Potential IRA Interactions with Medicare Part D Risk Adjustment

Addendum: Calibration Data Timing Considerations

Commissioned by PhRMA

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This paper is an addendum to a publication entitled "Potential IRA Interactions with Medicare Part D Risk Adjustment: Model Considerations.[1]" The prior publication, which was also commissioned by PhRMA, discussed the implications of the Inflation Reduction Act (IRA) for risk adjustment, including considerations related to the timing of data used to calibrate the RxHCC model. A significant data lag in the RxHCC model calibration leads to differences in risk model coefficients relative to plan costs because the model does not effectively capture all major market events affecting plan liability that occur during the gap between model calibration and model application.

Historically, the gap between the calibration data period and the application period has been three to four years. The current 2023 payment year model is calibrated using 2018 diagnoses and 2019 expenditures.[2] Based on past models, it is reasonable to assume the 2025 payment year model would be based on 2021 or 2022 expenditure data. However, during a risk adjustment user group call held on September 14, 2023, the Centers for Medicare and Medicaid Services (CMS) reported results using the same 2018 and 2019 time period, and stated they are still "evaluating options for more recent data years to use for the model calibration.[3]" In this paper, which was commissioned by PhRMA, we explore potential impacts to plans resulting from calibrating the 2025 RxHCC model using data from more recent time periods.

Data Considerations

In the table below, we outline considerations for each of the data periods available for use in calibrating the 2025 RxHCC model.

Diagnosis Period	Expenditure Period	Considerations
2018	2019	This data period is the same as that used to calibrate the 2023 model. It would not reflect any market events occurring since 2019.
2019	2020	The expenditure data period is during the height of the COVID-19 pandemic. However, studies have shown that the pandemic had little impact on overall prescription drug spending.[4]
2020	2021	The diagnosis data period is during the height of the COVID-19 pandemic. Since medical visits, and therefore diagnoses, were significantly depressed during the pandemic,[5] this period may not accurately predict the relationship between health conditions (RxHCCs) and costs in other years.
2021	2022	This data is the most recent available, and therefore likely the most accurate representation of future costs. However, it may require additional resources for CMS to appropriately summarize and review the more recent data for use in the model.

The impact of COVID-19 on the healthcare system creates unique complications for assessing the relative impact of using each data period to predict future expenditures. The remaining considerations are a tradeoff between more recent, and therefore, likely more predictive, data and the effort required to incorporate more recent data.

[1] https://www.milliman.com/en/insight/potential-ira-interactions-with-medicare-part-d-risk-adjustment
[2] The current model reflects a 4 year lag, which is atypical due to COVID-related legislation.
[3] https://www.csscoperations.com/internet/csscw3_files.nsf/F2/PtDUserGroupSlideDeck_20230914_508.pdf/$FILE/PtDUserGroupSlideDeck_20230914_508.pdf
[4] https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf
[5] https://www.census.gov/library/stories/2021/09/pandemic-disrupts-some-trends-in-health-care-services.html

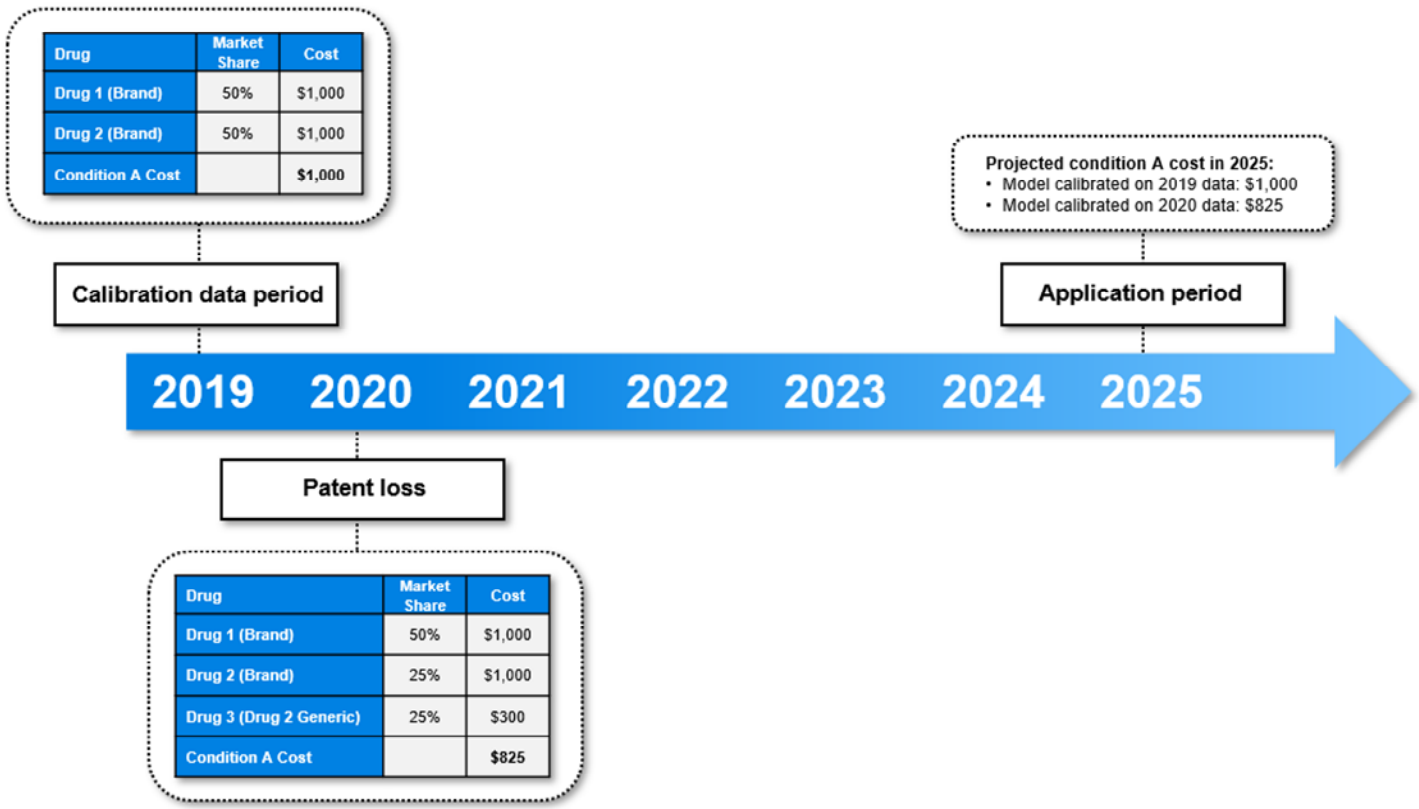
Areas of Impact

If the 2025 RxHCC model is calibrated using 2019 expenditure data, plans may not be appropriately compensated for patients with conditions treated by drugs with significant market events occurring after 2019. CMS does account for typical cost trend between years. However, if costs associated with a certain condition changed at a different rate than overall prescription drug costs between the calibration period and model application period, then the RxHCC model would not accurately predict costs for this condition. Significant market events can either increase or decrease a condition's cost and include:

- New drug launches
- Expanded indications
- Significant price changes
- Patent losses
- Regulatory changes
- Any other changes that impact Part D plan liability for a patient with a given diagnosis

Many such changes have occurred between 2019 and today. Figure 1 provides an illustration of the impact that a patent loss may have on plan payments.

FIGURE 1: ILLUSTRATIVE IMPACT OF PATENT LOSS ON PLAN PAYMENTS



In this simplified example, Condition A is treated by two brand drugs used by an equal number of patients in 2019. Both drugs have a cost to the plan of $1,000 per year. In 2020, the patent for Drug 2 expires and a generic version launches with a cost to the plan of $300 per year. Half of patients using Drug 2 switch to the generic version and half remain on the brand. In 2025, assuming no other changes, the plan's average cost for patients with Condition A is $825 (3/4 of patients use one of the two $1,000 products and 1/4 of patients use the $300 generic). However, a model calibrated on 2019 data would not capture the new launch and would predict that the plan cost is still $1,000 per year (all patients using the brands). A model calibrated using 2020 or more recent expenditure data would capture the impact of the patent loss. Typically, roughly 30 to 50 patent losses occur each year.

Any market event that materially changes the mix of utilization or cost per script associated with a condition between the calibration data period and the model application period can result in a mis-estimation of plan costs. A timing gap is necessary as it would be nearly impossible to use real-time data in this risk adjustment model. Almost certainly there will be some market events during the gap, but the longer the gap, the higher the likelihood is for impactful events to occur. Figure 2 below shows examples of how prescription costs changed between 2019 and 2021[6] for multiple conditions that had major market events – some with new brand or generic launches and others with price decreases. These events are described in more detail below.

These examples focus on therapeutic classes closely associated with specific conditions in the RxHCC model. Please note, these costs are specific to these therapeutic classes and do not represent total average costs for patients with the listed condition. Additionally, we focus on gross Part D costs for simplicity, though the RxHCC model is calibrated to the portion of claim costs paid by plan sponsors. The market events captured in each of these classes are explained below. Often, new launches have higher prices than other products in the class due to their specialized indications or improved efficacy. In other situations, plan costs for a condition may decrease due to a patent loss or a price decrease from a highly utilized product.

FIGURE 2: ANNUAL TRENDS FOR SAMPLE OF CONDITIONS ASSOCIATED WITH MAJOR MARKET EVENTS BETWEEN 2019 AND 2021

Annual Cost Per Beneficiary Trend	
	Annual Trend*
Part D Total	6%
Migraine Headaches	17%
Motor Neuron Disease	15%
Chronic Kidney Disease	-1%
Multiple Sclerosis	-2%
Disorders of Lipoid Metabolism	-2%

**Annualized change in cost per beneficiary using drugs associated with each condition between 2019 and 2021 based on the CMS Part D Spend Dashboard.*

- **Increased cost examples – Migraine headaches (RxHCC 166) and Myasthenia gravis, amyotrophic lateral sclerosis and other motor neuron disease (RxHCC 156):** These are three examples of conditions where costs increased, in contrast to the average annual Part D trend of around 6%. Risk scores calculated using older data would very likely be underpredicted in the RxHCC model compared to risk scores calculated using more recent data.
  - Migraine headaches: Prior to 2020, calcitonin gene-related peptide (CGRP) drugs for migraine prophylaxis were limited to injectables only. With the launch of oral CGRP inhibitors in 2020 and 2021, utilization in this class has increased due to ease of use and expanded indications.[7,8]
  - Myasthenia gravis, amyotrophic lateral sclerosis and other motor neuron disease: Historically, treatment options have been limited to cholinesterase inhibitors, such as pyridostigmine, which have shown mild effectiveness for LEMS.[9] However, in late 2018, the FDA approved the first treatment specifically for Lambert-Eaton myasthenic syndrome (LEMS). The average cost per beneficiary for treatment of LEMS increased between 2019 and 2021, primarily driven by greater utilization of the new product, which has a higher cost per beneficiary than other LEMS treatments.[6,10]
- **Decreased cost examples – Chronic kidney disease (RxHCCs 262 and 263), Multiple Sclerosis (RxHCC 159), and Disorders of lipoid metabolism (RxHCC 45):** These are three examples of conditions where costs decreased, in contrast to the average annual Part D trend of around 6%[6]. Risk scores calculated using older data would very likely be overpredicted in the RxHCC model compared to risk scores calculated using more recent data.
  - Chronic kidney disease: Costs for this condition decreased due to a generic launch in mid-2019.[6]
  - Multiple Sclerosis: Costs for this condition decreased due to a generic launch in mid-2020.[6]
  - Disorders of lipoid metabolism: Costs for this condition decreased due to price decreases for a number of brand and generic products between 2019 and 2021.[6]

When using less recent calibration data, the plan's risk score and resulting direct subsidy payment may reflect an underprediction of the plan's liability for members with conditions where there is a new launch or rapid utilization growth. In other cases, such as for conditions associated with patent losses or price decreases, use of older calibration data may cause the plan's risk score to reflect an overprediction

[6] 2021 was selected since it represents the most recent data available in the CMS Drug Spending Dashboard.
[7] https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug
[8] DataMonitor
[9] https://www.mda.org/disease/lambert-eaton-myasthenic-syndrome/medical-management
[10] https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-lambert-eaton-myasthenic-syndrome-rare-autoimmune-disorder

of plan liability. Further, since the RxHCC model is calibrated to a 1.0 market average, risk scores for all conditions are impacted by changes to other conditions, even if they do not have an explicit associated market event.

IMPLICATIONS OF AN RXHCC MODEL CALIBRATED USING LESS RECENT DATA

For plans: Although there will likely be some conditions that are overpredicted and others that are underpredicted, over / underprediction of a given plan's risk scores will likely not balance out in aggregate. Plans with a disproportionate share of beneficiaries with underpredicted conditions will have more adverse impacts on their payments relative to the rest of the market. Further, an RxHCC model that does not predict costs well for certain conditions due to the data lag may have unintended consequences for plan decision making. For example, plans may make formulary changes to avoid attracting beneficiaries with conditions treated by newer, high-cost products since they will be underpaid for these members. Conversely, plans may try to attract beneficiaries with conditions treated by products with recent price drops or generic launches in the short term while their risk scores are likely overpredicted, though they may later limit formulary coverage once the calibrated model reflects the lower costs.

Assuming a three-year lag, a model calibrated using claims experience representing the full 2025 Part D redesign would not be incorporated into the model calibration until 2028. Similarly, a model capturing claims experience reflecting 2026 maximum fair prices (MFPs) would not be incorporated until 2029. Even if CMS re-adjudicates claims under a 2025 defined standard benefit design to calibrate the 2025 payment year model, this may not capture changes in utilization patterns or beneficiary behavior resulting from the significant changes to cost sharing under the IRA.

For patients: If plans adjust their formularies as described above, patients on new drugs may have limited plan options or may have to pay a higher premium for a richer (more enhanced) plan. Patients may be subject to disruptive formulary changes to the extent plans use formularies as a means to manage costs and optimize direct subsidy payments.

While payers adjust formularies every year for a variety of reasons, increased cost pressure in 2024 caused by additional plan liability in the catastrophic phase without an offsetting adjustment to the RxHCC model may have influenced plans to put additional scrutiny on formulary coverage of high-cost classes. For example, we observed significant reductions in coverage in the pulmonary arterial hypertension class between 2023 and 2024. This class is not protected and consists of 11 products, most of which are high cost. We reviewed pulmonary arterial hypertension coverage for 15 PDP formularies[11] across the five largest payers. We observed 10 formularies had removed at least 1 product and 3 formularies removed 2 or more.[12] No formularies added coverage to the class.

Caveats and Limitations

This information was developed to help PhRMA understand how the Medicare Part D risk adjustment model may be impacted from the benefit redesign provisions in the IRA. This information may not be appropriate, and should not be used, for other purposes.

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We relied upon the CMS Part D Spend Dashboard, as well as other publicly available information. We accepted these items without audit. To the extent the data and information is not accurate or is not complete, the values provided in this report may, likewise, be inaccurate or incomplete.

Milliman developed certain models to estimate the values included in this report. The intent of the models was to summarize Part D gross costs using the 2021 CMS Part D Spend Dashboard. We reviewed the models, including the inputs, calculations, and outputs for consistency and reasonableness. We believe they are appropriate for intended purpose and in compliance with generally accepted actuarial principles and relevant actuarial standards of practice (ASOP).

Michelle Klein is an actuary for Milliman and a member of the American Academy of Actuaries. They meet the Qualification Standards of the Academy to render the actuarial opinion contained herein. To the best of their knowledge and belief, this information is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

[11] Available through CMS 2023 basic formulary files.
[12] As reported on Medicare Plan Finder.

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