

# Inadequate Response Rates and Associated Factors to Psoriasis Therapies Using a Claims-based Algorithm

Submission no. 31

Jeffrey Curtis<sup>1</sup>, Michael Grabner<sup>2</sup>, Russel Burge<sup>3,4</sup>, Chia-Chen Teng<sup>2</sup>, Mingyang Shan<sup>3</sup>, Alyssa Garrelts<sup>3</sup>, Terri Ridenour<sup>3</sup>, Keith Isenberg<sup>5</sup>

<sup>1</sup>University of Alabama at Birmingham, Birmingham, Alabama, USA; <sup>2</sup>HealthCore, Inc., Wilmington, DE, USA; <sup>3</sup>Eli Lilly and Company, Indianapolis, IN, USA; <sup>4</sup>University of Cincinnati, Cincinnati, Ohio, USA; <sup>5</sup>Anthem, Inc., Indianapolis, IN, USA

## BACKGROUND

- Psoriasis (PsO) is a chronic autoimmune disease that requires continuous treatment.
- Treatment for medications (e.g., Phosphodiesterase-4 inhibitors (PDE4i moderate-to-severe psoriasis involves biologics (TNFi and non-TNFi agents) and non-biologic)).<sup>1</sup>
- A significant proportion of patients (up to 40%) do not respond to common therapies for autoimmune diseases (inadequate response).<sup>2,3,4</sup>
- Patients' responses to PsO treatment are heterogenous and are affected by patient characteristics.<sup>2,3,4</sup> Identifying factors associated with inadequate response (IR) could improve treatment outcomes.<sup>2,3,4</sup>
- However, limited research has been done to identify patient factors associated with variability in responses using real-world data such as administrative claims.

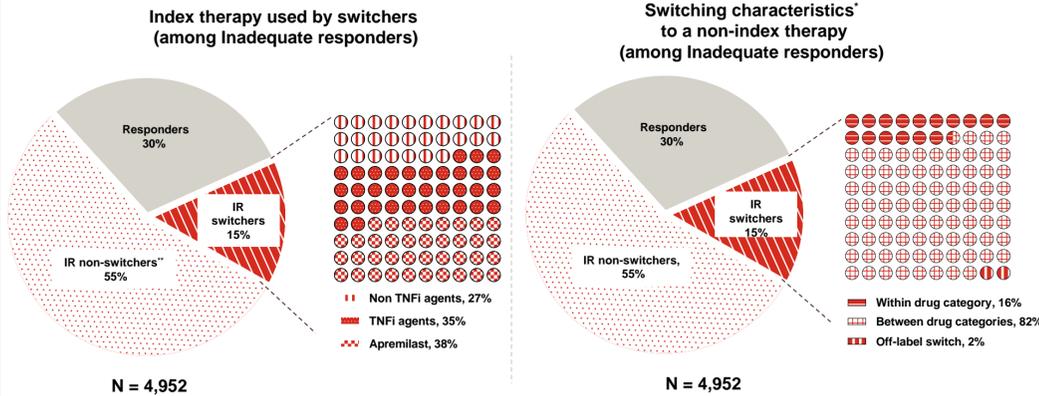
## OBJECTIVE

- To use claims data to estimate the frequency and factors associated with IR in patients with PsO
  - Estimate frequency of IR to therapies for PsO (biologic and PDE4i) using a claims-based algorithm<sup>5</sup>
  - Describe characteristics and treatment patterns among patients with IR
  - Describe treatment switching patterns in patients with IR

## KEY RESULTS

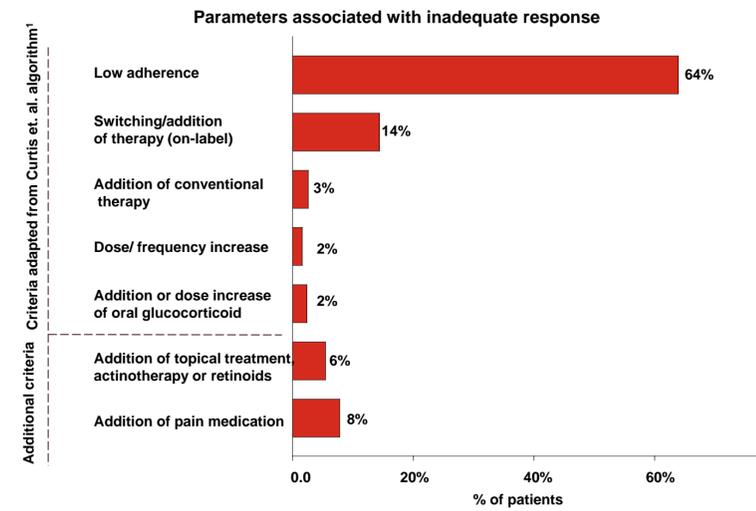
Overall inadequate response frequency was 70% among patients with psoriasis.

Switching was more frequently observed among inadequate responders (IR) using TNFi agents compared with non-TNFi agents or apremilast.



\*Switchers were defined as patients with IR, who have ≥1 claims for a non-index therapy over the one-year post-index period. \*\*Non-switchers were defined as patients with IR to their index therapy, who had no claims for a non-index therapy over the follow-up period. IR, Inadequate responder; TNFi, Tumor necrosis inhibitors; Non TNFi, Non tumor necrosis factor inhibitors

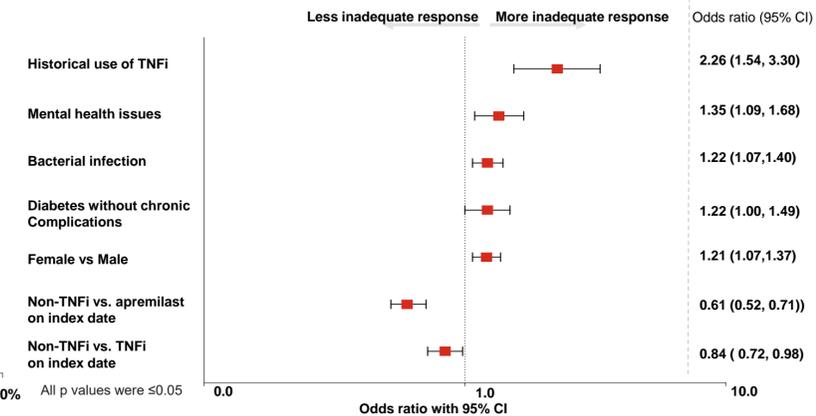
Primary reasons observed for inadequate response were low adherence followed by switching/addition of treatment



Inadequate response in patients can be due to more than one factor 1. Curtis et al. 2011;13(5):R155

Non-TNFi biologic agents were associated with significantly lower inadequate response rates compared with TNFi biologics and apremilast.

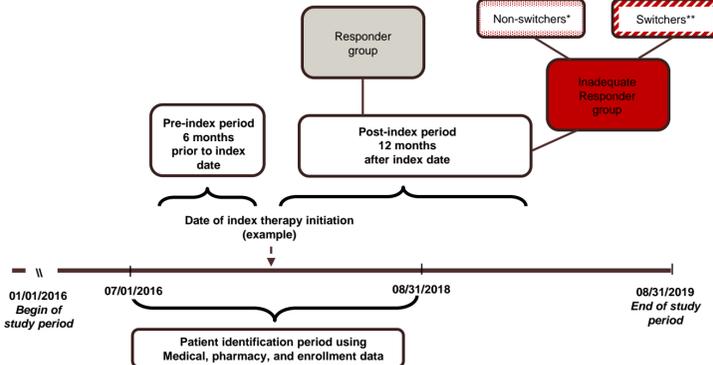
Factors and patient characteristics associated with inadequate response



Historical use was defined using indicated therapy prior to 6 months pre-index period; CI: Confidence interval.

## METHODS

### STUDY DESIGN



\*Non-switchers were defined as patients with inadequate response to their index therapy, who had no claims for a non-index therapy over the post-index period.; \*\*Switchers were defined as patients with inadequate response, who have ≥1 claims for a non-index therapy over the post-index period.

- Analyses population included patients (≥18 years old) with psoriasis (PsO) and:
  - ≥2 medical claims at least 7 days apart for PsO during the study period, of which ≥1 claim must occur in the pre-index period (used to define patients with psoriasis)
  - ≥6 months pre-index and ≥12 months post-index continuous medical and pharmacy health plan enrollment
  - patients with prior use of immunomodulatory therapies in the pre-index period
  - patients with diagnosis of other auto immune disorders during the study period.
- Claims-based algorithm used previously by Curtis et. al. for assessing inadequate response (IR) in rheumatic arthritis<sup>1</sup>, was modified to include additional criteria to evaluate IR in PsO.
  - Each parameter enlisted in the table below was scored 0/1. 0 indicated response. In case ≥1 parameter received a "1", then the patient was classified as inadequate responders.

Criterion evaluated over 1-year follow-up	
Curtis et. al. criteria <sup>1</sup>	Additional criteria for this study
Low adherence (PDC<80%)	Use of new topical treatment, actinotherapy, or retinoids not observed at baseline
Switch/add therapy	Use of new pain medication class not observed at baseline
Add new conventional therapy	
Increase in index drug dose or frequency	
Addition or increase in dose of oral glucocorticoid	

1. Curtis et al. 2011;13(5):R155, '>1 glucocorticoid injection/IV' was not applied for PsO population.

- Switchers are defined as patients with inadequate response (IR) to their index therapy and who have ≥1 claims for a non-index therapy over the follow up period:
  - Psoriasis (PsO) therapies considered in the study by category were:

PsO therapies	Drug categories		
	Biologic/TNFi	Biologic/Non-TNFi	PDE4i
	adalimumab, certolizumab, etanercept, infliximab	brodalumab, guselkumab, ixekizumab, secukinumab, ustekinumab	apremilast

Switching was considered within drug categories and between drug categories (listed in table above). 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

- Patient characteristics were compared using chi-square and t-tests between
  - responders and inadequate responders
  - switchers and non-switchers (among inadequate responders)
- Multivariable logistic regression models were constructed to identify baseline patient characteristics associated with IR.

## RESULTS: Demographics and baseline clinical characteristics

	Overall (N=4,952)	Responders (N=1,500)	Inadequate Responders (N=3,452)
<b>Demographics</b>			
Age*, mean (SD), years	46.8 (13.6)	48.2 (13.0)	46.3 (13.9)
Female <sup>†</sup> , %	47.7%	44.0%	49.3%
Health plan CDHP	22.0%	20.6%	22.5%
<b>Comorbidities</b>			
QCI, mean (SD)	0.28 (0.82)	0.27 (0.81)	0.29 (0.83)
Diabetes without chronic complication <sup>‡</sup> , %	11.7%	10.3%	12.3%
Mental health issues, %	21.0%	19.6%	21.7%
Anxiety or depression, %	14.8%	14.2%	15.1%
Other mental health issues <sup>§</sup> , %	9.9%	8.1%	10.7%
Infection <sup>¶</sup> , %	34.4%	30.9%	36.0%
<b>Medication History, %</b>			
Historical use of TNFi-Biologic <sup>††</sup>	3.9%	2.3%	4.6%
Historical use of Non-TNFi Biologic	3.7%	3.8%	3.6%

\* p<0.05; SD: Standard deviation; QCI: Quan-Charlson Comorbidity Index; Historical use was defined using advanced therapies prior to 6 months pre-index period

## LIMITATIONS

- The results may not be generalizable to those who had a different health insurance, were uninsured or living outside the United States.
- Psoriasis patients may have concomitant comorbidities like psoriatic arthritis which may have influenced switching characteristics.

## CONCLUSIONS

- Claims-based algorithm was used to analyse inadequate response rate in patients with psoriasis.
- Non-TNFi biologics had the lowest inadequate response rates compared with other therapy agents.
- Patient characteristics, treatment history and type of index therapy affected treatment response to psoriasis therapies.
- Switching was less frequent for patients initiating non-TNFi agents compared with apremilast or TNFi agents.
- Further studies are needed to validate this modified claims-based algorithm for evaluating inadequate response in psoriasis.

## 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 of Anthem Inc.
- A. Garrelts, T. Ridenour, M. Shan and R. Burge are employees and shareholders of Eli Lilly and Company.

## ACKNOWLEDGEMENTS

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