Economic Impact of Above-label Dosing with Biologics in Patients with Moderate-to-Severe Psoriatic Arthritis

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BACKGROUND & OBJECTIVE

- Psoriatic Arthritis (PsA) is a complex inflammatory condition, characterized by peripheral arthritis, axial arthritis, dactylitis, enthesitis, as well as skin psoriasis and nail disease.
- Biologic therapies are currently recommended as second-line treatment for patients with moderate-to-severe PsA.
- Dosing regimens for biologics established in clinical trials may vary from real-world clinical practice.
- Off-label dosing may include dose escalations to address non-responders or gaps in efficacy.
- This study assessed above-label dosing and associated costs for biologic therapies including etanercept (ETA), adalimumab (ADA), certolizumab (CER), golimumab (GOL), and ustekinumab (UST) among patients with moderate-to-severe PsA.

METHODS

Study Design & Patient Population

- We identified adult PsA patients enrolled in the Truven Health Analytics’ MarketScan® Commercial Claims database between January 1, 2010 and March 31, 2015.
- Inclusion criteria: ≥1 PsA diagnosis 12 months before or at the date of first biologic use, 2 pharmacy claim for ETA, ADA, CER, GOL, or UST from January 1, 2011 to December 31, 2013 (identification period), continuous enrollment and prescription drug benefit for 12 months before and 15 months after first biologic use (index event) in the identification period, and continuous treatment with at least one index biologic in the 3-month look forward period to qualify patients for continuous treatment.
- Exclusion criteria: <18 years of age, switched to a different biologic (including infliximab) following the use of their index biologic from the index event to end of look up period.

RESULTS

Patient Population

- This study identified 4,245 PsA patients on ETA (n=2,342), ADA (n=7,788), and GOL (n=115).
- Patients on CER (n=0) or UST (n=14) were not included due to small sample size, presumably due to their more recent approval.
- Baseline demographics were similar across treatment groups. The majority of patients were males, with a mean age of ~50 years of age.
- Patients on ETA, ADA, and GOL had above-label use, with 10% of patients in the ETA cohort, 9% in the ADA cohort, and 5% in the GOL cohort.

Excess Daily Costs (USD)

- The findings from the above-label use translate into excess daily costs per patient of $77 (ETA), $67 (ADA), and $4 (GOL) (Figure 1).
- The corresponding excess annual costs for each patient (mean values adjusted to 2014) were $21,483 (ETA), $19,564 (ADA), and $13,004 (GOL), respectively (Figure 2).

CONCLUSIONS

- This retrospective observational study of real-world dosing from a large US claims database reported that moderate-to-severe PsA patients treated with ETA, ADA, and GOL have above-label use, translating to excess cost of biologics to payers when compared with on-label use.

- The frequency of dose escalation may suggest an inadequacy of standard dosing regimens for PsA populations with a high proportion of PsA-related comorbidities.

References