Biologic Initiation Risk in Systemic-Naive Psoriasis Patients With Comorbid Psoriatic Arthritis Starting Treatment With Apremilast vs Methotrexate: 1-Year Retrospective Analysis of a US Claims Database

David L. Kaplan[1]; Jessie Yan[2]; Eunice Chang[2]; Michael S. Broder[2]; Sven Richter[3]; Ibrahim Khilfeh[3]

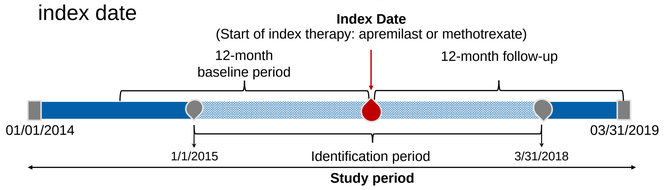
[1]Adult & Pediatric Dermatology, Overland Park, KS, USA; [2]Partnership for Health Analytic Research, LLC, Beverly Hills, CA, USA; [3]Amgen Inc., Thousand Oaks, CA, USA

Background & Objective

- The impact of apremilast treatment on biologic initiation in systemic-naive psoriasis patients with comorbid psoriatic arthritis (PsA) is not fully understood
- The objective of this study was to compare real-world biologic initiation risk, persistence, and restarts with apremilast vs methotrexate

Study Design & Patient Population

- Retrospective cohort study using (2014-2019) IBM® MarketScan® commercial and Medicare Supplemental claims data
  - **Inclusion:** Topical-experienced, systemic-naïve (including biologic naive), adult psoriasis patients with comorbid PsA initiating apremilast or methotrexate, continuously enrolled in 12-month baseline and 12-month follow-up periods
  - **Exclusion:** Other autoimmune diagnoses (except PsA) anytime; any claim for systemic agents during the 12-month pre-index or on index date



The first prescription date was the index date. Patients had ≥1 diagnosis code for psoriasis (ICD-9-CM code 696.1x or ICD-10-CM code L40.0, L40.8, or L40.9) within 12 months prior to or on the index date from a dermatologist or rheumatologist visit during the study period. In addition, patients had to have ≥1 diagnosis code for PsA (ICD-9-CM code 696.0x or ICD-10-CM code L40.50, L40.51, L40.52, L40.53, L40.54, or L40.59) during the baseline period. *Scan the QR code/click link for details of patient attrition.*

Methods

- Biologic initiation = any claim for a biologic in the post-index period
- Logistic regression model for adjusted odds ratio (OR) for biologic initiation and Cox regression model for time to biologic initiation
  - Models were adjusted for age group, sex, region, comorbidities, prescriber specialty, medication use, healthcare resource utilization, costs during the 1-year pre-index period, and the index year
  - Reference group = apremilast
- Discontinuation = treatment gap ≥60 days between prescription claims or initiation of any systemic agent for psoriasis with comorbid PsA before the treatment gap (switch)
- All outcomes reflect the 1-year post-index period

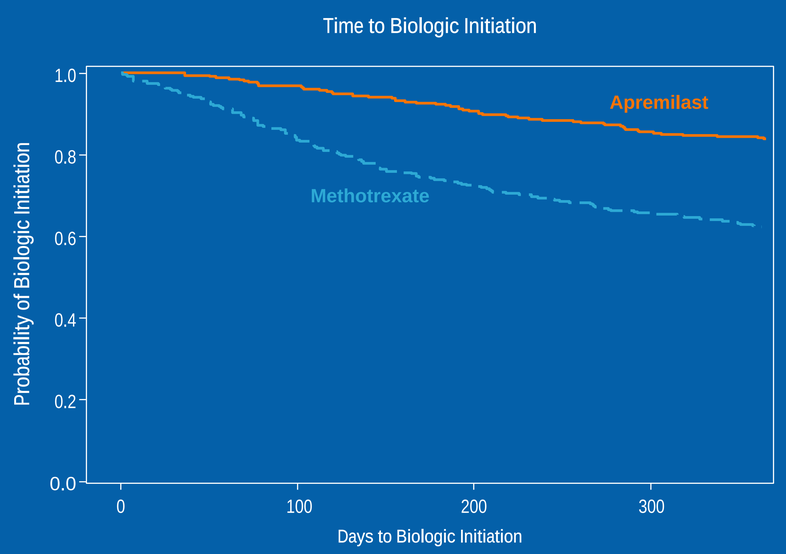
Baseline Characteristics

Baseline demographics and comorbidities were generally similar between groups *Scan the QR code/click link for additional baseline patient characteristics*

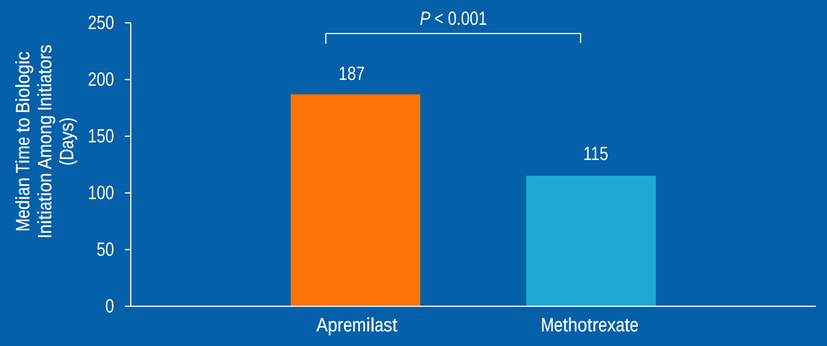
	Apremilast N = 438	Methotrexate N = 505	*P* Value
Age, mean (SD), years	50.5 (12.0)	50.1 (11.7)	0.585
Female, %	55.9	58.0	0.519
Insurance type, %			
Commercial	90.2	91.3	0.559
Medicare supplemental	9.8	8.7	
Charlson Comorbidity Index, mean (SD)	0.7 (1.3)	0.6 (1.2)	0.078
Comorbid condition, %			
Hyperlipidemia	40.2	39.8	0.905
Hypertension	24.0	20.8	0.242
Obesity	23.5	25.0	0.608
Diabetes	18.0	13.9	0.080
Anxiety	14.2	14.3	0.964
Cardiovascular disease	11.9	9.7	0.283
Depression	11.2	13.7	0.252
Non-alcoholic fatty liver disease	4.3	2.2	0.059
Serious infection	3.2	1.8	0.160
Chronic kidney disease	2.5	2.2	0.735
Metabolic syndrome	0.9	1.6	0.359

Apremilast demonstrated significantly lower biologic initiation vs methotrexate

- **Hazard ratio for biologic initiation for apremilast vs methotrexate was 0.40 (95% CI, 0.29-0.53) (*P* < 0.001)**



- **Adjusted 1-year risk of biologic initiation: 16.1% for apremilast vs 35.5% for methotrexate (*P* < 0.001)**



Scan the QR code/click link for the distribution of first biologics used during follow-up.

https://contents-amgen.com/prd/user-screen.html?content_id=138

For additional information, scan the QR code/click link

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Conclusions

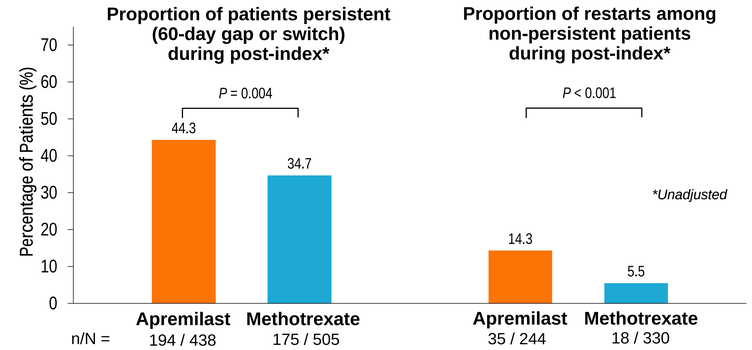
- Topical-experienced, systemic-naive psoriasis patients with comorbid PsA initiating apremilast had 65% lower odds of biologic initiation, a lower discontinuation/switch rate, and an almost 3-fold higher restart rate after discontinuation vs methotrexate in the following year

Additional Results

During post-index period, patients who initiated apremilast had longer treatment duration vs methotrexate

	Apremilast N = 438	Methotrexate N = 505	*P* Value
Duration of index therapy (60-day gap or switch) during post-index period, mean (SD) days*	233.7 (134.4)	200.9 (136.8)	< 0.001

Apremilast patients had significantly higher persistence, more restarts among those non-persistent, and similar healthcare resource utilization vs methotrexate



All-Cause Healthcare Resource Utilization (unadjusted)	Apremilast (N = 438)	Methotrexate (N = 505)	*P* Value
Inpatient hospitalization, n (%)			
0	404 (92.2)	464 (91.9)	
1	15 (3.4)	17 (3.4)	0.446
2	8 (1.8)	16 (3.2)	
3+	11 (2.5)	8 (1.6)	
Emergency department visits, n (%)			
0	353 (80.6)	426 (84.4)	
1	55 (12.6)	55 (10.9)	0.348
2	26 (5.9)	19 (3.8)	
3+	4 (0.9)	5 (1.0)	
Number of office visits, mean (SD)	13.1 (13.2)	13.8 (12.8)	0.435

Strengths & Limitations

- Our study had a number of strengths, including the use of a large and representative sample of patients with diverse demographics and clinical characteristics in a real-world setting
- There were also several limitations, including:
  - Unmeasured clinical differences between groups could have biased the results and may not be fully adjusted for using the available variables
  - Administrative claims data may contain coding errors that could affect the study findings
  - This study was limited to only those individuals with commercial or Medicare supplemental health insurance and may have limited generalizability beyond that population

Disclosures & Funding Statement

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ATTRITION TABLE: PATIENT SELECTION

Total (N = 440,145)		Identified Psoriasis Cases During the Study Period (1/1/2014-3/31/2019)
Apremilast	Methotrexate	
12,928	22,947	Initiation of apremilast or methotrexate (index date) during the study identification period (1/1/2015–3/31/2018)
7,570	13,146	Continuous enrollment 1 year before (baseline period) and follow-up for at least 1 year after the index date
5,770	7,728	At least 1 claim of topical treatment during the baseline period
5,571	6,758	One diagnosis for psoriasis during the baseline period or on the index date
5,551	6,591	At least 18 years of age on the index date
3,942	3,411	No prescription for any systemic treatment* during the baseline period
3,288	2,578	No other biologic-indicated autoimmune conditions† during the baseline or follow-up period, except psoriatic arthritis
3,288	2,572	Did not receive multiple systemic medications on the index date
438	**505**	**Comorbid with psoriatic arthritis (final sample)**

*Non-biologic and biologic. †Other biologic-indicated autoimmune conditions included ulcerative colitis, Crohn's disease, rheumatoid arthritis and other inflammatory polyarthropathies, ankylosing spondylitis, juvenile idiopathic arthritis, and cancer (malignant neoplasms excluding non-melanoma skin cancer).

ADDITIONAL BASELINE PATIENT CHARACTERISTICS

	Apremilast N = 438	Methotrexate N = 505	*P* Value
Prescriber specialty*			
Dermatologist, %	26.7	12.5	<0.001
Rheumatologist, %	13.7	52.7	
Primary care/PA/NP, %	14.4	5.3	
Other/unknown	45.2	29.5	
Baseline Medication Use			
Anti-diabetic medications, %	15.5	13.1	0.003
Lipid lowering medications, %	28.1	26.7	0.643
Anti-hypertensive medications, %	42.9	43.6	0.843
Pain medications, %	57.5	72.1	<.001
Phototherapy, %	0	0	-
Glucocorticoids, %	35.6	42.6	0.029
Baseline Healthcare Resource Utilization			
Any baseline inpatient hospitalizations, %	9.1	7.3	0.313
Any baseline Emergency Department Visits	17.6	20.4	0.272
Number of baseline office visits, mean (SD)	13.6 (13.4)	13.4 (13.0)	0.829
Baseline total healthcare costs, mean (SD)**	14,762 (43,654)	10,431 (17,094)	0.052

*If specialty on index fill is missing, the specialty noted on the closest medical claim with a PsO diagnosis within ±90 days of index date was used instead.
**Adjusted to 2019 US Dollars

DISTRIBUTION OF FIRST BIOLOGIC USED DURING THE 1-YEAR FOLLOW-UP PERIOD

Biologic, n (%)	Apremilast N = 70	Methotrexate N = 190
Adalimumab	23 (32.9)	121 (63.7)
Secukinumab	17 (24.3)	10 (5.3)
Etanercept	12 (17.1)	38 (20.0)
Ustekinumab	11 (15.7)	5 (2.6)
Ixekizumab	2 (2.9)	–
Golimumab	2 (2.9)	–
Infliximab	2 (2.9)	7 (3.7)
Certolizumab pegol	1 (1.4)	8 (4.2)
Abatacept	–	1 (0.5)