PCSK9i Utilization, Cost, Utilization Management Impact and Discontinuation Rate among 13 Million Commercially Insured Americans

C.I. Starner[1,2], J.L. Giguere[1], B.G. Gunderson[1], P.P. Gleason[1,2], S.V. Johnson[1] [1]Prime Therapeutics LLC, Eagan, MN, United States; [2]University of Minnesota, College of Pharmacy, Minneapolis, MN, United States

No external funding provided for this research

Background

- Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i) increase liver removal of circulated low density lipoprotein cholesterol (LDL-C) from the blood. The Food and Drug Administration (FDA) approved PCSK9i drugs alirocumab (Praluent®) on July 24, 2015 and evolocumab (Repatha™) on Aug. 28, 2015 to be used as an "adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH) [Repatha™ only] or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C."[1,2]
- The approval of PCSK9i drugs ushered in a new era of hypercholesterolemia management and costs. However, unlike statins, PCSK9i therapy impact on outcomes is unknown. The PCSK9i prescribing information contains the statement: "The effect of alirocumab or evolocumab on cardiovascular morbidity and mortality has not been determined."[1,2]
- While statins have a pennies per day cost, both PCSK9i drugs have a cost of over $14,000 per year and prior to launch were expected to substantially increase health care system costs.[3]
- Because PCSK9i morbidity and mortality outcomes have not been determined, long term safety data is unavailable. With the drug cost high, health insurers have implemented utilization management (UM) programs to ensure PCSK9i drugs are used according to their FDA approved indication.
- Since they are new to the market, little is known about the PCSK9i drugs utilization trends, costs, UM clinical prior authorization (PA) impact and discontinuation rate.

Objective & Purpose

- To examine commercially insured PCSK9i utilization, cost, UM clinical PA impact and discontinuation rate in the first seven months post launch.

Methods

- Prescription claims data from an average of 13.1 million commercial members subject to UM (PCSK9i clinical PA criteria) were queried for PCSK9i transactions (including rejected claims) from Aug. 1, 2015 through Feb. 26, 2016. The date Aug. 1, 2015 was selected as that was the first day a PCSK9i was available for claim submission.
- Throughout the analysis period, both alirocumab and evolocumab were in a preferred formulary status.
- All unique members with at least one paid or rejected PCSK9i transaction were quantified.
- The primary reasons for rejected claims include clinical PA required and non-PA rejections. The most common non-PA rejection was a network rejection, caused by the plan requiring members to obtain their specialty drugs (e.g., PCSK9i) through a limited pharmacy network. Claims may have also rejected for other reasons (e.g., missing/invalid prescriber, member eligibility).
- PCSK9i clinical PA criteria
  - Confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) or heterozygous familial hypercholesterolemia (HeFH), AND
  - Currently on maximally tolerated high intensity statin containing regimen and adherent to the regimen for the past 180 days, OR
  - The patient is intolerant to at least two different statins, AND
  - Low-density lipoprotein cholesterol (LDL-C) uncontrolled while on maximally tolerated statin therapy.
- PCSK9i utilizers are reported as treated members per day per 100,000 commercially insured members.
- PCSK9i paid claims cost is reported as total paid which is defined as the pharmacy plan paid plus the member share.
- The per member per month (PMPM) costs were calculated based on all paid claims from Aug. 1, 2015 through Feb. 26, 2016 for 13.1 million members.
- Prescriber specialty was based on national provider identifier (NPI) recorded on the paid claim.
- PCSK9i discontinuation among 15 million commercial members regardless of UM status
  - Evaluated for all members regardless of UM status who had their first PCSK9i paid claim between Aug. 1, 2015 and Oct. 31, 2015. These members were followed through Feb. 12, 2016. All members assessed for PCSK9i discontinuation had at least 90 days follow up from their initial PCSK9i paid claim.
  - Discontinuation was defined as a gap of 28 or more days after their most recent paid PCSK9i claim supply ran out.

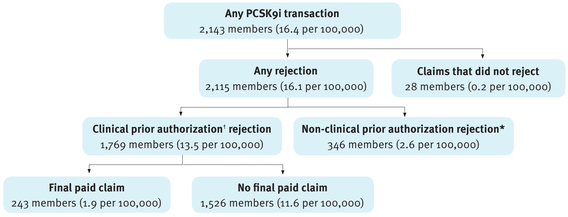
Results

- Of the 13.1 million commercially insured members subject to a clinical PA, 2,143 (16 per 100,000) unique members had at least one paid or rejected PCSK9i claim transaction between Aug. 1, 2015 through Feb. 26, 2016. **(Figure 1)**
- In total 296 (13.8 percent) members had 771 final paid PCSK9i claims accounting for $861,865 total paid, $1,118 average total paid per claim and $0.01 PMPM for the period of Aug. 1, 2015 to Feb. 26, 2016.
- Of the 2,143 members with a submitted PCSK9i claim,
  - 1,769 (82.5 percent) members experienced a clinical PA rejection.
    - 243 (13.7 percent) members experienced a clinical PA rejection with at least one subsequent paid claim.
    - 1,526 (86.3 percent) members experienced a clinical PA rejection without a subsequent paid claim.
  - 346 (16.1 percent) members experienced a non-PA rejection,
  - 28 (1.3 percent) members had claims that did not reject.
- PCSK9i utilization has trended upwards over the seven months post launch starting at 0.02 members per 100,000 per day in August 2015 and ending at 1.6 members per 100,000 per day in February 2016. **(Figure 2)**
- Two-thirds of the final paid PCSK9i claims were prescribed by a cardiology or endocrine specialist.
- PCSK9i discontinuation among 15 million commercial members regardless of UM status. **(Figure 3)**
  - 122 members had a PCSK9i on or before Oct. 31, 2015.
  - 26 (21.3 percent) of 122 members discontinued the drug.
  - 96 (78.7 percent) of 122 remained on therapy (persisted).

Limitations

- Administrative pharmacy claims have the potential for miscoding and include assumptions of member actual medication use, therefore the data may represent information that is false-positive or -negative.
- We were not able to evaluate any differences in benefit design among members. For example, information and differences about enrollment in a consumer-driven health plan was not assessed.
- The data used in this study is limited to a commercial population.
- The utilization and discontinuation rates may be over- or under-estimated due to preapprovals, coupons and sampling provided by pharmaceutical manufacturers. Drug samples are not submitted to the pharmacy benefit manager and are therefore not included in the analysis.
- This analysis is unable to draw conclusions on the impact of formulary exclusion because both PCSK9i drugs were in a preferred formulary status.

Figure 1. PCSK9i Final Claim Status Flow Diagram among 13.1 Million Commercial Members Subject to Utilization Management



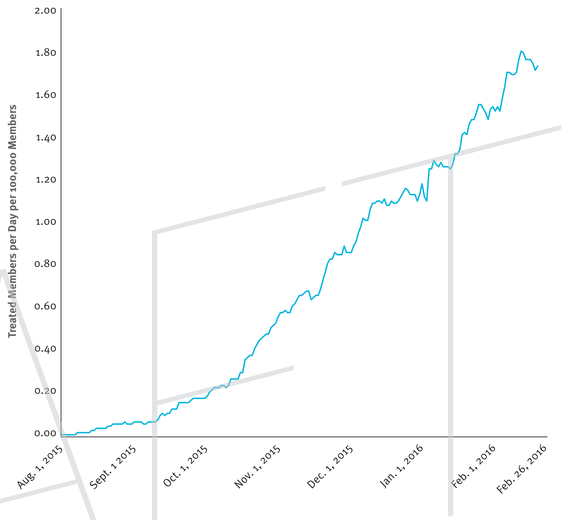
PCSK9i claims from Aug. 1, 2015 through Feb. 26, 2016

† See methods for clinical prior authorization criteria.

* Non-prior authorization rejections were most commonly pharmacy network rejections. Members may also have had rejects for other reasons (e.g., missing/invalid prescriber, member eligibility).

Both alirocumab and evolocumab were in a preferred formulary status.

Figure 2. PCSK9i Member Utilization Rate per Day per 100,000 Commercial Members Subject to Utilization Management

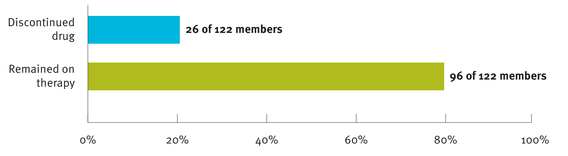


PCSK9i claims from Aug. 1, 2015 through Feb. 26, 2016 among 13.1 million commercial members.

See methods for clinical prior authorization criteria.

Both alirocumab and evolocumab were in a preferred formulary status.

Figure 3. PCSK9i Discontinuation among 122 Commercial Members Followed for a Minimum 90 Days



Both alirocumab and evolocumab were in a preferred formulary status.

PCSK9i discontinuation among 15 million commercial members regardless of UM status was evaluated for 122 members with their first PCSK9i paid claim between Aug. 1, 2015 and Oct. 31, 2015, and followed to Feb. 26, 2016.

See methods for discontinuation criteria.

Conclusions

- In seven months after launch, commercially insured PCSK9i utilization was low resulting in minimal impact on drug spend in part due to the high rate of utilization management claim rejections without a subsequent paid claim.
- Although utilization is currently low, utilization appears to be on an upward trend.
- PCSK9i utilization was predicted to be 112 commercial members per 100,000 one year post launch with utilization management.[4] As of January 2016, in this commercially insured population subject to utilization management, the actual utilization rate was 1.2 per 100,000.
- PCSK9i utilization is substantially lower than predicted due to multiple factors including lack of outcomes data, the injectable route of administration, availability of substantially less costly generic statins that have long term safety data and cardiovascular event reduction outcomes data, and utilization management criteria to ensure appropriate PCSK9i use.[5]
- Of concern is one in five members initiating PCSK9i therapy appeared to discontinue, which is more than twice the discontinuation rate reported in the manufacturer prescribing information.[1,2]
- Health insurers should continue to monitor their own PCSK9i utilization trends and evaluate the impact of their clinical programs.

References

1. Alirocumab (Praluent®) prescribing information accessed at: https://www.praluenthcp.com. February 17, 2016.
2. Evolocumab (Repatha™) prescribing information accessed at: https://www.repathahcp.com. February 17, 2016.
3. PR Newswire. High Cholesterol PCSK9 Drugs Could be Next To Bust Budgets, Stretch Pocketbooks. June 9, 2015. http://www.prnewswire.com/news-releases/high-cholesterol-pcsk9-drugs-could-be-next-to-bust-budgets-stretch-pocketbooks-300096091.html accessed February 17, 2016.
4. Prime Therapeutics Industry Insights. Repatha™ approved; Joins Praluent® in the marketplace. September 14, 2015. http://blog.primetherapeutics.com/blog/connect/repatha%E2%84%A2-approved%3B-joins-praluent-in-the-marketplace accessed February 29, 2016.
5. Edlin, M. Best candidates for PCSK9 inhibitors. Managed Healthcare Executive. February 2016;41–42. http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/best-candidates-pcsk9-inhibitors accessed February 29, 2016.

4085-F © Prime Therapeutics LLC 03/16
1305 Corporate Center Drive, Eagan, MN 55121
AMCP, April 2016, San Francisco, CA, USA

Catherine Starner, 800.858.0723, ext. 5073
cstarner@primetherapeutics.com

03002231