Background

- Propensity score analysis studies type 2 diabetes (PCSK9i) increase low level of circulating low density lipoprotein cholesterol (LDL-C) from the blood. The Food and Drug Administration (FDA) approved PCSK9i drugs alirocumab (Praluent®) in July 2015 and evolocumab (Repatha®) in November 2015. Both drugs are used to lower cholesterol in patients who are intolerant or unable to tolerate statins (e.g., statin allergy, severe liver disease, severe renal disease) or who have not responded to the maximum tolerated dose of statins.

- The approval of PCSK9i 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.”

- While there has been a perception that these drugs cost an average of $27,000 per year and prior to launch were expected to substantially increase health care system costs.

- Since they are new to the market, little is known about the PCSK9i drugs utilization trends, costs, PMPM clinical PA impact and discontinuation rates.

Methods

- Prescription claims data from an average of 13.1 million commercially insured members by the plan requiring members to obtain PCSK9i through a preferred pharmacy network. Prescription claims data from an average of 13.1 million commercial members subject to utilization management (UM) clinical PA impact and discontinuation rate (pMPM) from Aug. 1, 2015 through Feb. 26, 2016 (8 months).

- Administrative pharmacy claims have the potential for miscoding and include assumptions that can be used as an indicator of independent therapy. “Empire Blue Cross Blue Shield of Michigan” was used to test if independent third party vendors, who are not associated with the plan requiring members to obtain PCSK9i through a preferred pharmacy network, were used to fill any submitted PCSK9i claims.

- All claims data was obtained from Empire Blue Cross Blue Shield of Michigan. The plan was chosen because of their large size, geographic diversity, and independent pharmacy network.

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

Results

- Of the 13.1 million commercially insured members subject to a PC, 2,143 (13.5 per 100,000) experienced a clinical PA rejection. Of these, 2,115 members (16.1 per 100,000) were rejected for a non-PA rejection, i.e., a network rejection, caused by the plan requiring members to obtain their specialty drugs through a preferred pharmacy network. Members may also have had rejects for other reasons (e.g., missing/reward prescriber, member eligibility).

- Discontinued therapy (persisted).

- The patient is intolerant to at least two different commonly used (e.g., statin, bile acid sequestrant) regimens for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or heterozygous familial hypercholesterolemia (HoFH) or heterozygous familial hypercholesterolemia (HoFH) and LDL-C uncontrolled while on maximally tolerated statin therapy.

- PCSK9i utilizers are reported as total paid claims cost is reported as total claims excluding the member share paid per claim and $0.01 PMPM for the年末

- The per member per month (PMPM) costs of 2,143 members experienced a clinical PA rejection.

- Since they are new to the market, little is known about the PCSK9i drugs utilization trends, costs, PMPM clinical PA impact and discontinuation rates.

Limitations

- Prescription claims data from an average of 13.1 million commercially insured members subject to a PC.

- Of the 2,143 members with a submitted PCSK9i claim, the sample was limited to 2,115 members (16.1 per 100,000) who had at least one subsequent paid claim.

- The per member per month (PMPM) costs of 2,143 members experienced a clinical PA rejection.

Conclusions

- In seven months after launch, commercially insured PCSK9i utilization was low resulting in internal impact on drug spend in part due to the high rate of utilization management claims rejections without a subsequent paid claim.

- Although utilization of PCSK9i appears to be on an upward trend, utilization appears to be on an upward trend. PCSK9i utilization was predicted for 13.1 million commercially insured population subject to utilization management, the actual utilization rate was 1.2 per 100,000.

- PCSK9i utilization in substantially lower than predicted due to multiple factors including lack of outcomes data, the availability of substantially less costly generics that have long term safety data and cardiovascular event outcomes data, and utilization management criteria to ensure appropriate PCSK9i use.

- 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.

- Health insurers should continue to monitor their own PCSK9i utilization trends and evaluate the impact of the clinical programs.

References

