Treatment Patterns in New and Continuing Patients with Psoriasis Treated with Biologic Agents in the United States

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Abstract

Objective: Etanercept (ETN), adalimumab (ADA), or ustekinumab (UST) are approved for moderate to severe plaque PsO, and infliximab (INF) for severe only. This study evaluated persistence, switching, discontinuation and restarting these biologics in new and continuing patients with PsO in US patients with employer sponsored health insurance.

Methods: The MarketScan Commercial Database was used to identify patients (18-63 years of age) with ≥1 claim for ETN, ADA, INF, or UST from Jan 1, 2008 to Dec 31, 2010 preceded by ≥6-months of enrolment and a diagnosis of PsO. The first drug claim meeting these criteria defined the index date and biologic. Patients with claim for their index biologic prior to their index date were “Continuing” otherwise, they were “New”. Patients were followed for 360 days post-index. Patients were classified as “persistent” if they continued on their index biologic until the end of the follow-up period without a gap of ≥45 days; "switching" if they had a claim for a different biologic, "restarting" if had a ≥45-day gap followed by a subsequent claim for their index drug. Patients were classified as discontinuing if they had a ≥45-day gap in therapy and did not restart for the remainder of the follow-up period.

Results: Of 14,000 patients with PsO 58% were male and the mean age was 44.6 years (SD 11.0). There were 6,694 (48%) new and 7,306 (52%) continuing patients. Among new patients, 52% indexed on ETN, 43% on ADA, 2% on INF, and 4% on UST compared to 68% ETN, 29% ADA, 3% INF, and 1% UST in continuing patients. Persistence was lower in new (33% ETN, 45% ADA, 45 INF, and 29% UST) vs continuing patients (45% ETN, 50% ADA, 64% INF, and 52% UST) and discontinuation was more common in new (36% ETN, 31% ADA, 26% INF, and 24% UST) vs continuing patients (21% ETN, 21% ADA, 13% INF to 25% UST). Switching rates were similar in new and continuing patients, (12% ETN, 9% ADA, 17% INF, and 3% UST in new vs ; 12% ETN, 10% ADA, 13% INF, and 6% UST in continuing). Restart rates were higher in new 19% ETN, 15% ADA, 13% INF, and to 44% UST than in continuing patients 23% ETN, 18% ADA, 10% INF, and 17% UST.

Conclusions: Less than half of patients newly initiating biologics for PsO were persistent at 1 year. Switching between biologics occurred infrequently, and nearly half of the patients with a ≥45 day gap restarted before the end of the year. More research is needed to understand reasons for low persistence and high restart rates in this population.
Tumor necrosis factor (TNF) inhibitors and other biologic agents are important treatment options for moderate to severe plaque psoriasis

- Moderate to severe: etanercept, adalimumab, and ustekinumab
- Severe: infliximab

Rates of treatment persistence in patients with psoriasis are lower than those of other conditions treated with biologics

- Persistence in psoriasis ranges from 22 – 36%, versus:
  - 45 – 57% in rheumatoid arthritis
  - 47 – 56% in psoriatic arthritis
  - 34 – 48% in ankylosing spondylitis

An understanding of the treatment patterns with these biologics may be useful for clinicians making treatment decisions

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Objectives

Objectives

• To evaluate persistence, switching, discontinuation, and restarting of biologic therapies in new and continuing patients with psoriasis in the US with employer-sponsored health insurance
Methods

Study Design

• Retrospective observational cohort study of administrative data for commercially-insured patients from the MarketScan® Commercial Claims and Encounters Databases from Truven
  – Contains inpatient, outpatient, and prescription data of millions of employees and their dependents
  – Includes fee-for-service and capitated health plans, including exclusive provider, preferred provider, and health maintenance organizations
  – Includes detailed cost, use, and outcomes in inpatient and outpatient settings data
Methods

Patients

• Inclusion criteria
  – At least 1 claim for etanercept, adalimumab, infliximab, or ustekinumab from 1 January 2008 to 31 December 2010 preceded by ≥180 days of continuous enrollment in the health plan
    • The first claim meeting this criterion defines the index date and index biologic
  – Adults, 18 – 63 years of age on the index date
  – A diagnosis of psoriasis (ICD-9: 696.0x) 180 prior to or 30 days following the index date
    • Data were also collected from patients with (ICD-9) rheumatoid arthritis (714.0x), psoriatic arthritis (696.0x), and ankylosing spondylitis (720.0x), but these data are not presented
  – Continuous enrollment in the insurance plan for 360 days after the index date

• Exclusion criteria
  – Patients with >1 claim for a biologic therapy of interest on the index date
  – Diagnosis (ICD-9) of juvenile idiopathic arthritis (714.3x), non-Hodgkin’s lymphoma (200.xx and 202.xx), chronic lymphocytic leukemia (204.1.x), ulcerative colitis (556.xx), or Crohn’s disease (555.xx) ≥180 days prior to and 360 days following the index date
Methods

Definitions

- **Index date**: first observed claim for etanercept, adalimumab, infliximab, or ustekinumab

- **Patient categories**
  - **New Initiators**: patients without a claim for the index biologic within the 180 days prior to the index date
  - **Continuers**: patients with a claim for the index biologic within the 180 days prior to the index date
  - **Persistent**: patients who continued on treatment for 12 months following the index date, with any gap in treatment <45 days
  - **Switched**: patients with a claim for a different biologic therapy within 12 months of the index date of their original biologic therapy
  - **Restarted**: patients with a ≥45 day gap in treatment with a subsequent claim for the same initial biologic therapy within 12 months following the index date
  - **Discontinued**: patients with a ≥45 day gap in treatment without a subsequent claim for any biologic therapy for 12 months following the index date
Methods

Statistical Analysis

• Cohorts were stratified by index drug and claim status (New Initiators or Continuers)

• Descriptive statistics were calculated for patients in each of the four biologic therapy cohorts
  – Stratified by New Initiators and Continuers

• Outcomes:
  – Number of patients on index therapy
  – Rates of treatment persistence, discontinuation, restarting, and switching for New Initiators and all patients
Results

_Treatment Distribution_

- Of the 14,000 patients with psoriasis, 48% (n=6,694) were New Initiators and 52% (n=7,306) were Continuers

<table>
<thead>
<tr>
<th>Treatment</th>
<th>New Initiators, n (%)</th>
<th>Continuers, n (%)</th>
<th>Total, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etanercept</td>
<td>3,470 (51.8)</td>
<td>4,998 (68.4)</td>
<td>8,468 (60.5)</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>2,854 (42.6)</td>
<td>1,967 (26.9)</td>
<td>4,821 (34.4)</td>
</tr>
<tr>
<td>Infliximab</td>
<td>112 (1.7)</td>
<td>246 (3.4)</td>
<td>358 (2.6)</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>258 (3.9)</td>
<td>95 (1.3)</td>
<td>353 (2.5)</td>
</tr>
</tbody>
</table>
## Results - Demographic Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Etanercept (N=8,468)</th>
<th>Adalimumab (N=4,821)</th>
<th>Infliximab (N=358)</th>
<th>Ustekinumab (N=353)</th>
<th>All (N=14,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>44.7 (11.0)</td>
<td>44.5 (10.9)</td>
<td>43.7 (11.7)</td>
<td>44.4 (11.3)</td>
<td>44.6 (11.0)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>4,977 (58.8)</td>
<td>2,720 (56.4)</td>
<td>185 (51.7)</td>
<td>192 (54.4)</td>
<td>8,074 (57.7)</td>
</tr>
<tr>
<td>Plan Type, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HMO</td>
<td>1,340 (15.8)</td>
<td>752 (15.6)</td>
<td>66 (18.4)</td>
<td>38 (10.8)</td>
<td>2,196 (15.7)</td>
</tr>
<tr>
<td>Indemnity</td>
<td>189 (2.2)</td>
<td>102 (2.1)</td>
<td>4 (1.1)</td>
<td>7 (2.0)</td>
<td>302 (2.2)</td>
</tr>
<tr>
<td>Point of Service</td>
<td>845 (10.0)</td>
<td>458 (9.5)</td>
<td>28 (7.8)</td>
<td>38 (10.8)</td>
<td>1,369 (9.8)</td>
</tr>
<tr>
<td>PPO</td>
<td>5,245 (61.9)</td>
<td>2,957 (61.3)</td>
<td>224 (62.6)</td>
<td>209 (59.2)</td>
<td>8,635 (61.7)</td>
</tr>
<tr>
<td>Other</td>
<td>356 (4.2)</td>
<td>204 (4.2)</td>
<td>18 (5.0)</td>
<td>33 (9.3)</td>
<td>611 (4.4)</td>
</tr>
<tr>
<td>Unknown</td>
<td>493 (5.8)</td>
<td>348 (7.2)</td>
<td>18 (5.0)</td>
<td>28 (7.9)</td>
<td>887 (6.3)</td>
</tr>
<tr>
<td>Region, n (%)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Northeast</td>
<td>1,392 (16.4)</td>
<td>676 (14.0)</td>
<td>67 (18.7)</td>
<td>64 (18.1)</td>
<td>2,199 (15.7)</td>
</tr>
<tr>
<td>North Central</td>
<td>2,153 (25.4)</td>
<td>1,221 (25.3)</td>
<td>76 (21.2)</td>
<td>63 (17.8)</td>
<td>3,513 (25.1)</td>
</tr>
<tr>
<td>South</td>
<td>3,473 (41.0)</td>
<td>2,214 (45.9)</td>
<td>175 (48.9)</td>
<td>179 (50.7)</td>
<td>6,041 (43.2)</td>
</tr>
<tr>
<td>West</td>
<td>1,313 (15.5)</td>
<td>663 (13.8)</td>
<td>33 (9.2)</td>
<td>45 (12.7)</td>
<td>2,054 (14.7)</td>
</tr>
<tr>
<td>Unknown</td>
<td>137 (1.6)</td>
<td>47 (1.0)</td>
<td>7 (2.0)</td>
<td>2 (0.6)</td>
<td>193 (1.4)</td>
</tr>
<tr>
<td>Prescriber, n (%)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>General/Family</td>
<td>938 (11.1)</td>
<td>522 (10.8)</td>
<td>21 (5.9)</td>
<td>35 (9.9)</td>
<td>1,516 (10.8)</td>
</tr>
<tr>
<td>Internal Medicine</td>
<td>1,189 (14.0)</td>
<td>577 (12.0)</td>
<td>57 (15.9)</td>
<td>47 (13.3)</td>
<td>1,870 (13.4)</td>
</tr>
<tr>
<td>Dermatology</td>
<td>3,730 (44.0)</td>
<td>2,233 (46.3)</td>
<td>88 (24.6)</td>
<td>182 (57.6)</td>
<td>6,233 (44.5)</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>57 (0.7)</td>
<td>60 (1.2)</td>
<td>49 (13.7)</td>
<td>1 (0.3)</td>
<td>167 (1.2)</td>
</tr>
<tr>
<td>Other(^a)</td>
<td>2,344 (27.7)</td>
<td>1,313 (27.2)</td>
<td>140 (39.1)</td>
<td>85 (24.1)</td>
<td>3,882 (27.7)</td>
</tr>
<tr>
<td>Unknown</td>
<td>210 (2.5)</td>
<td>116 (2.4)</td>
<td>3 (0.8)</td>
<td>3 (0.8)</td>
<td>332 (2.4)</td>
</tr>
</tbody>
</table>

\(^a\) Includes physicians with an unknown specialty and those with multiple specialties
Results

Demographic Characteristics (continued)

- New Initiators were younger than Continuers, mean age 43.7 vs. 45.3 years
- More New Initiators vs. Continuers were female (46% vs. 40%)
- More New Initiators vs. Continuers were prescribed their treatment by dermatologists (49% vs. 41%)
Results - *Treatment Persistence, Discontinuation, and Switching in New Initiators*

**Etanercept (N=3,470)**
- Discontinued: 35.5%
- Restart After ≥45 Day Gap: 19.3%
- Switched: 12.3%
- Persistent: 32.8%

**Adalimumab (N=2,854)**
- Discontinued: 31.1%
- Restart After ≥45 Day Gap: 14.9%
- Switched: 9.1%
- Persistent: 44.9%

**Infliximab (N=112)**
- Discontinued: 25.9%
- Restart After ≥45 Day Gap: 12.5%
- Switched: 17.0%
- Persistent: 44.6%

**Ustekinumab (N=258)**
- Discontinued: 24.0%
- Restart After ≥45 Day Gap: 43.8%
- Switched: 3.1%
- Persistent: 29.1%
Results - Treatment Persistence, Discontinuation, and Switching in All Patients

Etanercept (N=8,468)

Adalimumab (N=4,821)

Infliximab (N=358)

Ustekinumab (N=353)
Conclusions

• Less than half of New Initiators were consistently persistent on their initial biologic therapy after 12 months (29% – 45%)
  – New Initiators had lower rates of persistence compared with Continuers (45% – 64%; data not shown)

• In patients who had a gap in treatment, approximately half restarted biologic therapy within 12 months
  – Overall restart rates ranging from 11% to 37%
  – Overall discontinuation rates ranged from 17% to 27%

• Rates of switching between biologic therapies was low, ranging from 4% to 14%

• Further research is need to understand both the low persistence and high restart rates in this population, as well as how gaps in treatments may effect disease progression
References


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