PCSK9-Inhibitor Persistence in a Medicare Population

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Introduction

- Lack of LDL control and plaque stabilization can be detrimental to health outcomes in members with ASCVD or familial hypercholesterolemia.¹
- The PCSK9i require less frequent dosing compared to their statin counterparts; however, they are typically associated with higher copays than generic statin therapy and require injectable administration.
- During the first year PCSK9 inhibitors were on the market, approximately one-third of patients who received a prescription from their provider actually received the medication.² In this observational study of 45,029 patients with PCSK9 inhibitor prescriptions only 47.2% received approval through their insurance company and of those 34.7% never filled the medication.²
- A 2017 study of 26,696 patients found 60-day non-persistency rates for PCSK9 inhibitors compared to high intensity statins to be non-statistically significant.³
- As these medications continue on the market and changes to prior authorization criteria are encouraged, it will be beneficial to know if members are not receiving these therapies due to restrictive criteria or if members are choosing not to fill due to other factors.

Purpose

- To evaluate the persistence of PCSK9 inhibitor therapy in patients who have received prior authorization approval for any reason.
- To evaluate similarities and dissimilarities of characteristics between groups with higher persistence and approval rates compared to those who were denied or never filled post-approval.
- To evaluate the proportion of initial approvals, proportion of members who
 filled post initial approval, and persistence in relation to low-income subsidy
 (LIS) members compared to non-LIS members will be evaluated for a Medicare
 Part D Plan.

Methods

Study Design, Data Source

- Retrospective analysis of a Medicare Part D Plan derived from the Magellan database was performed for prior authorization requests and claims from January 1, 2016 to June 30, 2018 for all members requesting and filling alirocumab or evolocumab.
- A 6 month window following the index date of first prior authorization approval was allowed to assess persistence, as the initial prior-authorization approval per plan policy is 6 months in duration.
- Members were excluded if they received alirocumab or evolocumab without a prior authorization approval or if they were not plan members for at least a duration of 6 months following the index date.

Methods continued

Study Outcomes Assessment

- The primary objective of overall post-approval persistence of PCSK9 inhibitor therapy in members for any indication across the Magellan Part D Plan was calculated from the number of days supplied post initial fill until the 6th month following the index date or the medication was discontinued, allowing for a 30-day refill gap.
- The proportion of members who filled post initial approval will be calculated from members who have a paid claim for evolocumab or alirocumab compared to the total number who received prior authorization approval.
- Persistence in relation to LIS members compared to non-LIS members will be evaluated for the Medicare Part D Plan based on CMS identifiers in the same manner as the primary endpoint.
- Patient characteristics including age, gender, number of concurrent medications, and number of concurrent cardiovascular medications were evaluated in correlation to the objectives.

Results

- The Magellan Medicare Part D Plan covering over 85,000 lives in 20 regions had 438 unique members who requested PCSK9i therapy during the study time frame and 342 who met inclusion criteria.
- Patients denied for initial prior authorization were similar to those who were approved in terms of mean age, sex, number of concomitant medications, use of cardiovascular medications, use of diabetes medications, and use of statin therapy.
- The overall approval rate for PCSK9i therapy was 70% (241) and the proportion of those members who filled post-approval was 61% (147).
- The post-approval persistence of PCSK9 inhibitor therapy in members who
 received at least one fill post-approval during the initial 180 day approval
 duration was 127 ± 60.41 days.
- The majority 66% (71) of members who requested re-authorizations were initially approved, and 75% were approved following appeal. However, 55% (133) of members never asked for a reauthorization following their initial 6 month approval.
- Persistence during the initial 180 day approval duration in relation to Low Income Subsidy (LIS) and non-LIS members following initial approval was 143 ± 55.83 and 117 ± 61.11 respectively.

Limitations

- Cause of discontinuation or lack of initial fill cannot be determined.
- Rationale for authorization denials was not included or evaluated.
- Claims not billed to the health plan were not captured.
- Findings may not correlate to other populations such as Medicaid or Commercial plans.
- This was a retrospective analysis across different claims databases and is subject to limitations of conducting research using large administrative databases.

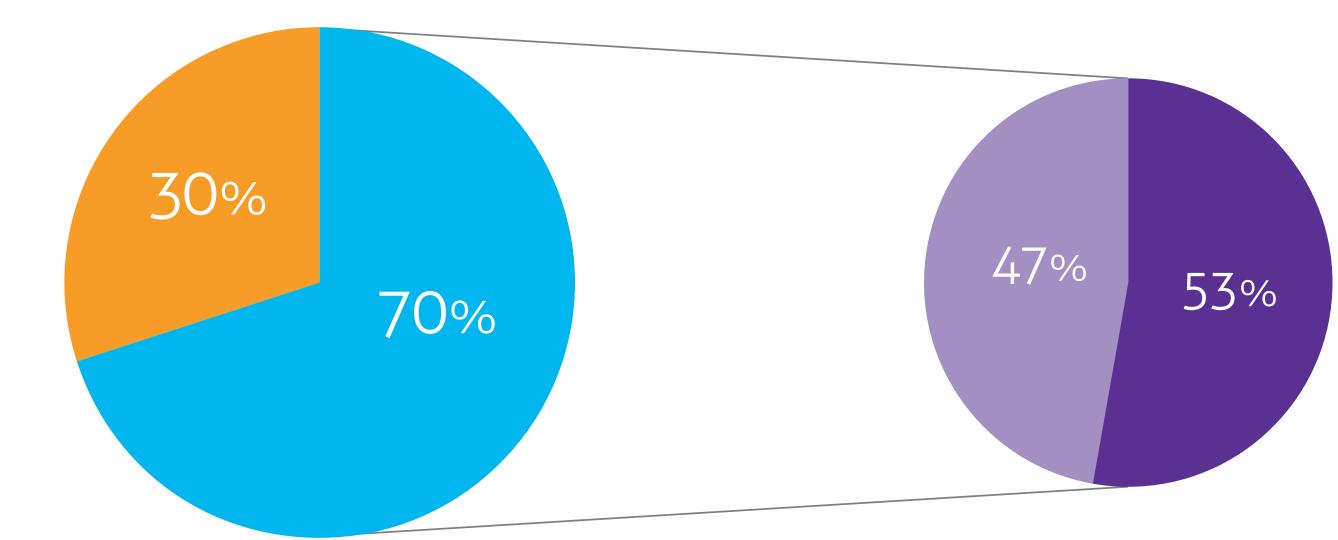
Results continued

Baseline Characteristics

	Population n=342	PCSK9i Approved Prior Authorization n=241	PCSK9i Prior Authorization Denied n=101
Age	69.02 [8.47]	68.99 [8.36]	69.09 [8.73]
Female Gender	203 (59%)	141 (59%)	62 (61%)
Number of Concomitant Medications per Member	10.58 [5.48]	10.71 [5.51]	10.25 [5.38]
Number of Members on Concomitant Statin Therapy	168 (49%)	115 (48%)	53 (52%)
Number of Members on Concomitant Cardiovascular Medications	325 (95%)	230 (95%)	95 (94%)
Number of Members on Concomitant Diabetes Medications	144 (42%)	100 (41%)	44 (44%)

Continuous variables: Mean [Standard deviation]
Discrete Variables: Count (percent)

Prior Authorization Approval Rates



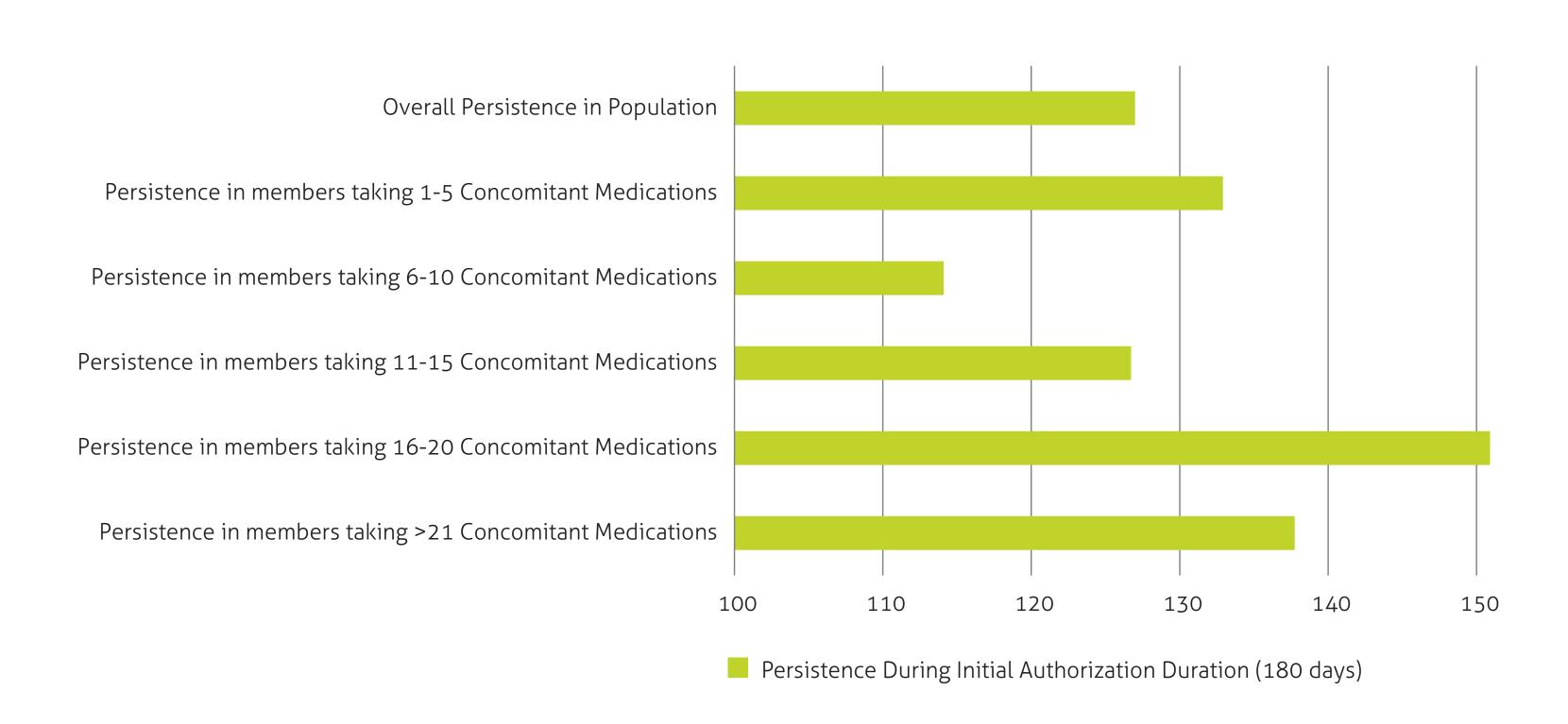
■ Denied Prior Authorization Request (final determination) ■ Approved Following a Supsequent Appeal or Redetermination

Approved on Initial Request

The overall initial approval rate for members requesting PCKS9i therapy was 70%, with 53% (128) initially approved and 47% (113) approved following a subsequent appeal or redetermination.

Time to Discontinuation

Post-approval Persistence of PCSK9i Therapy in Members for Any Indication Across a Medicare Part D Plan During the Initial 180 Day Approval Duration



Conclusion

- Nearly three-quarters of members were initially approved for PCSK9i therapy, and there was no distinct differences between those who received approval and those who were denied.
- Overall, members were relatively persistent during the initial 180 day approval duration.
- Compared to early studies, initial approval rates have increased, while the percent of the population with no fills post-approval has remained relatively constant.

References

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P-value: 0. 1180

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Disclosures

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