Retrospective real-world study assessing treatment patterns of United States adult patients with moderate-to-severe psoriasis initiating advanced therapies and their dispositions

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Background

Psoriasis (PsO) is a chronic inflammatory skin condition treated by several advanced therapies (ATs) in the United States, including tumor necrosis factor (TNF) inhibitors, interleukin (IL) inhibitors (e.g., IL-12/23, IL-23, IL-17), apremilast, deucravacitinib, and biosimilars of TNF-inhibitors and IL-12/23 inhibitors.

Biologics are more effective than new non-biologic treatments for treating PsO, but their higher cost limits clinical use.[1] Non-biologic treatments could offer a more affordable option, although concerns exist regarding efficacy loss and safety profile changes when switching from biologics.

Guidelines on moderate-to-severe PsO treatments do not specify the order of therapies, leading patients to receive multiple therapies over time, and sometimes deferring the initiation of more effective therapies. Treatment switching is an important driver of PsO-related healthcare costs, a raising concerns for payers.[2] Additionally, treatment patterns and outcomes for patients initiating ATs are not well understood.

Objectives

The objectives of this study were to describe treatment patterns among moderate-to-severe PsO patients and the disposition of these patients in the real-world setting.

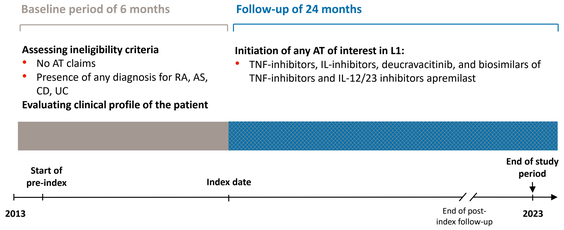
Methods

Patients were identified from the **Merative® MarketScan® Commercial Claims Database** (Commercial Claims and Encounters) between January 2013 and December 2023 based on the following criteria:

- Adult with at least **2 PsO diagnoses** spaced at a minimum of 30 days apart.
- **Initiated a first-line (L1) of AT** indicated for moderate-to-severe PsO: TNF inhibitors (originator or biosimilar), IL inhibitors (originator or biosimilar), apremilast or deucravacitinib.
- **Continuously enrolled for 30 months** with a 6-month pre-index period (baseline period) prior to therapy initiation and 24 months of follow-up post-index, where the index date is the date of the first claim for any of the AT of interest after the first PsO diagnosis.
- **Excluded** if they had any AT claims of interest during baseline period, or any diagnoses claims for rheumatoid arthritis (RA), ankylosing spondylitis (AS), Crohn's disease (CD), or ulcerative colitis (UC) during baseline period or at index date.

The clinical assessment of patients' profile consisted in gathering baseline information such as age, sex, dermatologist visit, number of previous delivered topicals, and the Charlson Comorbidity Index (CCI).

***Figure 1**: Illustration of study design for a given patient*



***Abbreviations**: **AS**=Ankylosing Spondylitis, **AT**=Advanced Therapy, **CD**=Crohn's Disease, **IL**=Interleukin, **RA**=Rheumatoid Arthritis, **TNF**=Tumor Necrosis Factor, **UC**=Ulcerative Colitis*

Key Takeaways

- Biologics represented approximately 68% of treatment initiated in L1. Among them, 99.8% were originator and only 0.2% were biosimilar.
- TNF-inhibitors, apremilast, and IL-inhibitors represented 38%, 32%, and 27% of treatment initiated in L1, respectively.
- The median time on L1 treatment (before L1 discontinuation) was 8.5 months with 75% of patients switching to another line of treatment.

Methods (continued)

Two outcomes were of interest:

1. The treatment patterns

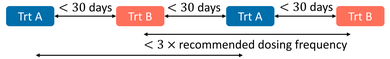
Treatments included monotherapies and combinations from index date to 2 years of follow-up, captured in pharmacy drug and injections claims.

- **Monotherapy**: a delivery or an uninterrupted succession of deliveries of the same treatment, occurring within the three times of the recommended dosing frequency.

***Figure 2**: Line of monotherapy*

- **Combination**: an uninterrupted period with claims for the same two treatments, each administered within three times the recommended dosing frequency, and the claim for the second treatment occurring within 30 days of the first throughout the period.

***Figure 3**: Line of combination of therapies*



Proportions of treatments among the three first lines (L1, L2, L3) were generated, as well as a sunburst graph to visualize treatment patterns and dynamics over time.

2. The time to treatment failure (TTF)

TTF was estimated based on **treatment discontinuation,** defined as a gap in prescription refills exceeding twice the labelled dosing interval,[3] or by a **change in prescription(s)**,[4] including switches between biosimilars and originators.

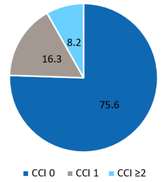
Kaplan-Meier methodology was used, censoring patients without failure at their end of follow-up date. The rates of patients with treatment discontinuation (gap or switch) in L1 were also estimated.

Results

Baseline characteristics

- **33,924 patients** were identified, **52%** were female and mean age was **45 years old**. Most common comorbidities included psoriatic arthritis (20%) and hypertension (19%).

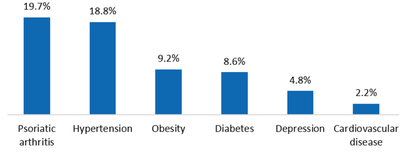
***Figure 4**: Charlson Comorbidity Index (CCI) distribution*



Mean number of previous visits to dermatologist (SD): 2.54 (5.16)

Mean number of previous delivered topicals (SD): 0.95 (1.01)

***Figure 5**: Comorbidities distribution*



***Abbreviations**: **AT**=Advanced Therapy, **CCI**=Charlson Comorbidity Index, **PsO**=Psoriasis, **SD**=Standard Deviation*

Description of the treatment patterns

- For L1 monotherapies, **38.0%** of patients received TNF-inhibitors, **31.7%** apremilast, **27.2%** IL-inhibitors; **3.0%** received combination of ATs. Among L1 biologics, 99.8% were originators and 0.2% were biosimilars.
- Regarding subsequent therapies, **19.6% of patients** received three consecutive lines of TNF-inhibitors, the most common treatment pattern.

***Figure 6**: Sunburst of treatment patterns*

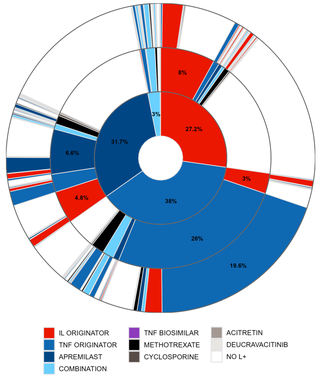


***Table 1**: Patients' most received therapies under L1 AT*

Treatments – N (%)	N=33,924
L1 top 3 most received combinations	
ADA + METH	522 (1.5%)
ETA + METH	182 (0.5%)
Apremilast + METH	99 (0.3%)
L1 top 5 most received therapies	
Apremilast	10,746 (31.7%)
ADA	9,349 (27.6%)
ETA	3,008 (8.9%)
Ustekinumab	2,828 (8.3%)
Risankizumab	1,941 (5.7%)

***Abbreviations**: **ADA**=Adalimumab, **AT**=Advanced Therapy, **ETA**=Etanercept, **L1**=First-Line, **METH**=Methotrexate, **PsO**=Psoriasis*

***Note**: The sunburst graph illustrates the distribution of treatments across the three first lines of therapy. The inner circle represents the proportion of each treatment administered as first-line, while the subsequent circles depict the proportions of treatments received in the following lines, building upon the previous lines. Thus, 27.2% of the patients received IL originator as first-line, and 8% received IL ORIGINATOR for first and second lines.*

***Abbreviations**: **IL**=Interleukin, **PsO**=Psoriasis, **TNF**=Tumor Necrosis Factor*

The time to treatment failure (TTF)

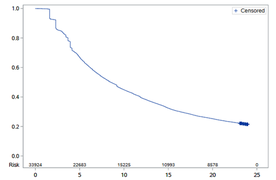
- The median time on L1 treatment was **8.5 months**. Approximately **21.4% of patients** were censored prior to the end of the observation period (censored within the two years of follow-up).
- Among patients who discontinued treatment in first-line, around **75%** of patients switched to another line of treatment.

***Table 2**: Rates of patients with L1 discontinuation*

	N=33,924
TTF event breakdown – N (%)	
Discontinuation (treatment failure)	26,665 (78.60%)
Discontinuation due to line switch	25,349 (74.72%)
Discontinuation with no subsequent new line	1,316 (3.88%)
No discontinuation (censored)	7,259 (21.40%)
Median TTF in months [95% CI]	**8.51 [8.31,8.71]**

***Abbreviations**: **CI**=Confidence Interval, **L1**=First-Line, **TTF**=Time to Treatment Failure.*

***Figure 7**: Kaplan-Meier curve, time in months to L1 discontinuation*



***Note**: The discontinuation definition based on the days of supply and twice the labelled dosing interval, led to a drop of patients with only one claim:*

- *at month 1.6 (49 days), 2,123 (6.25%) patients discontinued etanercept,*
- *at month 2.3 (70 days), 1,763 (5.19%) patients discontinued adalimumab,*
- *at month 3.9 (120 days), 162 (0.48%) patients discontinued apremilast.*

Discussion

- The definition of the claim-based treatment pattern algorithm was based on a limited number of publications; however, the relevant publications identified were consistent in their methods for determining treatment lines, making the approach used in this study relatively robust.
- The inclusion of patients only covered by commercial healthcare plans may fail to generalize to other populations.
- Reason for therapy discontinuation was not reported in the database although treatment discontinuation was used as a proxy to define failure.
- PsO is a disease characterized by phases of remission and relapse, leading to interruptions in the treatment sequence. Patients with prescriptions for ATs during the baseline period were excluded, however some may have received treatment before the baseline period and thus might not be considered as newly treated with ATs.

ABBREVIATIONS: ADA=Adalimumab, **AS**=Ankylosing Spondylitis, **AT**=Advanced Therapy, **CCI**=Charlson Comorbidity Index, **CD**=Crohn's Disease, **CI**=Confidence Interval, **ETA**=Etanercept, **IL**=Interleukin, **L1**=First-Line, **L2**=Second-Line, **METH**=Methotrexate, **NR**=Not Reached, **PsO**=Psoriasis, **RA**=Rheumatoid Arthritis, **SD**=Standard Deviation, **TNF**=Tumor Necrosis Factor, **TTF**=Time to Treatment Failure, **UC**=Ulcerative Colitis

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