Magellan Rx MANAGEMENT

Description of Adherence, Switches, and Discontinuations Among Statin Users in a Regional Medicare Health Plan

Statin Utilization

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Objective

- To describe utilization patterns and adherence to statins within a regional Medicare health plan.

Background

- Statin therapy is the current standard of care for patients with hypercholesterolemia or at high risk for cardiovascular disease.
  - High-intensity statin therapy, defined as atorvastatin 40 mg to 80 mg or rosuvastatin 20 to 40 mg, is recommended as first-line treatment for high risk patient groups.
- Two novel injectable LDL-lowering monoclonal antibodies, PCSK9 inhibitors, alirocumab and evolocumab, have been recently FDA-approved for use in patients with clinical atherosclerotic cardiovascular disease or hereditary hypercholesterolemia who require additional lowering of LDL despite maximally tolerated statin therapy.
- Poor adherence or inability to tolerate statins can lead to less than optimal LDL cholesterol control and an increase in overall mortality.
  - Furthermore, the Centers for Medicare and Medicaid Services (CMS) have incorporated adherence to cholesterol medications into their Part D Medicare Health and Drug Plan Quality and Performance Ratings (STAR ratings).
- As payers develop utilization management strategies to target the use of PCSK9 inhibitors for patients who are inadequately controlled with or intolerant to statin therapy, there is concern that certain patients may be misclassified as statin resistant or intolerant due to poor adherence or lack of proper statin trials.

Methods

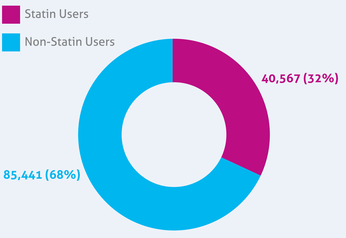
- In this retrospective analysis, pharmacy claims of patients of one regional Medicare plan (approximately 150,000 total covered lives) were reviewed.
- Inclusion criteria: Continuously enrolled patients with at least one claim for a statin between January 1, 2013 and December 31, 2014 were identified.
- Pharmacy claims data were collected for identified patients to determine adherence (using proportion of days covered [PDC] method), number of patients switching statin potencies, statin intolerance, and discontinuations.
  - Potency was defined based on the ATP-IV guideline definitions.
  - A switch was defined as a change in statin potency.
  - Discontinuation was defined as patients who had greater than a 90 day gap in therapy with no statin fills during the remainder of the measurement period.
  - New starts were defined as patients who received a first fill of a statin 90 days or later after the start of the measurement period.
  - Potential statin intolerance was defined as patients who tried at least 2 low potency statins with the last fill being a low potency statin.
- Results were analyzed using descriptive statistics.

Results

Statin Use and Potency Breakdown

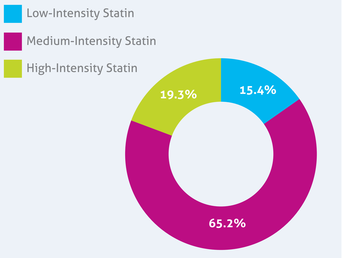
Statin Rx Use	Number of Patients (%)
Atorvastatin	15,145 (37.3)
Fluvastatin	62 (0.2)
Lovastatin	4,781 (11.8)
Pitavastatin	86 (0.2)
Pravastatin	7,928 (19.5)
Rosuvastatin	2,803 (6.9)
Simvastatin	15,018 (37.0)
Total	40,567 (100)
Statin Rx Potency	**Number of Patients (%)**
Low-Intensity	7,312 (18.0)
Medium-Intensity	28,328 (69.8)
High-Intensity	9,268 (22.8)
Total	40,567 (100)

Enrollment*

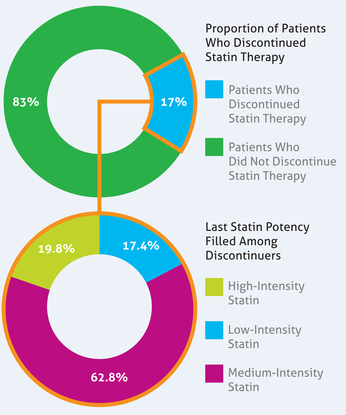


*Data represents 126,008 patients who were continuously enrolled in a regional Medicare plan Among the 40,567 patients on statins, 14,297 were designated as "new starts"

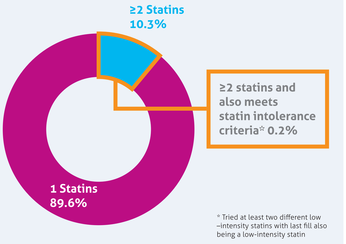
First Statin Potency Filled Among "New Starts"



Statin Discontinuations

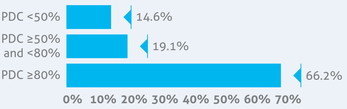


Number of Statin Potency Switches



* Tried at least two different low –intensity statins with last fill also being a low-intensity statin

Proportion of Patients within Specific PDC Thresholds*



*Overall Mean PDC for All Patients was 79.9%

Discussion

- A high proportion of patients are unable to maintain a PDC of 80% or higher which may potentially increase their risk of not meeting LDL-C treatment goals. Additional LDL-lowering therapy (such as a PCSK9 inhibitor) may be inappropriately requested for these patients without first addressing adherence.
- The 17% of patients who discontinued statin therapy may be a part of the patient pool who seek further treatment with PCSK9 inhibitors. However, only 0.2% of statin users in this population would meet suggested criteria for statin intolerance based on guideline recommended diagnostic protocols, which includes requiring patients to try at least 2 low potency statins with the last fill being a low potency statin.
  - Out of the patients who discontinued statin therapy, only 17% had a last fill of a low-intensity statin suggesting that many patients are not following recommended protocols to determine statin intolerance before discontinuing therapy.
- Limitations of this study include:
  - Patient history and progress notes were unavailable to identify reason(s) for choice of statin therapy, reason for switches, or possible clinical explanations for poor adherence.
  - True reason for discontinuation is unknown. Pharmacy claims alone cannot determine if reason for discontinuation was due to statin intolerance or alternative reason.
  - This study was limited to a Medicare population. Results for adherence and statin utilization would likely differ for a commercial population.

Conclusion

- Many statin patients do not appear to be adherent, and patients who discontinue statin therapy may not have been given a sufficient trial of an alternative statin regimen, and thus are prematurely classified as statin intolerant.
- Adherence and proper diagnosis of statin intolerance is recommended to be considered as part of a prior authorization criteria when determining which patients are appropriate to receive alternative lipid lowering therapy such as a PCSK9 inhibitor.
- Managed care organizations may benefit from the implementation of a clinical program aimed at improving statin adherence, encouraging proper titration of statin therapy, and appropriate diagnosis of statin intolerance to promote quality and cost-effective care.
  - Furthermore, this type of program could improve the identification of patients who are appropriate candidates for additional LDL-lowering treatment outside of statin therapy.

Disclosures

- This research was conducted by Magellan Rx Management, Newport, RI, without external funding.

References

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