Biologic Initiation Rates in Psoriasis After First-Line Systemic Use of Apremilast Versus Methotrexate

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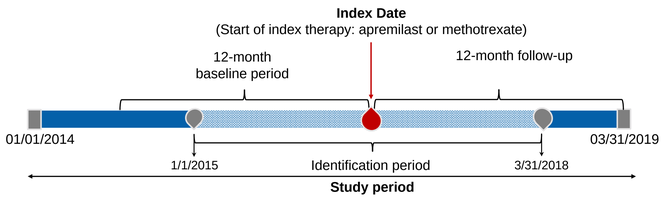
Background & Objective

- The impact of apremilast treatment on biologic initiation in systemic-naive psoriasis patients 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-naive, adult psoriasis patients initiating apremilast or methotrexate
  - **Exclusion**: Other autoimmune diagnoses anytime (except psoriatic arthritis [PsA]); 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 within 12 months of or on the index date (ICD-9-CM code 696.1x or ICD-10-CM code L40.0, L40.8, or L40.9 from a dermatologist or rheumatologist visit during the study 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 (including PsA), 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 before the treatment gap (switch)
- All outcomes reflect the 1-year post-index period

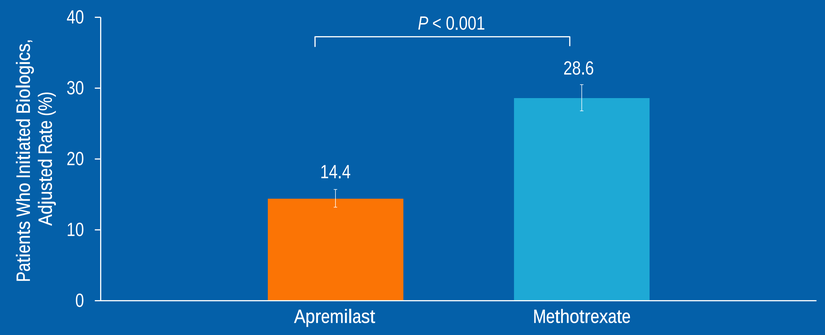
Results

Baseline demographics and comorbidities were generally similar between groups

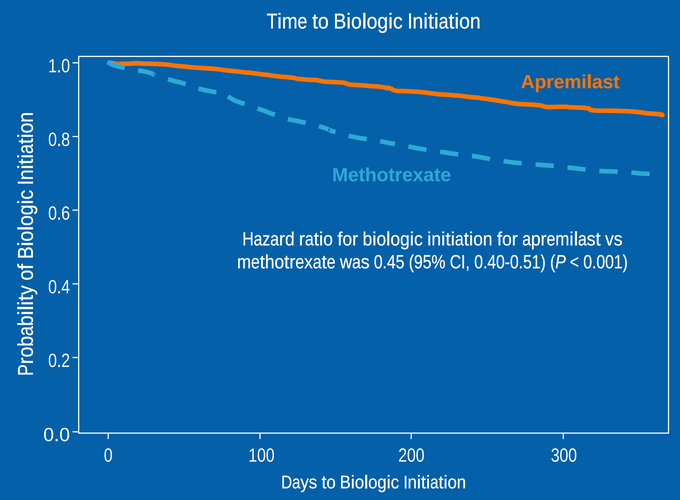
	Apremilast N = 3,288	Methotrexate N = 2,572	*P* Value
Age, mean (SD), years	49.2 (12.9)	49.5 (13.2)	0.289
Female, %	53.9%	55.1%	0.360
Insurance type, %			0.949
Commercial	89.9%	89.9%	
Medicare supplemental	10.1%	10.1%	
Charlson Comorbidity Index, mean (SD)	0.6 (1.2)	0.5 (1.1)	0.121
Comorbid condition, %			
Hyperlipidemia	36.1%	35.0%	0.392
Obesity	18.7%	18.9%	0.859
Hypertension	17.6%	20.0%	0.017
Diabetes	15.5%	13.9%	0.093
PsA	13.3%	19.6%	<0.001
Anxiety	12.5%	13.5%	0.258
Cardiovascular disease	10.0%	10.1%	0.897
Depression	9.9%	11.8%	0.022
Non-alcoholic fatty liver disease	3.1%	2.4%	0.092
Chronic kidney disease	2.1%	1.6%	0.183
Serious infection	1.6%	1.4%	0.657
Metabolic syndrome	0.8%	1.0%	0.305

Apremilast demonstrated a significantly lower adjusted biologic initiation rate vs methotrexate

- **With apremilast vs methotrexate, OR for any biologic initiation post-index was 0.42 (95% CI, 0.37-0.48) (*P* <0.001)**



Among biologic initiators, median time to biologic initiation during post-index period was 184 days with apremilast vs 119 days with 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=135

For additional information, scan the QR code/click link

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Conclusions

- Topical-experienced, systemic-naive psoriasis patients initiating apremilast had 58% lower odds of biologic initiation, a lower discontinuation/switch rate, and a 2-fold higher restart rate after discontinuation vs methotrexate in the following year

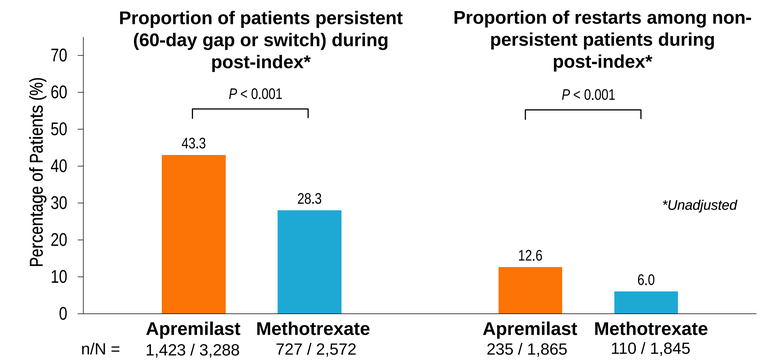
Results

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

	Apremilast N = 3,288	Methotrexate N = 2,572	*P* Value
Duration of index therapy (60-day gap or switch) during post-index period, mean (SD) days*	226.5 (135.4)	178.3 (134.9)	< 0.001

**Unadjusted.*

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 = 3,288)	Methotrexate (N = 2,572)	*P* Value
Inpatient hospitalization, n (%)			
0	3,094 (94.1)	2,407 (93.6)	0.813
1	84 (2.6)	67 (2.6)	
2	56 (1.7)	49 (1.9)	
3+	54 (1.6)	49 (1.9)	
Emergency department visits, n (%)			
0	2,756 (83.8)	2,138 (83.1)	0.375
1	331 (10.1)	271 (10.5)	
2	151 (4.6)	110 (4.3)	
3+	50 (1.5)	53 (2.1)	
Number of office visits, mean (SD)	12.5 (13.7)	12.8 (11.8)	0.338

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

IK: Amgen Inc. – employment. **JY, EC, MSB:** Partnership for Health Analytic Research, LLC – employment; under contract with Amgen Inc. to conduct these analyses. **NNG:** Bristol-Myers Squibb – employment (at time of study conduct). **DLK:** Celgene, BMS, and LEO Pharma – consultant; Amgen, Celgene, Dermira, and Pfizer – speaker; Sanofi-Regeneron – consultant and speaker.

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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**	**Final number of patients (who did not receive multiple systemic medications on the index date)**

*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).

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

Biologic, n (%)	Apremilast N = 467	Methotrexate N = 785
Adalimumab	210 (45.0)	515 (65.6)
Ustekinumab	113 (24.2)	66 (8.4)
Secukinumab	68 (14.6)	39 (5.0)
Etanercept	35 (7.5)	127 (16.2)
Ixekizumab	26 (5.6)	8 (1.0)
Guselkumab	9 (1.9)	7 (0.9)
Golimumab	3 (0.6)	1 (0.1)
Infliximab	2 (0.4)	13 (1.7)
Certolizumab pegol	1 (0.2)	8 (1.0)
Abatacept	–	1 (0.1)