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Analysis of access to treatment of patients with psoriatic arthritis within nationally founded treatment program B.35 "Treatment of active Psoriatic arthritis (PsA) (ICD-10 L 40.5, M 07.1, M 07.2, M 07.3)" in 2016–2021

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ABSTRACT

Introduction: Psoriatic arthritis (PsA), is a chronic disease affecting women and men in equal measure. It is characterised by a diverse course, usually progressive and severe in 20% of patients. The symptoms develop progressively. In almost 75% of patients, skin symptoms precede joint symptoms, while 10–15% experience simultaneous symptoms in both skin and joints. The disease is characterised by a highly fluctuating course, with periods of exacerbation and remission. Funding for the treatment of patients with psoriatic arthritis with biological drugs is guaranteed under the B.35 drug programme. The analysis of the performance of this programme is the aim of this work.

Material and methods: The statistical analysis was based on data published by the National Health Fund and the Ministry of Health.

Results: Between 2016 and 2021, 8 active substances were funded under the B.35 drug programme, 4 of which were added in the last 6 years. The number of patients increased by 2087. The largest group of patients received care from physicians in the Małopolskie Voivodeship. The most common active substance used under the B.35 drug programme was adalimumab, while the highest annual increase in patients treated under the programme was observed for the drug secukinumab. The value of contracts for drugs increased by PLN 15.7 million, while the value of contracts for programme operations increased by PLN 3.7 million. The number of providers implementing this drug programme has increased by one.

Conclusions: The B.35 drug programme is more substantial in terms of the number of patients treated and the value of funding than the B.47 (psoriasis) drug programme but smaller than the B.36 — ankylosing spondylitis (AS) drug programme implemented by rheumatologists. Virtually all drugs licensed for the treatment of moderate to severe psoriatic arthritis are currently reimbursed under the drug programme. Comparing epidemiological data in Poland and the number of patients in the drug programme, it should be pointed out that only about 1.8% of the total population of patients with PsA receives treatment. These very low values point to the need to further optimise the description of the drug programme or to transfer some drugs, for example, biosimilars, to outpatient health care.

Key words: psoriatic arthritis, biologicals, nationally founded treatment program

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INTRODUCTION

Psoriatic arthritis [(PsA), ICD-10: L40.5, M07.1, M07.2, M07.3] is a chronic immune-mediated inflammatory joint disease in patients with psoriasis. It is one of the seronegative spondyloarthropathies [1]. Psoriatic arthritis manifests as inflammation of the peripheral joints, spinal joints, sacroiliac joints and/or tendinous attachments, but also overlaps with the aforementioned, forms of the disease [2].

The Moll and Wright criteria distinguish between five forms of PsA:

— asymmetric oligoarthritis — the arthritis is usually asymmetric (about 70% of patients);
— symmetric polyarthritis resembling rheumatoid arthritis (RA) — 15–20% of patients;
— distal interphalangeal arthritis, with predominant inflammation of the distal interphalangeal joints, with frequent nail involvement (about 5% of patients);
— mutilating arthritis, with a very severe course (about 5% of patients);
— axial, resembling ankylosing spondylitis (AS), although asymmetric sacroiliac arthritis is typical (about 5% of patients).

All the above-mentioned types can overlap and, therefore, a division of psoriatic arthritis into three forms was developed in 1994:

— with asymmetric involvement of individual joints;
— with symmetrical involvement of multiple joints, including distal interphalangeal and spinal joints, often leading to deformational changes;

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— with predominant spinal lesions with possible involvement of individual minor joints [3].

The ICD-10 (International Statistical Classification of Diseases and Related Health Problems) classifies PsA as follows:
— L40.5 — arthropathic psoriasis;
— M07.1 — arthritis mutilans (L40.5+);
— M07.2 — psoriatic spondylitis (L40.5+);
— M07.3 — other psoriatic arthropathies (L40.5+) [4].

There are no precise data on the prevalence or incidence of PsA in Poland. The prevalence of PsA worldwide is estimated to be 0.02–0.2% [5]. There are currently 108 ongoing drug programmes. Drugs guaranteed under these benefits and indications cannot be funded under other reimbursement modes [6]. Treatment is provided in both dermatology and rheumatology centres implementing the above programme.

As in the case of the B.47 drug programme, patients qualified for the B.35 programme are also treated free of charge, while the decision on eligibility is made by a physician of a contracted facility after approval by the Coordination Team for Biological Treatment in Rheumatic Diseases [7].

The B.35 drug programme "Treatment of active form of psoriatic arthritis (ICD-10 L 40.5, M 07.1, M 07.2, M 07.3)" became effective from 1 July 2012 thanks to the great commitment of dermatologists and rheumatologists.

Aim of the paper

The aim of this paper is the analysis of the performance of the B.35 drug programme "Treatment of active form of psoriatic arthritis (PsA) (ICD-10 L 40.5, M 07.1, M 07.2, M 07.3)" from 2016 to 2021.

MATERIAL AND METHODS

The work examined publicly available data published by the Ministry of Health and the National Health Fund. The 2016–2021 reports for the B.35 drug programme were compared in terms of:
— access to drugs;
— number of patients;
— value of implementation contracts;
— the number of providers implementing the programme.

RESULTS

Access to drugs under the B.35 drug programme

In 2021, 8 active substances were funded under the B.35 drug programme:
— adalimumab;
— certolizumab;
— etanercept;
— golimumab;
— infliximab;
— ixekizumab;
— secukinumab;
— tofacitinib.

Adalimumab, etanercept and infliximab were the first publicly funded drugs under the B.35 programme in 2012. In 2014, golimumab was included in the reimbursed drugs list, while certolizumab was added in 2017. Secukinumab was the next reimbursed drug (2018). The last drug added to this programme was tofacitinib (2020). The dates of reimbursement coverage for individual drugs under the B.35 programme are presented in Table 1.

Number of patients covered by the B.35 drug programme

Over six years, the number of patients has increased by 2087. The number of patients increased proportionally year on year (Fig. 1):
— by 201 in 2017;
— by 235 in 2018;
— by 577 in 2019;
— by 373 in 2020;
— by 701 in 2021;

The Małopolskie Voivodeship accounts for the largest number of patients treated. In the space of six years, their number has increased by 513 patients. Opolskie Voivodeship is the voivodeship with the smallest number of patients, only 18. The number of patients treated under the B.35 drug programme between 2016 and 2021 by voivodeship against the population of the voivodeship is shown in Table 2. Figure 2 shows the difference between the number of patients treated under the B.35 drug programme in 2016 and 2021 by voivodeship.

Number of patients covered by the B.35 drug programme by drug

Over the 2016–2021 period, the largest number of patients were treated with adalimumab, while the smallest number of patients were treated with tofacitinib, which became reimbursed in September 2020. The number of patients covered by the B.35 drug programme between 2016 and 2021 by the drug is shown in Figure 3.

The drug secukinumab (Cosentyx) has the highest number of new patients in 2021, at 35%. No year-on-year reduction in the number of patients was observed in any of the provinces. In 2016, four active substances were available as part of the drug programme. Their share of the sales market varied by voivodeship. Adalimumab was the most used drug. The highest number of patients treated with adalimumab in 2016 was in the Śląskie Voivodeship, amounting to 128. The fewest patients (two) were treated with adalimumab in the Lubuskie Voivodeship (Fig. 4).

Another drug used in the programme was etanercept (Enbrel, Benepali). The largest number of patients was also treated in the Śląskie Voivodeship, amounting to 35 people.

Table 1. Dates of reimbursement coverage for individual drugs under the B.35 programme — own elaboration based on data from the Ministry of Health

Substance	Trade name	Reimbursement entry date	Reimbursement end date
Ixekizumab	Taltz	1.01.2021	
Tofacitinib	Xeljanz	1.09.2020	
Adalimumab	Idacio	1.03.2020	
Adalimumab	Amgevita	1.03.2019	
Adalimumab	Hyrimoz	1.03.2019	
Infliximab	Zessly	1.03.2019	
Adalimumab	Imraldi	1.01.2019	31.12.2021
Secukinumab	Cosentyx	1.11.2018	
Infliximab	Flixabi	1.01.2018	
Etanercept	Erelzi	1.11.2017	
Certolizumab pegol	Cimzia	1.01.2017	
Etanercept	Benepali	1.07.2016	30.04.2022
Golimumab	Simponi	1.03.2014	
Infliximab	Inflectra	1.01.2014	31.12.2021
Infliximab	Remsima	1.01.2014	31.12.2021
Etanercept	Enbrel	1.07.2012	
Infliximab	Remicade	1.07.2012	
Adalimumab	Humira	1.07.2012	28.02.2022

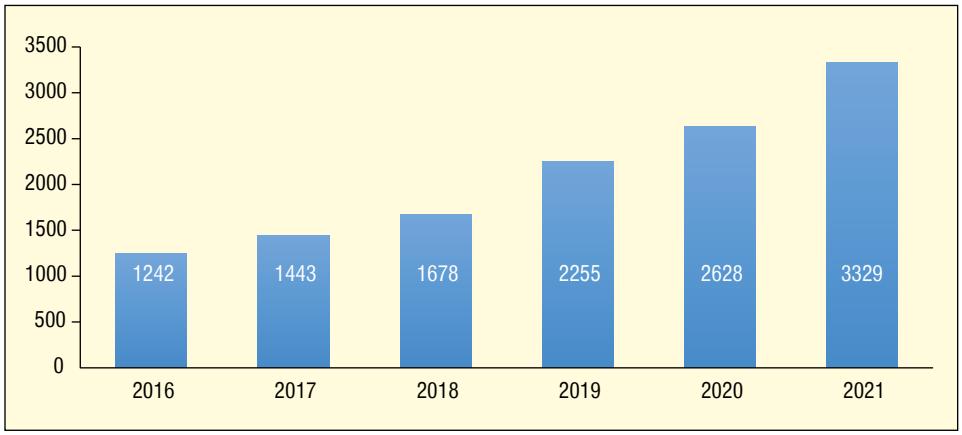

Figure 1. Number of patients in the B.35 drug programme between 2016 and 2021

The fewest (two) patients treated with etanercept in Poland in 2016 were in the Podlaskie Voivodeship (Fig. 5).

The third drug available within the B.35 programme in 2016 was golimumab. The highest number of patients was observed in the Małopolskie Voivodeship, at 49. The smallest number of patients treated with this drug (one patient each) occurred in the Warmińsko-Mazurskie and Opolskie voivodeships (Fig. 6).

The fourth drug available within the B.35 programme in 2016 was infliximab. This drug was used most frequently in the Wielkopolskie Voivodeship — in 10 patients. In contrast, it was not used in the Podlaskie and Opole voivodeships (Fig. 7).

Five years later, in 2021, eight active substances were already funded under the B.35 drug programme. Adalimumab (Humira and biosimilars) continued to be the market leader in sales. The proportion of individual drugs varied by voivodeship.

Adalimumab was used most frequently in the Śląskie Voivodeship — in 195 patients, 67 more than five years earlier. This time, the fewest patients (eight) were treated in the Opolskie Voivodeship (Fig. 8).

Etanercept was also most used in the Małopolskie Voivodeship, with 81 patients, 47 more than in 2016. The smallest number of patients treated with this drug was once again in the Podlaskie and Lubuskie voivodeships (Fig. 9).

Golimumab was used most frequently in the Małopolskie Voivodeship, with 124 patients, an increase of 75 patients

Table 2. Number of patients treated under the B.35 drug programme between 2016 and 2021 by voivodeship against the population of the voivodeship

Voivodeship	2016			2017			2018		
	Number of patients	Population	Number of patients *vs.* population ratio	Number of patients	Population	Number of patients *vs.* population ratio	Number of patients	Population	Number of patients *vs.* population ratio
Dolnośląskie	91	2 904 198	→ 0.000031	99	2 903 710	→ 0.00003409	116	2 902 547	→ 0.00003996
Kujawsko-Pomorskie	111	2 086 210	↑ 0.000053	133	2 083 927	↑ 0.00006382	130	2 082 944	↑ 0.00006241
Lubelskie	39	2 139 726	↓ 0.000018	40	2 133 340	↓ 0.00001875	51	2 126 317	↓ 0.00002399
Lubuskie	9	1 018 084	↓ 0.000009	13	1 017 376	↓ 0.00001278	21	1 016 832	↓ 0.00002065
Łódzkie	92	2 493 603	→ 0.000037	115	2 485 323	↑ 0.00004627	145	2 476 315	↑ 0.00005855
Małopolskie	162	3 372 618	↑ 0.000048	179	3 382 260	↑ 0.00005292	235	3 391 380	↑ 0.00006929
Mazowieckie	124	5 349 114	→ 0.000023	145	5 365 898	↓ 0.00002702	166	5 384 617	→ 0.00003083
Opolskie	8	996 011	↓ 0.000008	10	993 036	↓ 0.00001007	9	990 069	↓ 0.00000909
Podkarpackie	79	2 127 657	→ 0.000037	85	2 127 656	→ 0.00003995	107	2 129 138	↑ 0.00005026
Podlaskie	27	1 188 800	↓ 0.000023	29	1 186 625	↓ 0.00002444	41	1 184 548	→ 0.00003461
Pomorskie	61	2 307 710	→ 0.000026	76	2 315 611	→ 0.00003282	82	2 324 251	→ 0.00003528
Śląskie	176	4 570 849	↑ 0.000039	207	4 559 164	→ 0.00004540	240	4 548 180	↑ 0.00005277
Świętokrzyskie	34	1 257 179	→ 0.000027	43	1 252 900	→ 0.00003432	46	1 247 732	→ 0.00003687
Warmińsko-Mazurskie	15	1 439 675	↓ 0.000010	21	1 436 367	↓ 0.00001462	24	1 433 945	↓ 0.00001674
Wielkopolskie	134	3 475 323	↑ 0.000039	144	3 481 625	→ 0.00004136	162	3 489 210	→ 0.00004643
Zachodnio-pomorskie	80	1 710 482	↑ 0.000047	104	1 708 174	↑ 0.00006088	105	1 705 533	↑ 0.00006156
Total (Poland)	**1242**	**38 437 239**	→ **0.000032**	**1 443**	**38 432 992**	→ **0.00003755**	**1 680**	**38433558**	→ **0.00004371**
Voivodeship	**2019**			**2020**			**2021**		
	Number of patients	Population	Number of patients *vs.* population ratio	Number of patients	Population	Number of patients *vs.* population ratio	Number of patients	Population	Number of patients *vs.* population ratio
Dolnośląskie	162	2 901 225	→ 0.00005584	187	2 900 163	→ 0.00006448	247	2 891 321	→ 0.00008543
Kujawsko-Pomorskie	191	2 077 775	↑ 0.00009193	201	2 072 373	→ 0.00009699	227	2 061 942	→ 0.00011009
Lubelskie	59	2 117 619	↓ 0.00002786	62	2 108 270	↓ 0.00002941	72	2 095 258	↓ 0.00003436
Lubuskie	32	1 014 548	↓ 0.00003154	32	1 011 592	↓ 0.00003163	41	1 007 145	↓ 0.00004071
Łódzkie	201	2 466 322	↑ 0.00008150	219	2 454 779	→ 0.00008921	265	2 437 970	→ 0.00010870
Małopolskie	344	3 400 577	↑ 0.00010116	486	3 410 901	↑ 0.00014248	675	3 410 441	↑ 0.00019792
Mazowieckie	215	5 403 412	↓ 0.00003979	240	5 423 168	↓ 0.00004425	298	5 425 028	↓ 0.00005493
Opolskie	10	986 506	↓ 0.00001014	13	982 626	↓ 0.00001323	18	976 774	↓ 0.00001843
Podkarpackie	122	2 129 015	→ 0.00005730	129	2 127 164	→ 0.00006064	160	2 121 229	↓ 0.00007543
Podlaskie	51	1 181 533	→ 0.00004316	57	1 178 353	↓ 0.00004837	59	1 173 286	↓ 0.00005029
Pomorskie	112	2 333 523	→ 0.00004800	126	2 343 928	↓ 0.00005376	160	2 346 671	↓ 0.00006818
Śląskie	303	4 533 565	→ 0.00006683	351	4 517 635	→ 0.00007770	432	4 492 330	→ 0.00009616
Świętokrzyskie	68	1 241 546	→ 0.00005477	79	1 233 961	→ 0.00006402	97	1 224 626	→ 0.00007921
Warmińsko-Mazurskie	35	1 428 983	↓ 0.00002449	48	1 422 737	↓ 0.00003374	66	1 416 495	↓ 0.00004659
Wielkopolskie	220	3 493 969	→ 0.00006297	262	3498733	→ 0.00007488	333	3 496 450	→ 0.00009524
Zachodnio-pomorskie	130	1 701 030	↑ 0.00007642	137	1 696 193	→ 0.00008077	181	1 688 047	→ 0.00010722
Total (Poland)	**2 255**	**38 411 148**	→ **0.00005871**	**2629**	**38 382 576**	→ **0.00006849**	**3331**	**38 265 013**	→ **0.00008705**

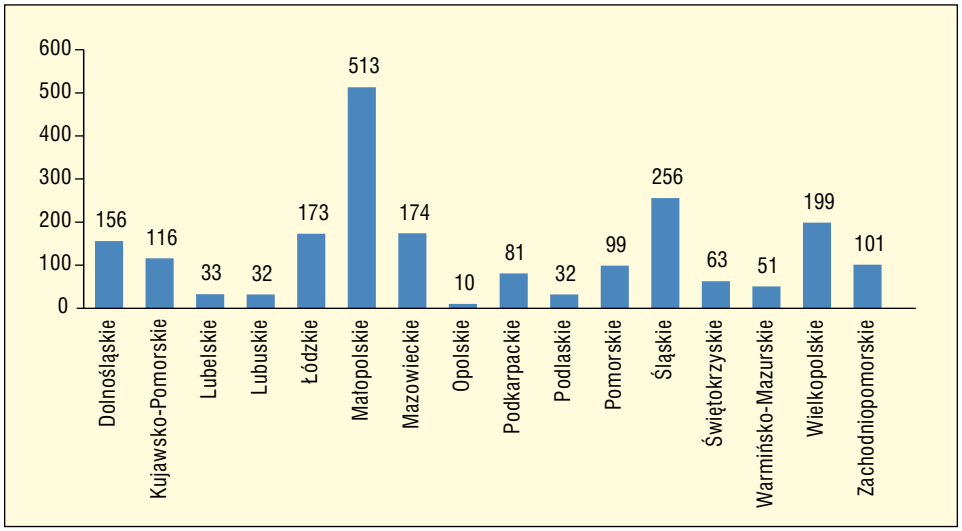

Figure 2. Difference between the number of patients treated under the B.35 drug programme in 2016 and 2021 by voivodeship

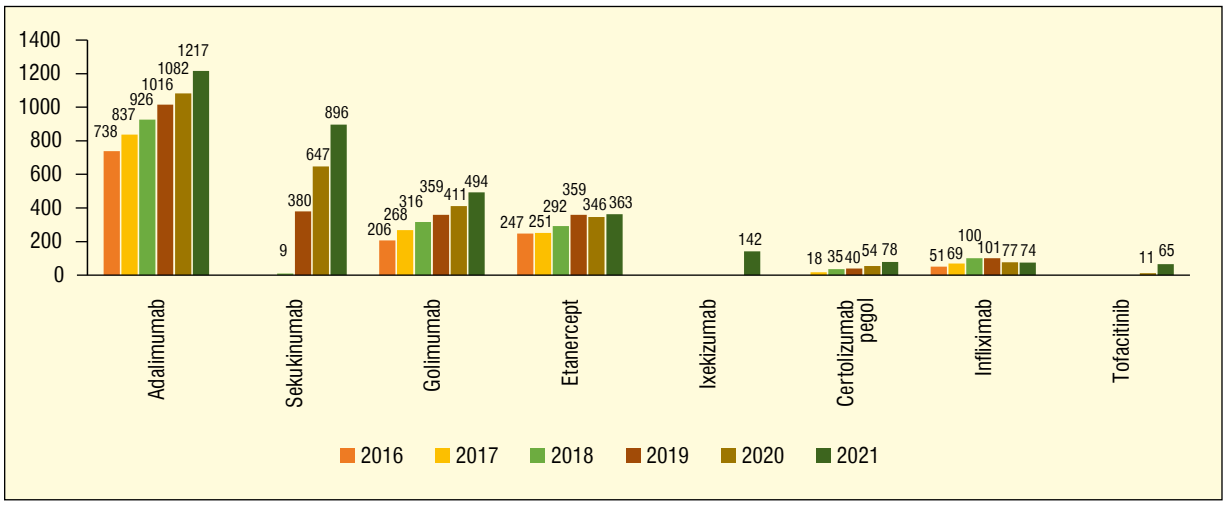

Figure 3. Number of patients under the B.35 drug programme between 2016 and 2021 by drug

over 6 years. The fewest patients (five) were treated in the Lubuskie Voivodeship (Fig. 10).

Infliximab was used most frequently in 2021 in the Lubelskie Voivodeship — in 13 patients. Two voivodeships (Podlaskie and Lubelskie) have not recorded treatment with this drug (Fig. 11).

A new drug, absent from the 2016 funding, was ixekizumab. The drug is reimbursed from 2021 and 142 patients were treated with it that year, the largest number in the Łódzkie Voivodeship — 23. Only in the Podlaskie, Opolskie and Świętokrzyskie voivodeships were there no patients registered with ixekizumab treatment in 2021 (Fig. 12).

Another new drug reimbursed from 2018 is secukinumab. In 2021, 896 patients were treated with this drug, the highest number, 224, in the Małopolskie Voivodeship. The fewest number of patients treated with secukinumab was in the Podlaskie Voivodeship — five (Fig. 13).

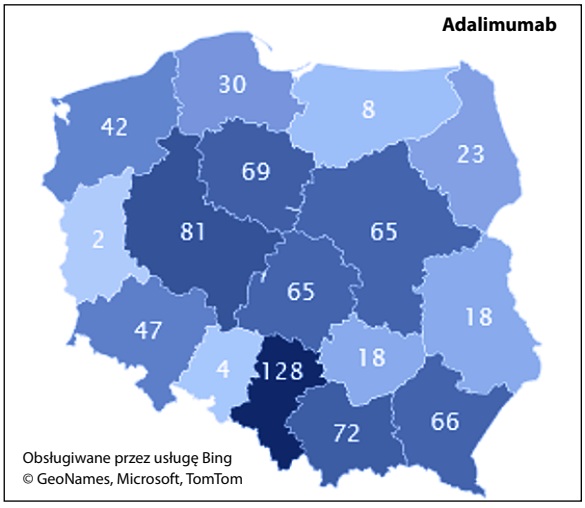

Figure 4. Number of patients treated with adalimumab under the B.35 drug programme in 2016; Microsoft product screenshot reprinted with permission from Microsoft Corporation

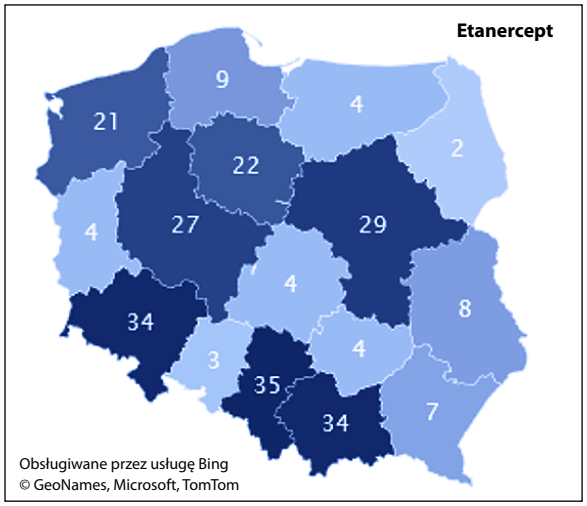

Figure 5. Number of patients treated with etanercept under the B.35 drug programme in 2016; Microsoft product screenshot reprinted with permission from Microsoft Corporation

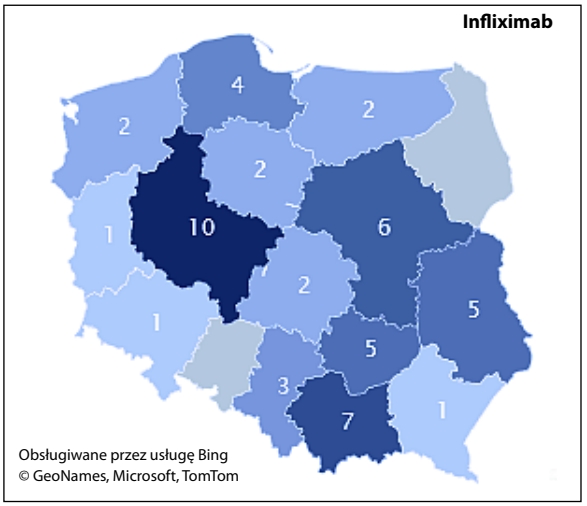

Figure 7. Number of patients treated with infliximab under the B.35 drug programme in 2016; Microsoft product screenshot reprinted with permission from Microsoft Corporation

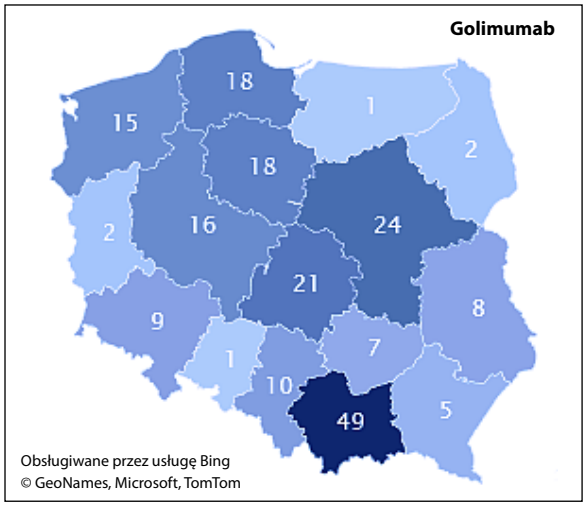

Figure 6. Number of patients treated with golimumab under the B.35 drug programme in 2016; Microsoft product screenshot reprinted with permission from Microsoft Corporation

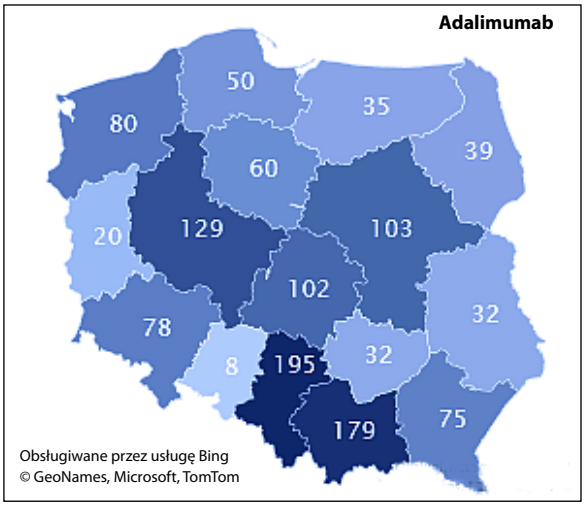

Figure 8. Number of patients treated with adalimumab under the B.35 drug programme in 2021; Microsoft product screenshot reprinted with permission from Microsoft Corporation

In September 2020, therapy with the drug tofacitinib was permitted. The drug was used most frequently in the Małopolskie Voivodeship — in 18 patients. In the Warmińsko-Mazurskie, Lubuskie, Dolnośląskie and Opolskie voivodeships, no therapy with this drug was registered in 2021 (Fig. 14).

As of 2017, certolizumab is also reimbursed. In 2021, the drug was the most used in the Małopolskie Voivodeship. Seventeen patients received treatment using this drug. At the same time, in Podlaskie and Opolskie voivodeships, this drug was not used under the B.35 drug programme (Fig. 15).

Contract values for the drug programme

In 2016, the value of benefits for drugs in the drug programme amounted to PLN 35.3 million. After six years, the value has increased by PLN 15.7 million. At the same time, the value of contracts to operate the drug programme also increased by PLN 3.7 million [8] (Fig. 16).

The largest increase in funding for both drugs and programme operation was in the Małopolskie Voivodeship, amounting to almost PLN 7.4 million for drugs and PLN 676 thousand for operation. On the other hand, in the Podkarpackie, Podlaskie and Zachodniopomorskie voivodeships, there was a reduction in funding for drugs by a total of almost PLN 590,000 (Tab. 3).

Number of providers implementing the drug programme

Over the five years, the number of providers implementing the B.35 drug programme has increased by one (Fig. 17).

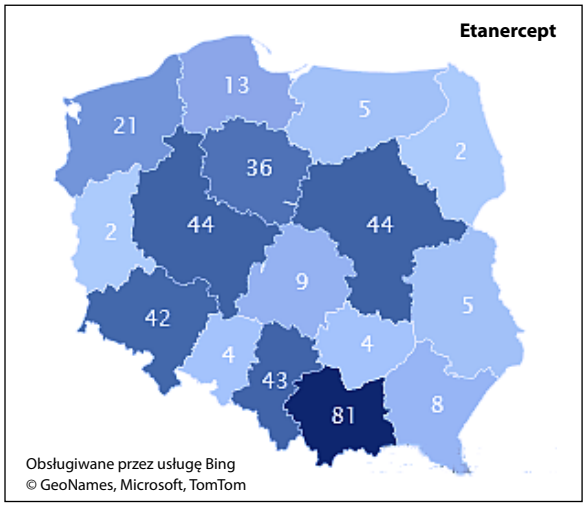

Figure 9. Number of patients treated with etanercept under the B.35 drug programme in 2021; Microsoft product screenshot reprinted with permission from Microsoft Corporation

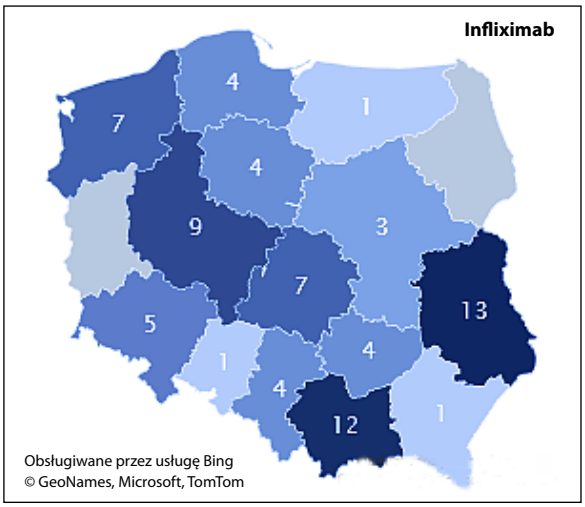

Figure 11. Number of patients treated with infliximab under the B.35 drug programme in 2021; Microsoft product screenshot reprinted with permission from Microsoft Corporation

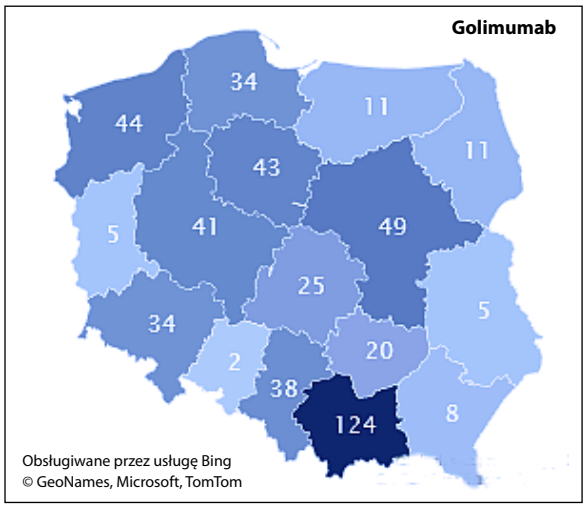

Figure 10. Number of patients treated with golimumab under the B.35 drug programme in 2021; Microsoft product screenshot reprinted with permission from Microsoft Corporation

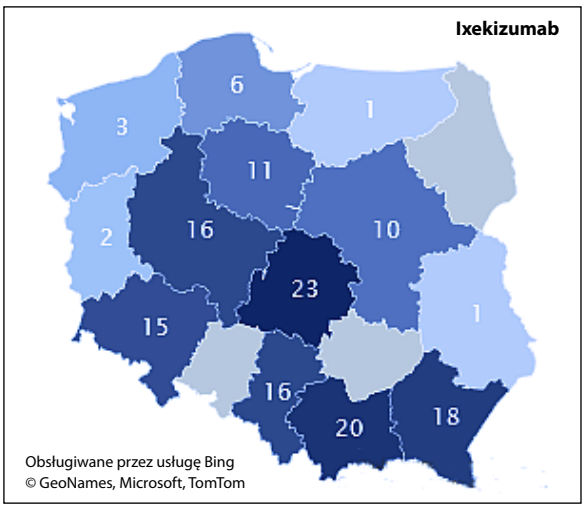

Figure 12. Number of patients treated with ixekizumab under the B.35 drug programme in 2021; Microsoft product screenshot reprinted with permission from Microsoft Corporation

In three voivodeships, the number of providers implementing the B.35 drug programme has decreased (by 1 in each case) in 2021:

— in the Opolskie Voivodeship;
— in the Świętokrzyskie Voivodeship;
— in the Podkarpackie Voivodeship.

At the same time, the number of B.35 programme implementers increased in three voivodeships:

— in the Dolnośląskie Voivodeship — by two;
— in the Małopolskie Voivodeship — by one;
— in the Mazowieckie Voivodeship — by one;

The change in the number of centres implementing the B.35 drug programme between 2016 and 2021 is shown in Figure 18.

DISCUSSION

The B.35 programme is a small drug programme both in terms of funding and the number of patients receiving therapy. The value of contracts for drugs and services within this programme represents only around 1% of the total funding for drugs within drug programmes. At the same time, the number of patients treated within B.35 is also small

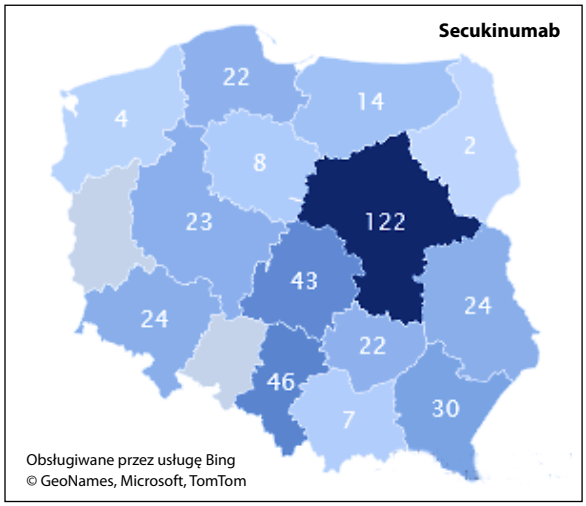

Figure 13. Number of patients treated with secukinumab under the B.35 drug programme in 2021; Microsoft product screenshot reprinted with permission from Microsoft Corporation

compared to the total number of patients treated within drug programmes and is also around 1% [9].

Psoriatic arthritis is characterised by periods of exacerbation and remission. The symptoms develop progressively. Usually, the onset of the disease is difficult to pick up, plus the time from first symptoms to diagnosis is often prolonged [10]. In most patients (75%), skin symptoms precede joint symptoms. It is estimated that 10–15% of patients experience symptom manifestation simultaneously on the skin and in the joints. In the remaining patients, joint symptoms usually come first [11]. The progression of the disease can lead to motor disability resulting from, among other things, joint deformity. After only a few years, in the most severe cases, usually, when the peripheral and axial forms of the disease coexist, joint deformity and disability occur. When the disease has a milder course, then it is character-

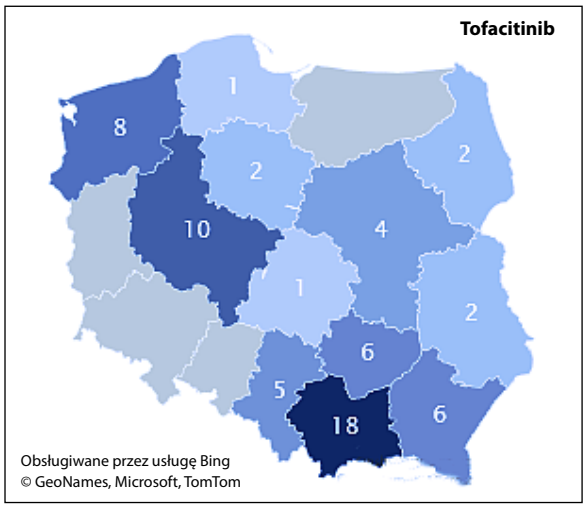

Figure 14. Number of patients treated with tofacitinib under the B.35 drug programme in 2021; Microsoft product screenshot reprinted with permission from Microsoft Corporation

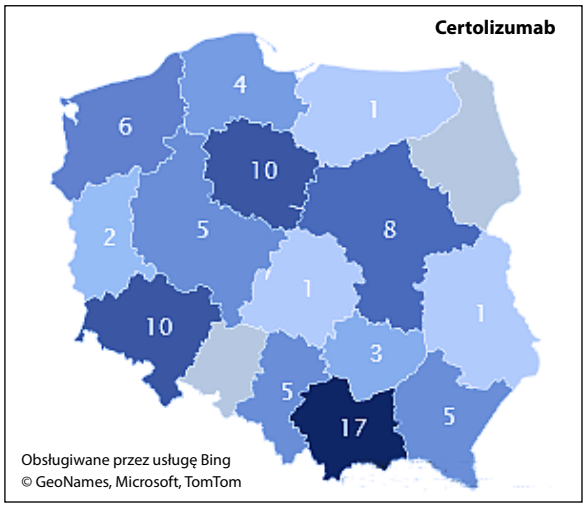

Figure 15. Number of patients treated with certolizumab under the B.35 drug programme in 2021; Microsoft product screenshot reprinted with permission from Microsoft Corporation

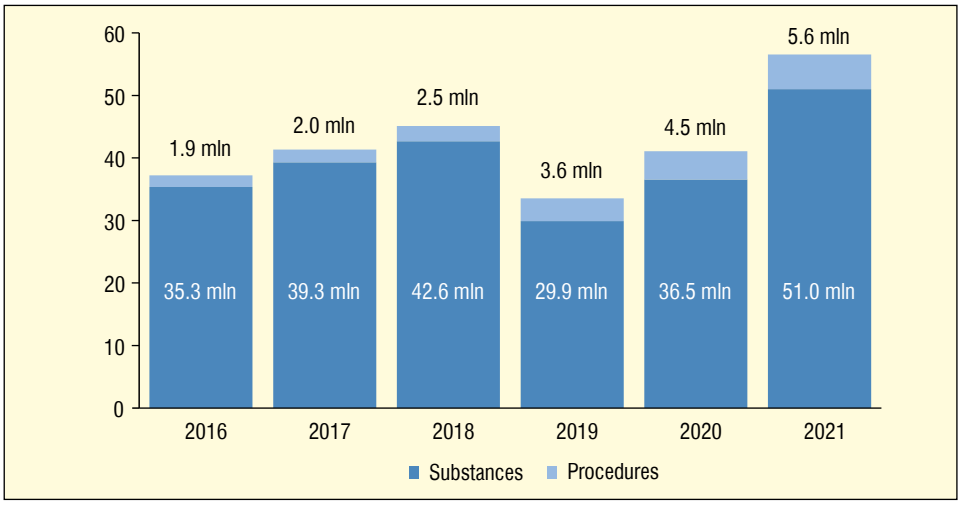

Figure 16. Value of contracts for drugs and operation of the B.35 drug programme between 2016 and 2021 (in PLN currency)

Table 3. Comparison of the value of contracts for drugs and the operation of the B.35 programme between 2016 and 2021 against the population in each voivodeship (in PLN currency)

Voivodeship branch	2016			2021			The difference in the value of contracts 2021/2016
	Contract	Population	Contract value index per 1 inhabitant of the voivodeship	Contract	Population	Contract value index per 1 inhabitant of the voivodeship	
Dolnośląskie	**2 688 889**	**2 904 198**	**0.93**	**4 325 161**	**2 891 321**	**1.50**	**1 636 272**
Kujawsko-Pomorskie	3 021 105	2 086 210	1.45	4 196 298	2 061 942	2.04	1 175 193
Lubelskie	1 085 116	2 139 726	0.51	1 022 867	2 095 258	0.49	–62 249
Lubuskie	197 380	1 018 084	0.19	612 368	1 007 145	0.61	414 988
Łódzkie	3 266 016	2 493 603	1.31	5 188 184	2 437 970	2.13	1 922 168
Małopolskie	4 710 376	3 372 618	1.40	12 760 037	3 410 441	3.74	8 049 661
Mazowieckie	3 440 617	5 349 114	0.64	4 855 779	5 425 028	0.90	1 415 162
Opolskie	309 136	996 011	0.31	170 875	976 774	0.17	–138 261
Podkarpackie	2 288 255	2 127 657	1.08	2 110 870	2 121 229	1.00	–177 385
Podlaskie	1 061 097	1 188 800	0.89	888 907	1 173 286	0.76	–172 190
Pomorskie	1 800 721	2 307 710	0.78	3 372 276	2 346 671	1.44	1 571 555
Śląskie	5 424 312	4 570 849	1.19	6 536 747	4 492 330	1.46	1 112 435
Świętokrzyskie	868 085	1 257 179	0.69	1 708 565	1 224 626	1.40	840 480
Warmińsko-Mazurskie	475 588	1 439 675	0.33	830 371	1 416 495	0.59	354 783
Wielkopolskie	3 934 529	3 475 323	1.13	5 191 427	3 496 450	1.48	1256 898
Zachodniopomorskie	2 637 758	1 710 482	1.54	2 796 897	1 688 047	1.66	159 139
Total (Poland)	**37 208 979**	**38 437 239**	**0.97**	**56 567 629**	**38 265 013**	**1.48**	**19 358 649**

ised by periods of exacerbation and partial remission, with gradually increasing joint mobility limitation [12].

Patients with PsA experience a significant impairment in quality of life (this impairment may be greater than in RA due to the co-occurrence of skin and joint lesions). Visible skin lesions are often accompanied by pain in the hands, feet and pruritus [13].

Psoriatic arthritis causes impairment of normal function and the ability to perform daily domestic and occupational activities [14]. The strong sense of shame and stigma associated with the awareness of the presence of visible, extensive skin lesions may lead to depressive disorders. Going to work and school, building social relationships and playing sports and leisure activities become major challenges.

Only about 1.8% of the population of patients with PsA receive treatment under drug programmes. This is, of course, very little, especially compared to other European countries [15]. The B.35 drug programme has now been available for 10 years. It has undergone numerous metamorphoses aimed at increasing patient access to innovative therapies. Currently, the dermatology and rheumatology communities believe that increasing access to therapy will only be possible by shifting treatment to outpatient clinics and changing the reimbursement availability of some of the drugs. It seems that, as in other European countries, physicians regardless of their place of work should be able to treat patients with biological drugs. Currently, almost all biological drugs registered for the treatment of patients with moderate to severe forms of PsA are publicly funded.

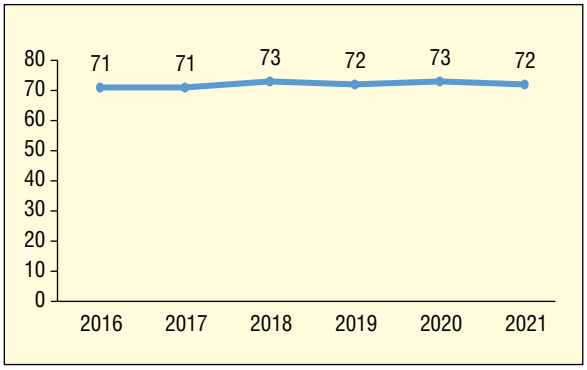

Figure 17. Number of centres implementing the B.35 drug programme between 2016 and 2021

According to the announcement of the Minister of Health on 21 December 2020 on the list of reimbursed drugs, foodstuffs for special nutritional use and medical devices for 1 January 2021, the criteria of the drug programme for patients with psoriatic arthritis have been adapted to current medical knowledge and international recommendations [16]. The changes to the description were preceded by a positive assessment by the Transparency Board of the Agency for Health Technology Assessment and Tarification (AOTMiT) and included:

- the removal of the administrative limits of treatment time for patients with PsA;
- permitting patients with PsA to qualify for the programme starting with a moderate degree of disease activity (at least 3 involved joints or tendon attachments or DAS28 > 3.2 or DAS > 2.4);
- permitting patients with PsA with active psoriasis defined as PASI > 10 and DLQI > 10 and BSA > 10 to qualify for the programme with involvement of fewer joints or tendon attachments, i.e. with inflammation and tenderness of at least one joint or tendon attachment;
- in the case of the peripheral form of PsA, removal of the requirement to confirm tendonitis by ultrasound

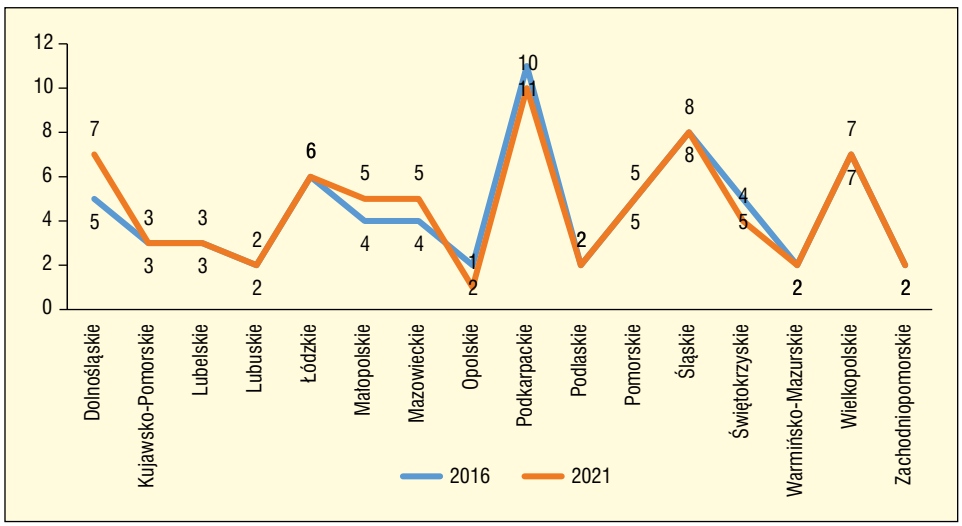

Figure 18. Change in the number of centres implementing the B.35 drug programme between 2016 and 2021

or MRI and giving the treating physician discretion to administer corticosteroids to the area of the inflamed tendon attachment as a local treatment option;

— making it possible to optimise drug dosing (reducing doses or extending the interval between successive doses) in all patients in whom the target of therapy was achieved;

— unification of the description regarding the timing of treatment efficacy assessments and monitoring studies and increasing the margin for all visits to 1 month.

The aim of these changes was, of course, to provide treatment options in line with current medical knowledge and recommendations to achieve and maintain disease remission and increase the likelihood of maintaining full function in an increasing number of patients.

CONCLUSIONS

The inclusion of funding for drugs for psoriatic arthritis patients under the B.35 drug programme was a response to the expectations of both dermatologists and rheumatologists, as well as the patient community. The constantly changing description of the drug programme undoubtedly increases patient access to therapy. In addition, the annual inclusion of new, innovative drugs in reimbursement brings Polish patients closer to the international standards for therapeutic management. The option to prescribe drugs to patients, who can take them at home, significantly improves their quality of life and helps them reduce the number of sick leaves and therefore decrease absenteeism from school and work.

Furthermore, some drugs have already been on the international market for several years and have a proven efficacy and safety profile. In most European countries, these drugs are available to patients on prescription in retail pharmacies. It, therefore, seems reasonable that some of them could be made more widely available to Polish patients under open-list reimbursement. Undoubtedly, shifting some of the drugs to outpatient health care would reduce the workload of physicians in clinical centres and involve more specialist physicians in the innovative, effective treatment of patients with PsA.

Conflict of interest

Lectures and consultancy for Abbvie, Novartis, UCB, Lilly and Janssen companies.

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