Early Challenges for PSCK9 Inhibitor Prescriptions & Patients: Rejections and Rates Unfilled

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Disclosures

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- **BT, KM, JM, AL**: salary by Amgen Inc.

- **AF, EF**: salary by Symphony Health.

Study funding from Amgen, Inc.
PCSK9i Approved, but Availability May be Limited

July/August 2015:
- **FDA approves** two PCSK9i therapies based on LDL-Lowering
- **High Cost** of therapy
- **Approval Criteria** developed by payors/PBMs
  - Variable processes
  - High provider burden

March 17, 2017
- **New CV Outcome Trial Data** may increase demand
Study Objectives

- Determine the proportion of patients prescribed PCSK9i who receive therapy
- Evaluate factors associated with receiving a PCSK9i once prescribed
- Assess the duration of time for the approval process
Study Design

Rx

Symphony Health Solutions
pharmacy transaction data
90% of retail pharmacies
60% mail order
70% specialty

New Patients Prescribed
Refills/renewals not evaluated
Aug 1, 2015 – July 31, 2016

24 hr and Ultimate Patient Status

Approved
Rejected
Study Design

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- pharmacy transaction data
- 90% of retail pharmacies
- 60% mail order
- 70% specialty

New Patients Prescribed
- Refills/renewals not evaluated
- Aug 1, 2015 – July 31, 2016

24 hr and Ultimate Patient Status

Rejected

Dispensed

Abandoned

Duke Clinical Research Institute
Study Design

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Rx

Rejected

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Symphony Health Solutions
pharmacy transaction data
90% of retail pharmacies
60% mail order
70% specialty

24 hr and Ultimate Patient Status
Multivariable logistic regression
to evaluate factors associated with receiving therapy
Patient Characteristics, n=45,029

- 80% Retail pharmacy
- 37% General Practice
- 48% Cardiology
- 40% Commercial
- 52% Government

- 19% Specialty

- 51.2% Female
- 66 [59-73] Years Old
- 9.8% Used a coupon
Fate of PSCK9i Prescriptions

N=45,029 Patients Prescribed PCSK9i

First 24 Hours

- 79.2% Rejected N=35,658
- 20.8% Approved N=9,371
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Ultimate Status
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- 47.2% Approved N=21,259
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34.7% Approved Never Picked Up
No Improvement in Approvals with Time

% of Prescriptions

Dispensed
Abandoned

Number of Prescriptions

08/2015 01/2016 07/2016
Rejection Rates – 1st 24 hours

- Overall: 79%
- Pharmacy:
  - Retail: 83%
  - Specialty: 67%
- Provider:
  - Cardiology: 78%
  - General Practice: 81%
  - Endocrinology: 81%
- Payor:
  - Commercial: 85%
  - Government: 76%
  - Both: 72%
Rejection Rates – Final Status

<table>
<thead>
<tr>
<th>Category</th>
<th>Rate</th>
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<tbody>
<tr>
<td>Overall</td>
<td>53%</td>
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<tr>
<td>Pharmacy</td>
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<tr>
<td>Retail</td>
<td>58%</td>
</tr>
<tr>
<td>Specialty</td>
<td>34%</td>
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<tr>
<td>Provider</td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>47%</td>
</tr>
<tr>
<td>General Practice</td>
<td>59%</td>
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<tr>
<td>Endocrinology</td>
<td>55%</td>
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<tr>
<td>Commercial</td>
<td>71%</td>
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<tr>
<td>Government</td>
<td>40%</td>
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<tr>
<td>Both</td>
<td>41%</td>
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</table>
Abandonment is High After Approval

Overall

- Abandoned: 34.7%
- Dispensed: 65.3%

Commercial vs. Medicare

- Commercial: 20.2%
- Medicare: 41.5%

Coupon Program vs. No Coupon Program

- Coupon Program: 15.3%
- No Coupon Program: 39.0%

Compared to other docs, Cardiologists have 10% higher abandonment rates (34.4%)
## Factors Associated with Receiving Drug

<table>
<thead>
<tr>
<th>Compared with</th>
<th>Specialty Pharmacy:</th>
<th>Mail Order Pharmacy:</th>
<th>Institutional Pharmacy:</th>
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<tr>
<td>Retail Pharmacy</td>
<td>1.7 (1.6 – 1.8)</td>
<td>4.4 (3.3 – 5.9)</td>
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<th>Other HCP:</th>
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<td>General Practice</td>
<td>1.6 (1.5 – 1.7)</td>
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<tr>
<td>Commercial Insurance</td>
<td>3.1 (2.9 – 3.3)</td>
<td>4.4 (4.0 – 4.8)</td>
<td>0.8 (0.6 – 0.9)</td>
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**Coupon program:** OR 16.9 (15.5-18.3)
N=13,892 ultimately dispensed

- 45.2% approved on day 1
- Median Time to **Approval**: 3.0 days [IQR 0-18.8]
- Median Time to **Dispensing**: 9.9 days [IQR 0.7 - 31.7]
N=13,892 ultimately dispensed

- 45.2% approved on day 1
- Median Time to **Approval**: 3.0 days [IQR 0-18.8]
- Median Time to **Dispensing**: 9.9 days [IQR 0.7 - 31.7]

**25% of dispenses >1 month**
Rejection Rate Varies by Payor/PBM

Top 10 Pharmacy Benefit Managers

Managed Medicaid
Other Medicaid
Medicare

Top 10 Payors/Plans

PBM 33.1-74.7%
Government 37.9-83.5%
Payors 33.2-77.6%
Limitations

- Indication and clinical data unavailable. Some rejections may be clinically appropriate.

- Analysis based on patient, starting with first prescription.

- ~80% pharmacy representation. Complex interactions; ultimate payor attribution difficult.

- Early snapshot in first year may not reflect today’s experience.
Rejections/Abandonment Impact Patient Access

>2/3 patients prescribed a PCSK9i never get therapy

- 80% initially rejected
- Over 50% never approved
- Once approved, 1/3 never pick up drug

Variability by payor and lack of improvement suggest not all rejects due to clinical factors

Prolonged prescription process impacts doctors and patients

- Over 1 month for >25% of patients