Background

- With the introduction of proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, a new class of drugs that decrease low-density lipoprotein cholesterol (LDL-C), health plans are re-evaluating how best to allocate premium dollars to help lower the burden of atherosclerotic cardiovascular disease (ASCVD) and its populations.

- The Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) inhibitors were approved in the United States, as well as Europe and Japan1,2. An analysis of these prices, where high intensity strategies are now available at generic prices, has been done by the authors.

- PCSK9 inhibitors lack safety data beyond two point and cardiovascular mortality outcome data. Therefore, their introduction into routine clinical practice and their use in individuals at high risk and with diabetes has not been determined.

Objective & Purpose

- The goal of this study is to understand the value and ongoing care strategies for optimizing cholesterol-lowering drug therapy. We will:
  - Determine the frequency of coronary events in a cohort stratified by claims evidence of established ASCVD, diabetes, or intermittent claudication agent (cilostazol or aggregration inhibitor (clopidogrel, prasugrel, or a pharmacy claim for a nitrate).
  - With the introduction of proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, a new class of drugs that decrease low-density lipoprotein cholesterol (LDL-C), health plans are re-evaluating how best to allocate premium dollars to help lower the burden of atherosclerotic cardiovascular disease (ASCVD) and its populations.

Methods

- All members were in a health plan ages 45 to 74, and continuously enrolled from January 1, 2011, to January 1, 2012 (with three-months health plan enrollment after January 1, 2011), and had a claim diagnosis codes for the first 365 days of observation (1/1/2012).
- All medical claims for these members included evidence of coronary artery disease (CAD) from claims based on the 2011 claims year and/ or 2012 claims year.
- Members were assigned to one of six categories based on their 2011 claims:
  - 2,389 ASCVD, no statin
  - 2,389 ASCVD, + statin
  - 113,974 ASCVD, + statin
  - 33,660 no statin
  - 93.5% no statin

Results

- The cohort consisted of 257,525 members, 51.2% female with mean age 43.5 years (SD 13.7) and mean follow-up 2.2 years, median 3.0 years. These were categorized as:
  - 257,525 (4.5%) diabetes and age 40 to 74 years without ASCVD
  - 80,314 (70.5%) had a statin claim in 2011 (“ASCVD, no statin”)
  - 5,341,659 (93.5%) all others

- Members were assigned to one of six categories based on claims evidence of established ASCVD, diabetes, or intermittent claudication agent (cilostazol or aggregration inhibitor (clopidogrel, prasugrel, or a pharmacy claim for a nitrate).

- The finding that the incremental medical and pharmacy costs were somewhat higher than baseline in the first three months after their duration of continuous enrollment after January 1, 2012 was 51.2% female with mean age 43.5 years (SD 13.7) and mean follow-up 2.2 years; median 3.0 years.

Limitations

- Members were assigned to one of six categories based on claims evidence of established ASCVD, diabetes, or intermittent claudication agent (cilostazol or aggregration inhibitor (clopidogrel, prasugrel, or a pharmacy claim for a nitrate).

- Administrative claims based criteria may erroneously identify some members as having ASCVD, as PCSK9 inhibitors are not a part of the Medicare or Medicaid populations.

Conclusions

- The finding that the incremental medical and pharmacy costs were somewhat higher than baseline in the first three months after their duration of continuous enrollment after January 1, 2012 was 51.2% female with mean age 43.5 years (SD 13.7) and mean follow-up 2.2 years; median 3.0 years.

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References

- Medicare claims for the first 365 days of observation (1/1/2011), members were assigned to one of six categories based on their 2011 claims:
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- For each of the six categories, cumulative incidence of a CHD event over a three year follow-up period, defined as a hospital inpatient claim with a diagnosis code for acute myocardial infarction and/or a PTCA or CABG.

- The mean baseline expense was $6,672 for those with a CHD event and $3,035 for those with no events.

- Members with ASCVD had no statin therapy during follow-up, defined as a hospital inpatient claim with a diagnosis code for acute myocardial infarction and/or a PTCA or CABG.

- Interim analysis using the Kaplan-Meier method.

- Members were assigned to one of six categories based on claims evidence of established ASCVD, diabetes, or intermittent claudication agent (cilostazol or aggregration inhibitor (clopidogrel, prasugrel, or a pharmacy claim for a nitrate).

- A log-rank test was performed after adjusting for the alternative hypothesis.

- A total of 1,857,524 members had claims evidence of a CHD event during follow-up (Table 1, Figure 1).

- Table 1: CHD Events During Follow-up by Risk Category Based on 2011 Claims

- The mean baseline expense was $8,000 for those with an ASCVD no statin, 2,7% diabetes+statin, 2.4% diabetes and age 40 to 74 years without ASCVD, and members with diabetes not receiving drug therapy use, we estimated:

- Members were assigned to one of six categories based on claims evidence of established ASCVD, diabetes, or intermittent claudication agent (cilostazol or aggregration inhibitor (clopidogrel, prasugrel, or a pharmacy claim for a nitrate).

- Members with statin claim in 2011, categorized by 2011 claims-based risk criteria.

- CHD=coronary heart disease. There were 35,238 members with a CHD event.

- Members categorized as ASCVD were not on statin therapy during follow-up, defined as a hospital inpatient claim with a diagnosis code for acute myocardial infarction and/or a PTCA or CABG.

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