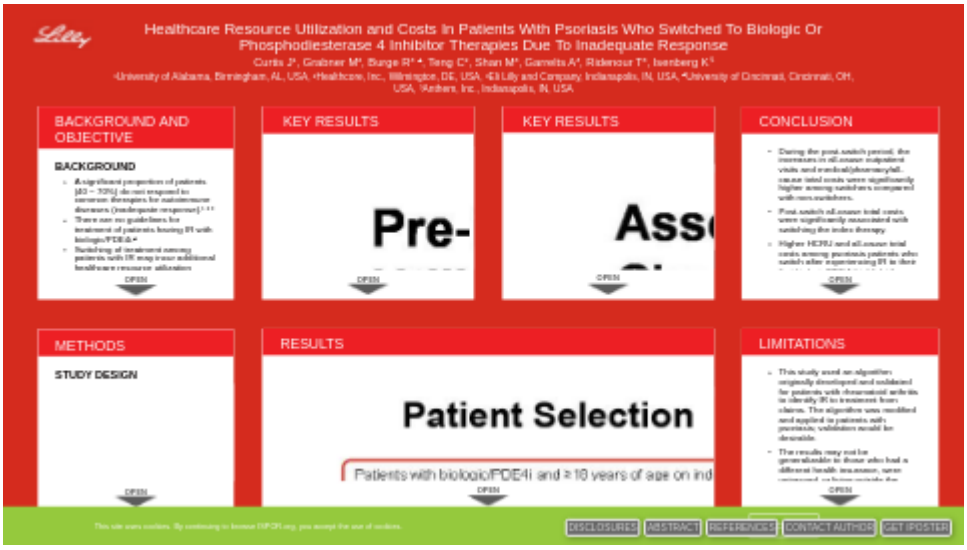
Healthcare Resource Utilization and Costs In Patients With Psoriasis Who Switched To Biologic Or Phosphodiesterase 4 Inhibitor Therapies Due To Inadequate Response



Curtis J[1], Grabner M[2], Burge R[3] [4], Teng C[2], Shan M[3], Garrelts A[3], Ridenour T[3], Isenberg K[5]

[1]University of Alabama, Birmingham, AL, USA, [2]Healthcore, Inc., Wilmington, DE, USA, [3]Eli Lilly and Company, Indianapolis, IN, USA, [4]University of Cincinnati, Cincinnati, OH, USA, [5]Anthem, Inc., Indianapolis, IN, USA

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BACKGROUND AND OBJECTIVE

BACKGROUND

- A significant proportion of patients (40 − 70%) do not respond to common therapies for autoimmune diseases (inadequate response).[1] [2] [3]
- There are no guidelines for treatment of patients having IR with biologic/PDE4i.[4]
- Switching of treatment among patients with IR may incur additional healthcare resource utilization (HCRU) and cost.[5]
- Real-world data comparing HCRU and cost among patients who switch and do not switch treatments are limited.

OBJECTIVE

- This study compared HCRU and costs for therapy switchers and non-switchers who previously had IR to biologic/PDE4i treatment for psoriasis.

KEY RESULTS

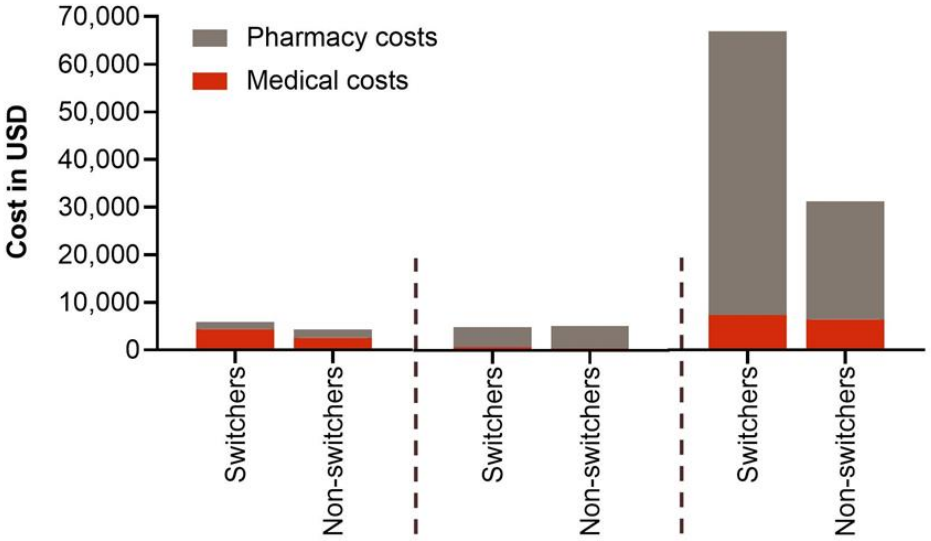
Pre-index, Index Period, and Post-switch Healthcare Resource Utilization among Switchers and Non-switchers

Healthcare resource utilization (mean number of visits/days/claims)	6-month pre-index		Index date to switch date (PPPM)		1-year post-switch date	
	Switchers	Non-switchers	Switchers	Non-switchers	Switchers	Non-switchers
All-cause inpatient hospitalizations	0.03	0.02	0.01	0.00	0.06	0.09
Length of hospitalization stay, days	3.58	5.48	NA	NA	4.72	4.55
All-cause emergency room visits	0.14	0.12	0.01	0.02	0.32	0.22*
All-cause outpatient visits	11.87	10.38*	2.04	1.54*	20.32	17.98*
All-cause specialist visits	1.89	1.61*	0.58	0.30*	2.79	1.88*
Systemic therapy claims	0.66	0.29*	0.72	0.68	7.79	3.99*

Abbreviations: NA: not applicable; PPPM: per-patient per-month
Note: Outpatient specialists included rheumatologist, dermatologist, nephrologist, and gastroenterologist.
*p<0.05; Chi-square test or Fisher's exact test were used for dichotomous variables, and t-test were used for continuous variables.

- All-cause outpatient visits and all-cause specialists visits were significantly higher among switchers than non-switchers during pre-index, index period, and post-switch.
- Post-switch, all-cause emergency visits were significantly higher among switcher than non-switchers.

Pre-index, Index Period, and Post-switch Healthcare Costs among Switchers and Non-switchers



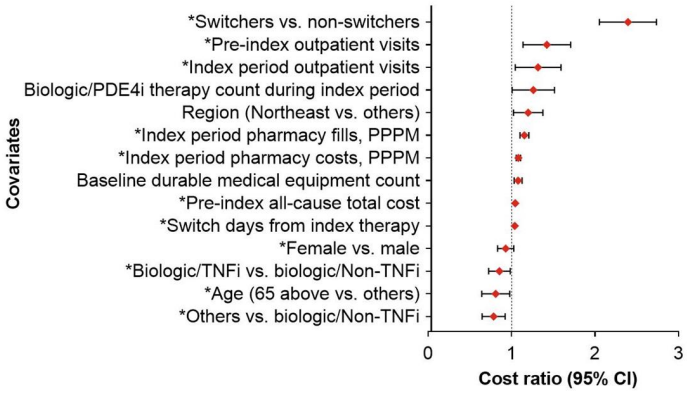
Healthcare costs (USD)	6-month pre-index		Index date to switch date, PPPM		1-year post-switch date	
Medical	$4,354	$2,591*	$700	$471*	$7,559	$6,600*
Pharmacy	$1,486	$1,791	$4,259	$4,708	$61,574	$25,629*
Total (medical + pharmacy)	$5,840	$4,382*	$4,959	$5,179	$69,133	$32,230*

Abbreviation: PPPM: per patient per month; USD: United States dollar
Note: All costs were adjusted to 2018 USD
*p<0.05; Chi-square or Fisher's exact test and t-test

- Pharmacy costs were not significantly different between the groups during pre-index and index period.
- Post-switch, pharmacy costs were significantly (140%) more for therapy switchers than non-switchers.
- During index period and post-switch, medical costs were significantly higher among switchers than non-switchers

KEY RESULTS

Association between Switching Status, Baseline/Pre-switch Characteristics, and Post-switch All-cause Total Costs



Abbreviations: CI: confidence interval; PPPM: per patient per month; TNFi: tumor necrosis factor inhibitor
Note: Results were obtained from Gamma regression using automatic stepwise selection with entrance and exit p-value cut-off of 0.15. Variables with prevalence rate <1% in either switcher or non-switcher cohorts were excluded from the model effects selection. Baseline and pre-switch cost variables are in thousands of USD. Costs were adjusted to 2018 dollars. *p<0.05. Association between cost and region, baseline durable medical equipment count, and biologic/PDE4i therapy count during index period were not significant at α=0.05.

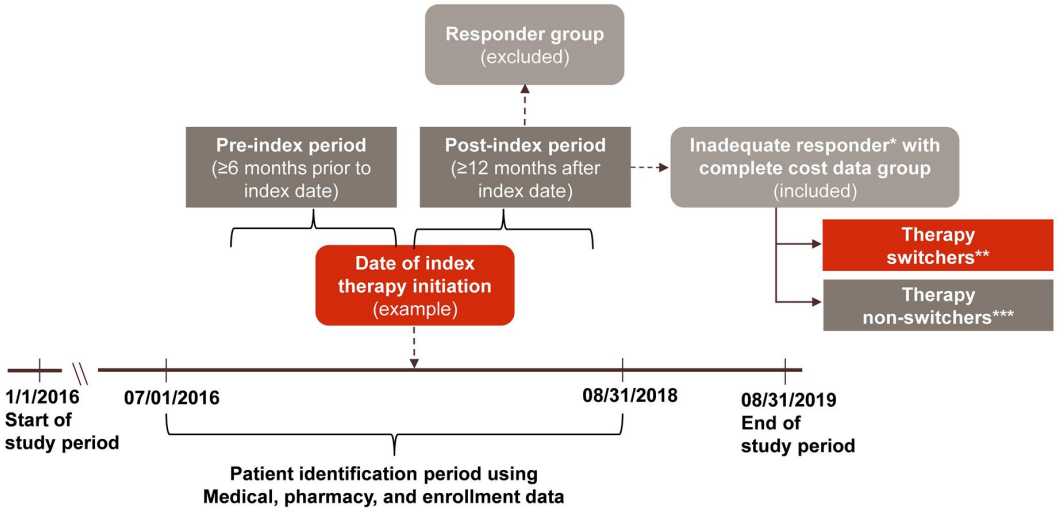
- All-cause total costs had:
  - a significantly high positive correlation with switching.
  - significant positive correlation with Index period per patient per month (PPPM) pharmacy fills and pre-index outpatient visits.
  - significant negative correlation with age >65 years and use of biologic/TNFi or other treatment.

CONCLUSION

- During the post-switch period, the increases in all-cause outpatient visits and medical/pharmacy/all-cause total costs were significantly higher among switchers compared with non-switchers.
- Post-switch all-cause total costs were significantly associated with switching the index therapy.
- Higher HCRU and all-cause total costs among psoriasis patients who switch after experiencing IR to their first biologic/PDE4i highlight the significance of selecting an appropriate index therapy to maximize potential for adequate response.

METHODS

STUDY DESIGN



*Inadequate response was defined as having either low adherence to, switching from/addition to index therapy, addition of conventional therapy, change in dose or frequency of index therapy, addition or dose increase of oral glucocorticoid, or use of new topical treatment, actinotherapy, or retinoids or pain medication not observed at baseline.

**Therapy switchers were defined as patients with ≥1 claims for a non-index biologic or PDE4i therapy over the post-index period;

***Therapy non-switchers were defined as patients with no claims for a non-index biologic or PDE4i therapy over the post-index period.

- The study was conducted using administrative claims from the HealthCore Integrated Research Database® (HIRD®), including patients enrolled in commercial, Medicare Advantage, or Medicare Supplemental plus Part D insurance plans
- The study included patients (≥18 years old) with:
  - ≥2 medical claims, ≥7 days apart for psoriasis, of which ≥1 claim must occur at baseline
  - IR to initial biologic/PDE4i during 12 months after starting therapy. Earliest biologic/PDE4i fill date was set as index date
  - ≥6-months pre-index and ≥12-months post-switch continuous health plan enrollment. For non-switchers, a hypothetical switch date was randomly imputed according to the distribution of switch dates for switchers
- The study excluded patients with:
  - >1 biologic/PDE4i therapy claim on index date or ≥1 biologic/PDE4i therapy claim during the 6-month baseline period
  - Claims for >1 disease of interest (rheumatoid arthritis, psoriatic arthritis, lupus, ankylosing spondylitis, Crohn's disease, ulcerative colitis) during the study period
  - Incomplete pharmacy cost data

- Treatments used among patients with psoriasis were:

Category	Drug/s
Biologic/TNFi agents	Adalimumab, certolizumab, etanercept, infliximab
Biologic/non-TNFi agents	Brodalumab, guselkumab, ixekizumab, secukinumab, ustekinumab
PDE4i	Apremilast

Abbreviations: PDE4i: phosphodiesterase 4 inhibitor; TNFi: tumor necrosis factor inhibitor
Note: Switching was considered within and between above listed drug categories. Risankizumab and tildrakizumab were included as drugs that patients could switch to, but not as possible index drugs, given their more recent approval.

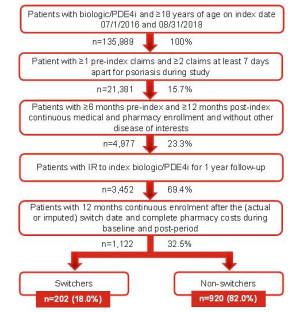
STATISTICAL ANALYSES

- HCRU frequency and costs were compared at 6 months pre-index, the period between index date and switch date, and 12 months post-switch between switchers and non-switchers using Chi-square test or Fisher's exact test (for dichotomous variables) and t-test (continuous variable).

- Generalized linear model regression with gamma distribution and log link was used to compare all-cause costs over 12 months from the (actual or imputed) switch date between switchers and non-switchers.

RESULTS

Patient Selection



Abbreviation: IR: inadequate response; PDE4i: phosphodiesterase 4 inhibitor

Patient Demographics on Index Date

	Switchers N=202	Non-switchers N=920	P-value
Age in years, mean (SD)	47.7 (13.4)	46.0 (14.4)	0.055
Men, %	50.5	51.7	0.749
Insurance plan type, %			
HMP	29.2	24.1	0.132
PPO	54.5	60.0	0.147
CDHP	16.3	15.9	0.870
Medicare Advantage/Supplemental and Part D Plan	-*	6.41	0.183
Geographic region, %			
Northeast	18.3	14.5	0.166
Midwest	29.2	27.5	0.624
South	36.1	37.3	0.761
West	15.4	19.2	0.197
Other/Unknown	-*	1.5	0.564
Index year, %			
2016	29.7	32.7	0.406
2017	59.4	55.5	0.316
2018	10.9	11.7	0.733

Abbreviations: CDHP: consumer driven health plan; HMO: health maintenance organization; PPO: preferred provider organization; SD: standard deviation
*Masked due to small sample sizes

Patient Clinical Characteristics before Index Date

	Switchers N=202	Non-switchers N=920	P-value
Comorbidities			
Quan-Charlson Comorbidity Index, mean (SD)	0.3 (0.7)	0.3 (0.8)	0.582
Infection, %	37.1	33.0	0.286
Hypertension, %	28.2	24.6	0.279
Mental health issue, %	22.8	21.1	0.597
Index biologic/PDE4i therapy prescribing specialty, %			
Dermatology	70.8	66.3	0.219
Non-physician clinician	21.8	26.7	0.145
Index biologic/PDE4i therapy, %			
Biologic/TNFi agents	50.5	31.4	<0.001
Biologic/non-TNFi agents	14.9	30.8	<0.001
Apremilast	34.7	37.8	0.398
Medical history %			
Biologic/TNFi agents	5.5	4.9	0.743
Biologic/non-TNFi agents	-*	3.8	0.200
Apremilast	-*	2.2	0.793
Any conventional therapy	21.8	12.4	0.001

Abbreviations: PDE4i: phosphodiesterase 4 inhibitor; SD: standard deviation; TNFi: tumor necrosis factor inhibitor
Biologic/TNFi agents: adalimumab, certolizumab, etanercept, infliximab
Biologic/non-TNFi agents: brodalumab, guselkumab, ixekizumab, secukinumab, ustekinumab
*Masked due to small sample sizes

- **Patient Demographics on Index Date:**
  - This study had equal proportion of men and women among switchers and non-switchers.
  - Preferred provider organization was the most common insurance plan type among both groups.
  - Most of the patients belonged to the Southern US region in both groups.
- **Patient Clinical Characteristics before Index Date:**
  - Both groups had infection, hypertension and mental health issues as the most common comorbidities.
  - In both groups, index drug was primarily prescribed by dermatologists.
  - Most of the patients had TNFi as index period treatment for psoriasis.

LIMITATIONS

- This study used an algorithm originally developed and validated for patients with rheumatoid arthritis to identify IR to treatment from claims. The algorithm was modified and applied to patients with psoriasis; validation would be desirable.
- The results may not be generalizable to those who had a different health insurance, were uninsured, or living outside the United States.
- Switching dates for non-switchers were imputed using a single random assignment. If a non-switcher patient had a period of high HCRU, imputing their start date before/after this period may underestimate/overestimate the effect of switching.
- Non-switchers include patients who persisted on their index advanced therapy as well as those who discontinued without switching; our results combined these two distinct groups when comparing their HCRU/costs to switchers.

Acknowledgments

- This study was sponsored by Eli Lilly and Company.
- Rahul Nikam, an employee of Eli Lilly Services India Pvt. Ltd. provided writing support.

DISCLOSURES

- J. Curtis consults for and has received research grants from Eli Lilly and Company.
- M. Grabner and C. Teng are employees of HealthCore Inc., a wholly owned subsidiary of Anthem Inc. HealthCore was under contract with Eli Lilly and Company for the conduct of the study.
- K. Isenberg is an employee and shareholder of Anthem Inc.
- A. Garrelts, T. Ridenour, M. Shan and R. Burge are employees and shareholders of Eli Lilly and Company.

ABSTRACT

OBJECTIVES

To assess healthcare resource utilization (HCRU)/costs for therapy switchers and non-switchers who previously had inadequate response (IR) to biologic/phosphodiesterase 4 inhibitor (PDE4i) treatment for psoriasis.

METHODS

A retrospective, observational, claims-based cohort study was conducted using HealthCore Integrated Research Database®. Index date was start date of biologic/PDE4i, ascertained 01-Jul-2016 to 31-Aug-2018. Adult patients (≥18 years) with psoriasis having IR to initial biologic/PDE4i 12 months after starting therapy and ≥6-months pre-index and ≥12-months post-switch continuous health plan enrollment were included. Non-switchers were assigned an imputed switch date according to switch date distribution (by month) for switchers. IR was defined as <80% biologic/PDE4i adherence; switching to non-index biologic/PDE4i; increasing index therapy dose/frequency; adding/increasing oral glucocorticoid dose/frequency; adding new conventional therapy/topical treatment/actinotherapy/retinoids/pain medication class. HCRU frequency and costs were compared during 6 months pre-index, 12 months pre-switch, and 12 months post-switch between switchers and non-switchers, without further adjustments.

RESULTS

Study included 1,122 patients with psoriasis (202 switchers and 920 non-switchers) having IR to biologic/PDE4i. Pre-index, mean systemic therapies pharmacy fill frequency was higher among switchers than non-switchers (0.7 vs. 0.3, $p<0.01$). Pre-switch, switchers compared with non-switchers had significantly ($p<0.01$) higher mean all-cause per-patient per-month outpatient visits (2.0 vs. 1.5), outpatient specialist visits (0.6 vs. 0.3), and all-cause prescription drug fills (2.1 vs. 1.9). Post-switch mean systemic therapies pharmacy fill frequency was also higher among switchers than non-switchers (7.8 vs. 4.0, $p<0.01$). Pre-index mean all-cause total costs were higher in switchers than non-switchers ($5840 vs. $4382, $p<0.01$). After switching, mean pharmacy and all-cause total costs were higher in switchers than non-switchers ($61,574 vs. $25,629 and $69,133 vs. $32,230; both $p<0.01$).

CONCLUSION

Among patients with psoriasis having IR to biologic/PDE4i, switching was associated with higher HCRU and all-cause total costs, which emphasizes importance of selecting an appropriate index therapy to maximize potential for adequate response.

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