REAL-WORLD EFFECTIVENESS OF BIOLOGIC AGENTS USED TO TREAT MODERATE-TO-SEVERE PLAQUE PSORIASIS IN POLAND: BETWEEN TREATMENT COMPARISON

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BACKGROUND

- Psoriasis is a chronic autoimmune dermatological disease characterised by patches of flaky skin. Plaque psoriasis is the most common variant of the disease.[1] The condition can significantly decrease patients' quality of life both because of pain in the affected parts of the body and social exclusion.[2]
- It is estimated that about 1 million people in Poland suffer from psoriasis, which makes it one of the most common dermatological diseases affecting patients there.[3]
- In Poland, the treatment of moderate-to-severe plaque psoriasis using biological agents is available through participation in a drug program B.47 "Treatment of moderate-to-severe plaque psoriasis (ICD-10: L40.0)".
- As of 2024, 11 distinct biologic agents are available for participants in this program.[4]

OBJECTIVE

- The objective of this study was to compare the real-world effectiveness of biologic agents used in treating moderate-to-severe plaque psoriasis in Poland.

METHODS

- The analysis was based on data from a Polish drug program number B.47 "Treatment of moderate-to-severe plaque psoriasis (ICD-10: L40.0)", covering biological treatment of the disease. The program started in 2013 and has continued to the present day. This study focused on data since the beginning of the program in 2013 until October 2023. The dataset comprised anonymised data of approximately 5,000 participants from the B.47 program from 2013 to 19th of October 2023.
- The patient-level data included age, gender, weight, date of program enrolment, baseline disease-severity measure values and repeated measurements collected throughout the participation in the program.
- The psoriasis-specific measures used to determine disease severity in the study were Psoriasis Area and Severity Index (PASI), Body Surface Area (BSA) and Dermatology Life Quality Index (DLQI) (Table 1).

Table 1. Psoriasis-specific measures of disease severity

Psoriasis Area and Severity Index (PASI)

Scale assessing both body area affected by the disease and its severity, ranging from 0 to 72[5].

PASI75 indicates the percentage of patients who achieved at least 75% reduction in PASI from baseline.

Body Surface Area (BSA)

% of body area affected by the disease[6]

Dermatology Life Quality Index (DLQI)

Dermatology-specific quality of life (QoL) questionnaire, score ranging 0 to 30 with 0 meaning no negative impact of disease[7].

DLQI 0/1 assesses the percentage of patients who attained DLQI score of 0 or 1.

- To evaluate the effectiveness of the biologics used in the drug program, PASI75 and DLQI 0/1 were assessed between the 12th and 16th weeks, as well as between the 36th and 40th weeks of treatment.
- The analysis concerned 10 biologics utilised in the drug program. Bimekizumab was removed from the analysis as data was not sufficient due to its recent introduction (March 2023).

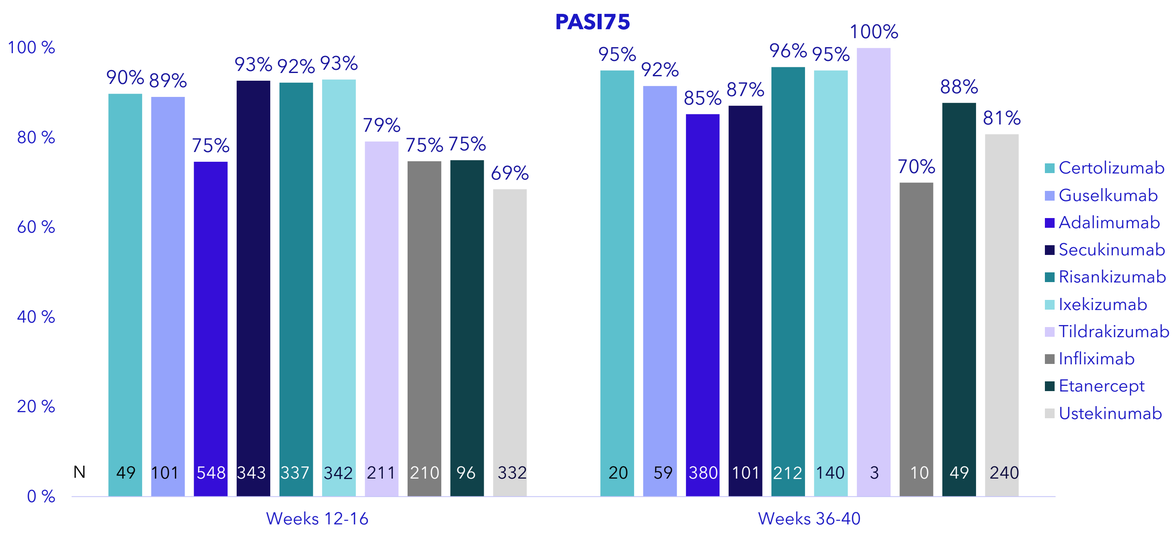

Figure 1. PASI75 between treatment comparison after 12-16 weeks and 36-40 weeks

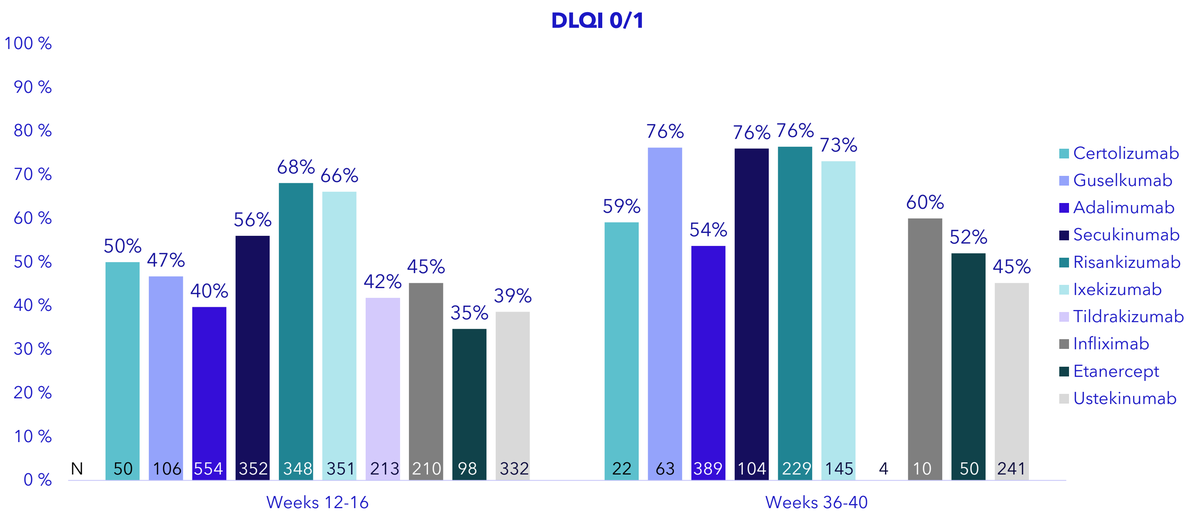

Figure 2. DLQI 0/1 between treatment comparison after 12-16 weeks and 36-40 weeks

- The key inclusion criteria of the B.47 program have been evolving over the years. One notable change was the inclusion of patients with PASI > 10 in the program in 2023 regardless of the treatment, in contrast to the previous criterion of PASI ≥ 18 established in 2013 as well as previous restrictions on treatment options for patients with lower PASI.
- As of 2024, the key inclusion criteria included age, diagnosis of moderate-to-severe plaque psoriasis, and previous unsuccessful systemic treatment (Table 2).[4]

Table 2. Key inclusion criteria of the B.47 program in 2024

Age	
Adalimumab	≥ 4 y.o.
Etanercept, ustekinumab, ixekizumab, secukinumab	≥ 6 y.o.
Other drugs	≥ 18 y.o.
Disease-severity	
Patients with moderate-to-severe plaque psoriasis:	
PASI	> 10
BSA	> 10
DLQI	> 10
Previous unsuccessful therapy	
Patients ≥ 18 y.o.	2 previous unsuccessful systemic therapies or contradictions for such therapy
Patients 4 – 18 y.o.	1 previous unsuccessful systemic therapy or contradictions for such therapy

y.o. – years old

RESULTS

- Overall, baseline patients' characteristics were similar for all the biologics. For certolizumab and tildrakizumab both PASI and BSA scores were slightly lower than for the other drugs, but no significant difference was found for DLQI.
- After 12 to 16 weeks of treatment, 69% to 93% program participants achieved ≥ 75% improvement in PASI score. The highest response rates were observed for secukinumab (93%), ixekizumab (93%) and risankizumab (92%), while the lowest effectiveness was shown for ustekinumab (69%).
- Between 36th and 40th weeks, the effectiveness of all biologics but two – infliximab and secukinumab – have increased with the percentage of patients reaching PASI75 ranging from 70% to 100%.
- In terms of DLQI 0/1, the highest response rates after 12 to 16 weeks were observed for risankizumab (68%) and ixekizumab (66%). The least effective in achieving DLQI 0/1 in this period were etanercept (35%) and ustekinumab (39%).
- After 36 to 40 weeks of treatment for all biologic agents the percentage of patients achieving DLQI 0 or 1 has increased ranging from 45% to 76%. For tildrakizumab the quantity of data for this period is insufficient to draw conclusions.

CONCLUSIONS

- **Biologic agents demonstrated high real-world effectiveness in PASI reduction in patients with moderate-to-severe plaque psoriasis in Poland.**
- **Real-world data also demonstrated benefits in DLQI reduction, highlighting the positive impact of biologic treatment on patients' quality of life.**
- **The effectiveness of treatments was relatively stable between the 12th and 40th week of treatment.**

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