Real World Treatment Usage of Biologic and Targeted Synthetic Disease-Modifying Anti-Rheumatic Drugs in US Patients with Psoriatic Arthritis: Persistence, Factors Associated with Non-Persistence, and Dosing Patterns

Sarah Welby,[1] Jie Song,[1] Chao Lu,[2] Olga Pilipczuk,[1] Damon Willems,[1] Silky Beaty,[2] Jason Eells,[3] and Maurille Feudjo Tepie[3]

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Objective

To report on real-world persistence, factors associated with non-persistence, and dosing patterns of biologic and targeted synthetic disease-modifying anti-rheumatic drugs in the first 12-months of treatment in patients with psoriatic arthritis in the United States.

Background

- Psoriatic arthritis (PsA) is a complex, immune-mediated, inflammatory disease that manifests heterogeneously across the peripheral and axial joints, skin and entheses;[1] there are several associated inflammatory and non-inflammatory comorbidities such as psoriasis and hypertension, respectively.
- Biologic and targeted synthetic disease-modifying anti-rheumatic drugs (b/tsDMARDs), including tumor necrosis factor alpha (TNF), interleukin (IL)-17A, IL-12/23, IL-23, phosphodiesterase-4 (PDE4), and Janus kinase (JAK) inhibitors, are recommended treatment options for PsA.[2]
- Between 30% and 70% of patients discontinue treatment within 12–24 months, with lack of efficacy reported as the principal cause.[3,4]
- Understanding persistence and identifying factors associated with non-persistence (including switching between treatments) are important to assist clinicians in tailoring therapeutic choices to maximize the benefit for their patients.

Methods

- This was an observational cohort study of patients in the United States using Merative™ MarketScan® Research Databases; adult patients with a clinical diagnosis of PsA initiating a new b/tsDMARD from January 1, 2017–September 30, 2020 were retrospectively identified.
  - b/tsDMARD-naive and -experienced patients were included.
- Follow-up was conducted until the earliest of: completion of 12 months of treatment, discontinuation, switch of index medication, death, or end of enrollment in Merative™ MarketScan® Research Databases.
- Persistence of index PsA treatment was estimated using Kaplan-Meier curves.
- Cox regression models were applied to test associations between patient characteristics (extra articular, peripheral manifestations, and comorbidities) and non-persistence (discontinuation defined as ≥90-day gap in therapy, and switch defined as change to a different b/tsDAMRD). Variables with p values <0.25 and/or clinically relevant factors in an initial univariate analysis were entered into the multivariate analysis. A stepwise elimination method was then used with a significance level of p=0.05 applied for entry and stay.
- Variables investigated included: age, sex, b/tsDMARD treatment history, route of b/tsDMARD administration, baseline inflammatory comorbidities, baseline non-inflammatory comorbidities, and baseline comedications. While the baseline period was a minimum of 12 months, a maximum baseline period was not defined (**Figure 1**). Patient characteristics that were first recorded following index b/tsDMARD initiation were also investigated for their association with non-persistence as part of the multivariate analysis; however, the results are not presented here.
- Dosing patterns of secukinumab are reported considering patients with PsA only and those with co-occurring psoriasis (PsA+PSO) due to different prescribing recommendations and dose formulations.
- There was no imputation of missing values.

Results

Patient demographics

- A total of 5,325 adult patients with PsA initiating a new b/tsDMARD were identified retrospectively (**Figure 1**). Baseline characteristics are reported in **Table 1.**
- Most patients were prescribed TNF inhibitors (55.3%; n=2,946), followed by PDE4 inhibitors (24.8%; n=1,323), IL-17A inhibitors (12.4%; n=662), IL-12/23 inhibitors (5.5%; n=294), JAK inhibitors (1.5%; n=80), and selective T cell costimulation modulators (0.4%; n=20).

Treatment persistence

- Of the 5,325 patients identified, 3,097 (58.2%) persisted on their index treatment, 1,707 (32.1%) discontinued, and 521 (9.8%) switched to another b/tsDMARD during the 12-month follow up period.
- The estimated 12-month drug survival probability (persistence) was 52.3% (**Figure 2A**).
- Drug persistence probabilities at 12 months (for most frequently prescribed [>100 patients]) were 62.4%, 55.4%, 52.4%, and 46.7% for IL-17A, IL-12/23, TNF, and PDE4 inhibitors, respectively (**Figure 2B**).
- Persistence was similar between b/tsDMARD-naïve and -experienced patients (52.4% versus 51.5%) (**Figure 2C**).

Predictors of non-persistence

- Non-persistence was higher in females and patients with baseline comorbidities, including ankylosing spondylitis (AS), allergies, systemic lupus erythematosus (SLE), sleep apnea, and having multiple non-inflammatory comorbidities (**Table 2**).

Secukinumab dosing patterns

- 288/518 (55.6%) of patients with PsA initiating secukinumab (with dose records available) were prescribed 300 mg as a starting dose.
- 33/101 (32.7%) patients with PsA-only started secukinumab at 300 mg and 45 (44.6%) started at 150 mg; 25 (24.8%) remained on 150 mg and 20 (19.8%) increased to 300 mg during follow-up.
- For PsA+PSO patients, 101/417 (24.2%) started at 150 mg and 255/417 (61.2%) started at 300 mg; 46 (11.0%) remained on 150 mg and 38 (9.1%) escalated to 300 mg during follow-up.
- The remaining patients had missing or otherwise unavailable data.

Summary

12-month persistence[a] of biologic and targeted synthetic DMARDs in patients with psoriatic arthritis was **52.3%**

Baseline factors associated with *increased* persistence

IL-17A inhibitors; Psoriasis; Methotrexate or sulfasalazine use

Baseline factors associated with *decreased* persistence

Female sex; Ankylosing spondylitis; Allergy; Systemic lupus erythematosus; Sleep apnea

[a]Persistence: estimated 12-month drug survival probability

Figure 1 Patient inclusion flow

Patients prescribed ≥1 b/tsDMARD in the identification period[a] (N=263,836)

↓

Patients prescribed only one b/tsDMARD; sensitivity analyses calculated with a 60, 90, and 120-day gap on index date (99.9%; N=263,675)

↓

Patients diagnosed with PsA before or on index date (8.1%; N=21,278)[b]

↓

Patients with dual medical/pharmacy enrollment in Merative™ MarketScan® Research Databases for ≥12 months prior to the index date (6.8%; N=17,903)

↓

Patients ≥18 years of age as of the index date (6.8%; N=17,821)

↓

Patients with no occurrence of index drug at baseline[c] (2.6%; N=6,857)

↓

Patients with ≤1 diagnoses of rheumatoid arthritis at baseline[d] (2.2%; N=5,670)

↓

Patients prescribed index drug with positive days' supply value (ongoing treatment [2.1%; N=5,639])

↓

Patients with ≥1 NDC code for the index drug during follow-up (2.0%; N=5,325)

↓

Final sample included in the analysis (2.0%; N=5,325)

[a]The identification period spanned January 1, 2017–December 31, 2020; [b]Patients must have had ≥2 ICD-10 code for PsA within the 12 months before baseline period or at the index date; [c]The baseline period was the time preceding each patient's index data, with no maximum baseline defined; [d]Patients with ≥2 diagnosis claims (ICD-10 code) of rheumatoid arthritis were excluded as PsA is often misdiagnosed as rheumatoid arthritis, therefore the dates of PsA diagnosis and b/tsDMARD initiation might not be accurate for patients with both diagnoses.

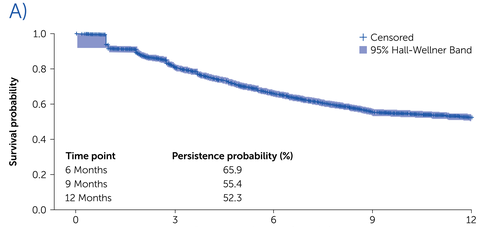
Table 1 Baseline demographics and characteristics

	TNF inhibitors N=2,946	IL-17A inhibitors N=662	IL-12/23 inhibitors N=294	PDE4 inhibitors N=1,323	JAK inhibitors N=80	Selective T cell[e] N=20
Age, years, mean (SD)	49.3 (11.2)	50.7 (10.8)	50.6 (11.9)	52.1 (11.4)	51.2 (11.5)	48.3 (10.4)
Sex, male, n (%)	1,236 (42.0)	284 (42.9)	134 (45.6)	501 (37.9)	22 (27.5)	4 (20.0)
History of b/tsDMARD treatment, n (%)						
b/tsDMARD-naïve	2,646 (89.8)	420 (63.4)	196 (66.7)	1,200 (90.7)	69 (86.3)	14 (70.0)
b/tsDMARD-experienced	300 (10.2)	242 (36.6)	98 (33.3)	123 (9.3)	11 (13.8)	6 (30.0)
Inflammatory comorbidities, n (%)						
None	346 (11.7)	54 (8.2)	18 (6.1)	136 (10.3)	10 (12.5)	1 (5.0)
1 comorbidity	1,266 (43.0)	330 (49.8)	146 (49.7)	570 (43.1)	32 (40.0)	4 (20.0)
≥2 comorbidities	1,334 (45.3)	278 (42.0)	130 (44.2)	617 (46.6)	38 (47.5)	15 (75.0)
Psoriasis	2,122 (72.0)	554 (83.7)	252 (85.7)	1,045 (79.0)	54 (67.5)	8 (40.0)
AS	822 (27.9)	157 (23.7)	65 (22.1)	357 (27.0)	28 (35.0)	13 (65.0)
Dactylitis	79 (2.7)	19 (2.9)	7 (2.4)	43 (3.3)	1 (1.3)	0
Enthesitis	79 (2.7)	14 (2.1)	9 (3.1)	34 (2.6)	1 (1.3)	0
IBD	75 (2.5)	7 (1.1)	13 (4.4)	18 (1.4)	6 (7.5)	0
Allergy	609 (20.7)	119 (18.0)	56 (19.0)	292 (22.1)	20 (25.0)	7 (35.0)
Asthma	391 (13.3)	75 (11.3)	33 (11.2)	196 (14.8)	12 (15.0)	6 (30.0)
SLE	58 (2.0)	7 (1.1)	4 (1.4)	29 (2.2)	1 (1.3)	4 (20.0)
Fibromyalgia	297 (10.1)	47 (7.1)	23 (7.8)	113 (8.5)	10 (12.5)	5 (25.0)
Non-inflammatory comorbidities, n (%)						
None	154 (5.2)	58 (8.8)	25 (8.5)	73 (5.5)	5 (6.3)	0
1 comorbidity	372 (12.6)	70 (10.6)	36 (12.2)	143 (10.8)	12 (15.0)	0
≥2 comorbidities	2,420 (82.1)	534 (80.7)	233 (79.3)	1,107 (83.7)	63 (78.8)	20 (100)
Anxiety	888 (30.1)	186 (28.1)	71 (24.1)	370 (28.0)	20 (25.0)	10 (50.0)
Cardiovascular disease	316 (10.7)	80 (12.1)	33 (11.2)	200 (15.1)	11 (13.8)	4 (20.0)
Depression	614 (20.8)	155 (23.4)	64 (21.8)	261 (19.7)	14 (17.5)	5 (25.0)
Diabetes	517 (17.5)	123 (18.6)	57 (19.4)	261 (19.7)	14 (17.5)	5 (25.0)
Fatigue	1,040 (35.3)	204 (30.8)	96 (32.7)	457 (34.5)	30 (37.5)	12 (60.0)
Malignancies	128 (4.3)	53 (8.0)	20 (6.8)	153 (11.6)	6 (7.5)	4 (20.0)
Hyperlipidemia	1,263 (42.9)	276 (41.7)	143 (48.6)	660 (49.9)	38 (47.5)	11 (55.0)
Hypertension	1,326 (45.0)	307 (46.4)	131 (44.6)	653 (49.4)	36 (45.0)	10 (50.0)
Joint pain	2,014 (68.4)	367 (55.4)	161 (54.8)	856 (64.7)	55 (68.8)	17 (85.0)
Chronic kidney disease	76 (2.6)	23 (3.5)	9 (3.1)	53 (4.0)	4 (5.0)	3 (15.0)
Liver disease	287 (9.7)	63 (9.5)	19 (6.5)	154 (11.6)	10 (12.5)	6 (30.0)
Lower back pain	986 (33.5)	203 (30.7)	94 (32.0)	431 (32.6)	37 (46.3)	9 (45.0)
Metabolic syndrome	77 (2.6)	16 (2.4)	4 (1.4)	45 (3.4)	2 (2.5)	2 (10.0)
Obesity and overweight	841 (28.5)	189 (28.5)	75 (25.5)	455 (34.4)	25 (31.3)	13 (65.0)
Osteoporosis	104 (3.5)	34 (5.1)	9 (3.1)	70 (5.3)	9 (11.3)	5 (25.0)
Sleep apnea	542 (18.4)	127 (19.2)	56 (19.0)	264 (20.0)	17 (21.3)	10 (50.0)
Comedications, n (%)						
None	323 (11.0)	125 (18.9)	59 (20.1)	194 (14.7)	9 (11.3)	0
1 comedication	338 (11.5)	104 (15.7)	50 (17.0)	213 (16.1)	11 (13.8)	5 (25.0)
≥2 comedications	2,285 (77.6)	433 (65.4)	185 (62.9)	916 (69.2)	60 (75.0)	15 (75.0)
NSAIDs[b]	991 (33.6)	177 (26.7)	74 (25.2)	403 (30.5)	24 (30.0)	6 (30.0)
Corticosteroids[b]	825 (28.0)	146 (22.1)	57 (19.4)	267 (20.2)	16 (20.0)	8 (40.0)
Antidepressants	928 (31.5)	240 (36.3)	99 (33.7)	372 (28.1)	18 (22.5)	8 (40.0)
Lipid regulators	569 (19.3)	139 (21.0)	77 (26.2)	320 (24.2)	15 (18.8)	6 (30.0)
Chemotherapy	1,296 (44.0)	138 (20.8)	46 (15.6)	332 (25.1)	29 (36.3)	4 (20.0)
Methotrexate	1,295 (44.0)	138 (20.8)	46 (15.6)	328 (24.8)	29 (36.3)	4 (20.0)
Sulfasalazine	203 (6.9)	29 (4.4)	11 (3.7)	82 (6.2)	8 (10.0)	1 (5.0)

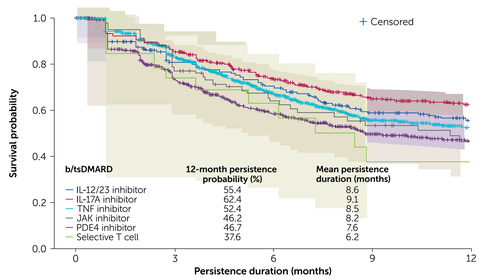
A cut-off value of ≥10% in any biologic treatment was used for comorbidities excluding dactylitis, enthesitis, and IBD; [e]Selective T cell costimulation modulator; [b]Excluding topicals.

Figure 2 Persistence of b/tsDMARD therapy in the first 12 months of treatment (A), by index b/tsDMARD type (B), by history of b/tsDMARD treatment (C)

A)



B)



C)

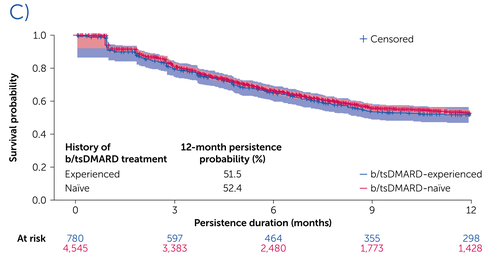


Table 2 Baseline variables associated with non-persistence of b/tsDMARD therapy in the first 12 months of treatment

Persistence vs non-persistence: Multivariate analysis[a]	Baseline variable (reference)	Risk of non-persistence with index b/tsDMARD HR (95% CI)		
		Overall non-persistence N=5,325	Risk of discontinuation N=4,804	Risk of switch N=3,618
Gender	**Female** (male)	1.53 (1.40–1.67)	1.58 (1.43–1.75)	1.50 (1.25–1.80)
Index b/tsDMARD type	**IL-17A inhibitor** (TNF inhibitor)	0.78 (0.67–0.91)	0.83 (0.70–0.98)	–
	PDE4 inhibitor (TNF inhibitor)	–	1.29 (1.16–1.45)	–
Inflammatory comorbidity	**Psoriasis** (no psoriasis)	0.82 (0.75–0.91)	0.78 (0.70–0.87)	–
	AS (no AS)	1.20 (1.09–1.32)	1.17 (1.05–1.30)	–
	Allergy (no allergy)	1.12 (1.01–1.24)	–	1.39 (1.13–1.71)
	SLE (no SLE)	1.47 (1.14–1.91)	1.58 (1.18–2.11)	–
	Urethritis (no urethritis)	–	2.05 (1.02–4.13)	–
Non-inflammatory comorbidity	**Anxiety** (no anxiety)	–	1.12 (1.01–1.24)	–
	Sleep apnea (no sleep apnea)	1.17 (1.05–1.30)	–	1.32 (1.07–1.64)
	Multiple (none)	1.30 (1.07–1.59)	–	–
	Methotrexate (no methotrexate)	0.82 (0.75–0.90)	0.78 (0.70–0.86)	–
	Sulfasalazine (no sulfasalazine)	0.75 (0.62–0.90)	0.72 (0.58–0.89)	–
Comedication	**Opioids** (no opioids)	–	1.18 (1.04–1.34)	–
	NSAIDs[b] (no NSAIDs)	–	–	1.43 (1.19–1.70)
	Corticosteroids[b] (no corticosteroids)	–	–	1.24 (1.02–1.50)

[a]Additional variables, including those recorded during follow-up, were included in multivariate analyses but not presented in the above table. Only gender, index b/tsDMARD type, baseline comorbidites, and comedications were considered here. [b]Excluding topicals. Cells denoted with '–' were not tested in the multivariate model. Higher HRs are associated with an increased risk of non-persistence.

Conclusions

These real-world data indicated that among United States patients with PsA initiating b/tsDMARD, overall persistence probability was suboptimal with approximately half of the patients discontinuing or switching treatment within 12 months, regardless of prior b/tsDMARD exposure. When initiating secukinumab, the majority (55.6%) of patients were prescribed 300 mg as a starting dose. b/tsDMARD usage and dosage appeared to be affected by specific baseline characteristics, which may identify patients who require additional management or tailoring of treatment.

AS: ankylosing spondylitis; **b/tsDMARD:** biological/targeted synthetic disease-modifying anti-rheumatic drug; **CI:** confidence interval; **HR:** hazard ratio; **IBD:** inflammatory bowel disease; **IL:** interleukin; **JAK:** Janus kinase; **NDC:** National Drug Code; **NSAIDs:** non-steroidal anti-inflammatory drugs; **PDE4:** phosphodiesterase-4; **PsA:** psoriatic arthritis; **PSO:** psoriasis; **SEC:** secukinumab; **SD:** standard deviation; **SLE:** systemic lupus erythematosus; **TNF:** tumor necrosis factor alpha.

Institutions: [1]UCB Pharma, Brussels, Belgium; [2]UCB Pharma, Smyrna, GA, USA; [3]UCB Pharma, Slough, UK.

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