Economic Model to Evaluate the Impact of Increased Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors Rebates while also Reducing Prior Authorization Criteria

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Background

- Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9) launched in 2015 as a new therapy for cholesterol management. 70 million Americans have elevated cholesterol and 15% experience statin intolerance. Statin therapy can cost around \$40 dollars a year while PCSK9 therapy can cost around \$14,308 a year.¹
- Figure 1 compares the current PCSK9 trend to the entire Dyslipidemia class trend, showing significant PCSK9 growth in comparison to the class which remains stable. While most Dyslipidemia patients take something other than PCSK9 the large cost of PCSK9 can mean a few patients can have a significant impact on drug spend. (All utilization is represented as per 100,000 members in this and following figures)
- Due to their cost compared to statin therapy and limited trial data many payers limited access to a small specific set of members who met the clinical criteria.
- Founded in 2006, the Institute for Clinical and Economic Review (ICER) is an independent and non-partisan research organization that objectively evaluates the clinical and economic value of prescription drugs, medical tests, and other health care and health care delivery innovations.²
- ICER recently updated their recommended price benchmarks for alirocumab based on the ODYSSEY outcomes trial recommending various prices based on the health of the patient.³

Objective

• Due to the ICER benchmarks covering a range of price types depending on the patient's health the study aims to create a model which can measure possible utilization changes at various prices which do not exceed forecasted drug spend.

Methods

- We pulled PCSK9 claims data from January 2016 to May 2018 for our commercial clients across the United States with stable membership and calculated the number of users per 100,000 members for each year month during that time period.
- We then used an ARIMA(0,1,1) model to estimate patients for each year month through December 2020 and used the average monthly plan cost of a patient after rebates to forecast an expected per member per month (PMPM) spend for the same time period.
- Statistical software ran various models and determined the ARIMA(0,1,1) model resulted in the lowest mean absolute percentage error. We also generated two other models, one which forecasts no growth and the other using the lower 95% confidence interval of the ARIMA(0,1,1) model.
- Figure 2 shows the forecasted PCSK9 patients per 100,000 members for the next two years under various statistical models. The ARIMA Model projects an average of 23 patients in 2019 and 30 patients in 2020 while the ARIMA lower confidence interval model projects an average of 19 patients in 2019 and 24 patients in 2020. The no growth model assumes 16 patients in both 2019 and 2020.
- We then used ICER value-based prices as a guide and then divide them by 12 to get the average monthly spend a patient would cost at various benchmarks. For each forecasted period we determine how many patients would be needed to equal the forecasted PMPM at current net prices. We assumed stable membership and at the start of each year we increased each price by 5% to account for inflation.

Results

- could increase PCSK9 patients by 256 percent to 266 percent (or 41 to 77 patients per 100,000 members).
- benchmarks and forecasted model.
- to 86 in 2020. The ARIMA model projects the number of patients to be 23 to 83 in 2019 and 29 to 106 in 2020.
- Figure 4 shows the average number of PCSK9 patients a plan can have in 2019 and 202 under the various pricing benchmarks and forecasted model.



Figure 1: Dyslipidemia Patients vs PCSK9 Patients

Figure 3: Additional PCSK9 Patients at Various **Pricing Benchmarks and Forecast Models**

| Model | \$4,500 - \$5,500 (Percent Increase) | \$2,300 - \$3,400 (Percent Increase) |
|-----------------------|---|---|
| 2019 No Growth Model | 13 (81%) | 41 (256%) |
| 2020 No Growth Model | 13 (81%) | 41 (256%) |
| 2019 ARIMA (Lower CI) | 16 (16%) | 49 (257%) |
| 2020 ARIMA (Lower CI) | 20 (20%) | 62 (258%) |
| 2019 ARIMA | 20 (20%) | 60 (260%) |
| 2020 ARIMA | 25 (25%) | 77 (266%) |

• If PCSK9s were priced around \$4,500 to \$5,500 a plan could increase PCSK9 patients by 81 percent to 87 percent (or 13-25 patients per 100,000 members) and spend the same amount they are today. At a price point of \$2,300 to \$3,400 a plan

• Figure 3 shows the average number of additional PCSK9 patients a plan can have in 2019 and 202 under the various pricing

• From a total patient perspective under the no growth model shows the patient count can from 16 to 57 depending on the price benchmark. The ARIMA lower confidence interval model projects patients can be anywhere between 19 and 68 in 2019 and 24



Figure 2: PCSK9 Forecasted User Growth

Figure 4: Patients Possible while Remaining Budget Neutral to Current Forecast



Limitations

Conclusions

- from lower prices.

Disclosures

Resources

Current Price \$4,500-\$5,500



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• Only pharmacy claims were used in this analysis, with medical claims it would be possible to approximate how many members might meet the new clinical criteria and match it up to this analysis.

• Data comes from our commercial book of business which is comprised of various industries and patient populations. Plans with an older population, Medicaid plans, as well as Medicare plans would likely not find these numbers applicable to their population; however, the methodology to generate the results would not change.

• As discussion around drug pricing continue, it is important to remember resources are not unlimited and appropriate management is critical to helping the most individuals.

Due to positive clinical results and an aging population PCSK9 utilization is forecasted to grow in the next few years. As payers and manufactures discuss prices and formulary status it will be important for payers to understand the break even point when establishing more open access, while manufactures see the potential market share increase

As more specialty drugs continue to release planning for the future becomes even more critical, finding models to measure the impact of various changes can help decision makers find the right solutions to help the most patients.

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2. The Institute for Economic and Clinical Review. About. https://icer-review.org/about/

3. The Institute for Economic and Clinical Review (2018, March 10) Institute for Clinical and Economic Review Updates Value-Based Price Benchmark for Alirocumab, a PCSK9 Inhibitor for Treatment of High Cholesterol Retrieved from https://icer-review.org/announcements/alirocumab-prelim-evidence-update/