[11] Patients report a significant improvement in quality of life, which is confirmed by numerous clinical trials.^[12] The ability to issue the drug for home use after proper instruction by medical personnel additionally increases the accessibility of the therapy, reducing the need for frequent visits to medical facilities.

An analysis of NHF's financial data from 2020–2023 shows a dynamic increase in outlays for the B.107 program. This growth reflects the increasing number of patients receiving treatment and the increasing number of healthcare providers delivering the program. Despite its relatively small effect on the budget compared to other drug programs, B.107 plays a key role in ensuring access to modern therapies for patients with CSU.

One of the challenges of the B.107 program is the uneven distribution of healthcare providers across the provinces. For example, in the Lubuskie Province, no center has decided to implement the program, resulting in a lack of access to treatment for patients from this region. It is therefore necessary to take steps to increase the number of centers implementing the program in underserved regions.

Another challenge is ensuring the continuity of program funding in the face of rising healthcare costs. The increase in expenditures on drug programs, including B.107, requires constant monitoring and optimization of fund allocation to ensure the sustainable development of the healthcare system.

The B.107 drug program is an example of an effective health intervention that significantly improves the quality of life of patients with chronic spontaneous urticaria. Its introduction and growth between 2020 and 2023 show that adequate funding and organization of drug programs can bring tangible health benefits. In the future, it will be necessary to continue monitoring and adjusting the program to meet the growing needs of patients and the challenges of the healthcare system.

Conclusions

The analysis of data from the National Health Fund (NHF) for the period 2020–2023 clearly shows the dynamic growth of the B.107 drug program: „TREATMENT OF CHRONIC SPONTANEOUS URTICARIA.” This program, although relatively small in terms of patient population and costs generated, plays a key role in providing access to modern therapies for patients with chronic spontaneous urticaria (CSU).

1. Increase in the number of patients and healthcare providers

The number of patients covered by the B.107 program increased from 225 in 2020 to 1,067 in 2023. At the same time, the number of healthcare providers implementing the program has increased, demonstrating the growing interest and commitment of medical facilities to CSU treatment. The increase in the number of patients and healthcare providers is a positive indicator of the effectiveness of the program and its acceptance in the medical community.

2. Financial efficiency

The B.107 program is characterized by relatively low costs compared to other drug programs, which makes it an efficient solution from the point of view of the NHF budget. Expenditures on the program increased from PLN 3,501,506 in 2020 to PLN 17,221,837 in 2023, reflecting the growing demand for omalizumab treatment. Despite the increase in costs, the program remains one of the more economical programs in the context of high-cost treatment.

3. Improvement of patients' quality of life

Treatment with omalizumab, the only drug used in the B.107 program, significantly improves the quality of life of patients with CSU. Patients report a reduction in symptoms, which translates into better functioning in daily life. The ability to issue the drug for home use after proper instruction by medical personnel additionally increases patient comfort, reducing the need for frequent visits to medical facilities.

4. Organizational challenges

Despite the program's successes, there are challenges associated with its implementation. The uneven distribution of healthcare providers across provinces, such as the Lubuskie Province, where no center has chosen to implement the program, shows the need for further actions to increase the availability of the treatment in underserved regions.

5. Future development directions

In the future, it will be necessary to continue monitoring and optimizing the B.107 program to meet the growing needs of patients and the challenges of the healthcare system. Introducing additional centers that implement the program and ensuring continuity of funding will be key to the program's continued success. In addition, developing new therapies and drugs may contribute to even better control of CSU symptoms and improve patients' quality of life.

Conclusions

The B.107 drug program is an example of an effective health intervention that significantly improves the quality of life of patients with chronic spontaneous urticaria. Its introduction and development between 2020 and 2023 show that adequate funding and organization of drug programs can bring tangible health benefits. In the future, it will be necessary to continue monitoring and adjusting the program to meet the growing needs of patients and the challenges of the healthcare system.

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