Financial implications of the Inflation Reduction Act are expected to lead to a reassessment of formulary strategies by Part D plans

The Part D benefit redesign will significantly increase Part D plans' liabilities, particularly for claims incurred in the catastrophic phase, which may trigger narrower formularies or greater use of utilization management techniques

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Executive Summary

With the implementation of the Inflation Reduction Act (IRA) Part D benefit redesign in 2025, health plans will face substantially higher drug liabilities than they do under current regulations. In particular, despite increased revenues from direct subsidies, the recalibration of risk scores, and higher retention of manufacturer rebates, we estimate that plans will face revenue shortfalls for beneficiaries treated with specialty drugs. We estimated this revenue shortfall for select therapeutic classes post-IRA and found that:

- Revenue shortfalls are likely to exist in the high-cost therapeutic classes we studied even after the recalibration of risk scores as, historically, risk scores have worked well on the average population but have undercompensated plans for high-cost beneficiaries (while overcompensating them for low-cost beneficiaries).
- These financial pressures will incentivize plans to reassess formulary strategies to manage spending in the catastrophic phase and protect from adverse selection.
- Large standalone prescription drugs plans (PDPs) may react with greater urgency to the changes introduced by the IRA, while some integrated Medicare Advantage Prescription Drug (MAPD) plans may take a gradual approach for additional formulary restrictions.
  - PDPs often focus on adverse selection, do not have other sources of revenue to offset plan cost headwinds, and do not have a direct link between beneficiary satisfaction and revenue.
  - MAPDs need to balance financial pressures with regulatory constraints,[1] medical costs, beneficiary satisfaction implications of formulary restrictions, and the potential revenue impact of star ratings.

This paper quantifies the post-IRA changes in Part D plan revenues and liabilities across a selection of therapeutic classes in the context of Part D formulary dynamics and highlights potential plan actions that could lead to narrower formularies or greater use of utilization management techniques.

PATIENT AFFORDABILITY AND THE TRANSFER OF CATASTROPHIC RISK TO PART D PLANS UNDER THE IRA

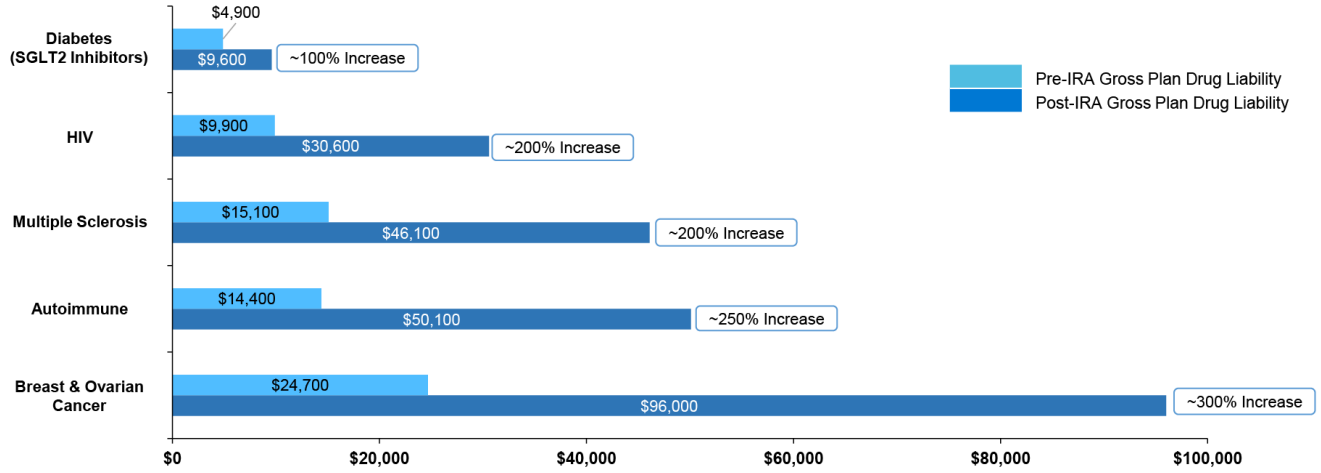
The IRA includes significant changes to the Part D benefit design intended to lower beneficiary out of pocket (OOP) costs, most of which will be implemented in 2025. Specifically, in 2025 the IRA will eliminate the coverage gap phase and cap beneficiary cost sharing at $2,000 per year and introduce a mechanism to spread beneficiary OOP costs over the calendar year (the Medicare Prescription Payment Plan[2]). As part of the redesign, Part D plan liability in the catastrophic phase will increase from 15% in 2023 to 60% in 2025, providing a greater financial incentive for Part D plans to manage drug costs in the catastrophic phase.

These changes to the Part D benefit, when combined, are expected to improve drug affordability for beneficiaries, especially for those who require treatment with high-cost drugs, and could result in an increase in the number of beneficiaries initiating therapy and adhering to therapy. At the same time, the benefit redesign combined with higher use of high-cost drugs will significantly increase Part D plan drug cost liabilities. While we expect a recalibration of government subsidies to Part D plans to account for higher average gross plan liabilities, the concentration of risk for high-cost beneficiaries will likely lead Part D plans to seek ways to limit specialty drug spending.

HOW WILL THE IRA IMPACT PART D PLAN'S FINANCIALS?

The Part D benefit redesign is expected to result in substantial increases in plan drug liabilities before rebates (gross plan liability) across the board, but particularly in high-cost therapeutic classes. To understand the plan financial impact of the 2025 IRA benefit redesign, we modeled changes to gross plan drug liabilities for five therapeutic classes: two protected classes[3] (HIV and breast and ovarian cancer), two non-protected classes of specialty drugs with high cost and relatively low volume (autoimmune and multiple sclerosis), and one non-protected class with low-cost, high-volume spend (sodium-glucose cotransporter-2 [SGLT2] inhibitors for diabetes). The classes selected for our analysis were among the top gross drug spending classes in Part D. As shown in Figure 1, we estimate that gross plan liability post-IRA will increase by 100% to 300% across the therapeutic classes analyzed.

FIGURE 1: PART D GROSS (BEFORE REBATES) PLAN DRUG LIABILITY PRE- AND POST-IRA, PER BENEFICIARY PER YEAR (2025)



Then, we modeled expected changes to direct subsidies and member premium to quantify the revenue shortfall in these select therapeutic classes before the change in revenue that is expected from the risk score recalibration. The annual per beneficiary revenue shortfall ranged from $16,700 to $77,100 in the specialty classes we analyzed, as displayed in Figure 2. For SGLT2 inhibitors for diabetes, which are not considered specialty, the revenue shortfall was $2,900 per year.

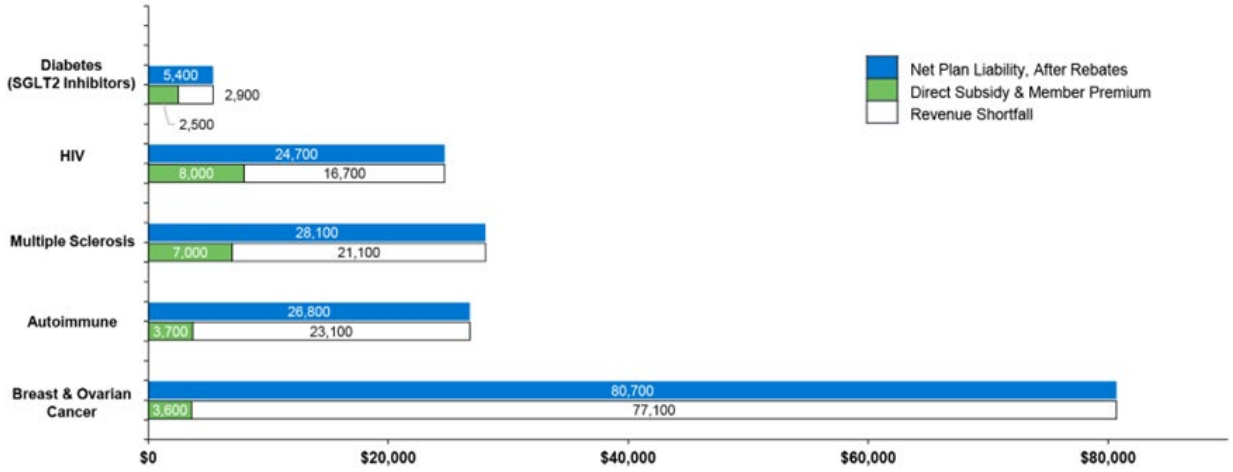
Gross plan liabilities are likely to be even more concentrated in a smaller portion of the population after implementation of the IRA. Prior Milliman research has estimated that the top 1% of Part D beneficiaries may account for 30% of overall gross plan liabilities,[4] up from 15% pre-IRA. This will result in plans increasing their scrutiny of their formularies, especially for high-cost therapeutic classes used by a subset of the population to avoid anti-selection and to manage high-cost spending. [5,6]

RISK ADJUSTMENT WILL PLAY A LARGER ROLE IN PART D POST-IRA

The federal government, through the Centers for Medicare and Medicaid Services (CMS), partially funds the Part D program through direct subsidies to plans, which are risk adjusted using the prescription drug hierarchical condition class categories (RxHCC) model to reflect the risk profile of beneficiaries enrolled in each plan. Part D plans submit an annual "bid" to CMS reflecting the expected cost to the plans, net of rebates, of providing standard Part D benefits to an average risk beneficiary (net plan liabilities), plus administrative costs and margin. Part D plans receive a direct subsidy equal to the risk-adjusted basic bid amount minus the basic member premium.

As gross plan liabilities increase with the benefit redesign, so will the bid amounts, and hence, the direct subsidies (particularly considering the cap on the national average member premium). However, we estimate that higher CMS direct subsidies alone are not expected to offset the additional net plan drug liability for the therapeutic classes we modeled, resulting in a revenue shortfall before the change in revenue that is expected from the risk score recalibration, as shown in Figure 2. Changes to the RxHCC risk score model, which assigns each beneficiary a Part D risk score according to their demographics and past medical diagnoses, could partially or fully offset the 2025 revenue shortfall we estimated. Regardless, the risk adjustment mechanism will be an even more important factor in managing plan risk post-IRA.

FIGURE 2: POST-IRA PART D PLAN REVENUE SHORTFALL FOR SELECT THERAPEUTIC CLASSES PRIOR TO 2025 RISK SCORE MODEL CHANGES, PER BENEFICIARY PER YEAR (2025)



PLAN'S IRA RISK-ADJUSTED FINANCIALS FOR BENEFICIARIES TREATED WITH SPECIALTY DRUGS

By design, risk scores work on a population-level basis to compensate plans for their overall risk profile and to minimize incentives for plans to avoid certain beneficiaries. Historically, risk scores have overcompensated plans for healthier beneficiaries and, conversely, undercompensated them for sicker beneficiaries.[7] Risk scores represent the relative gross plan liability for the average beneficiary with a diagnosis included in an HCC category, regardless of the use of Part D treatments, relative to an average beneficiary of 1.0 risk score. Therefore, the risk score model is likely to undercompensate plans for beneficiaries treated with specialty therapies due to their high cost.

For example, take two beneficiaries that are the same age with the same HCC diagnosis. Risk-adjusted plan revenue would also be the same, as it is based on demographics and diagnoses. But Part D costs could be different if one beneficiary takes a Part D drug and the other takes a Part B drug or does not take any drug at all. Plan costs could also be different if one beneficiary takes a brand drug and the other takes a generic drug. Because risk scores are intended to reflect their average costs (regardless of therapy choice, adherence, disease progression, and other biomarkers), this could overcompensate the plan for the beneficiary who does not take a drug (or who takes a generic drug) and undercompensate the plan whose beneficiary does take a drug (or takes a brand drug).

CMS expects to release a new RxHCC model in early 2024 for implementation in 2025. Preliminary information released by CMS suggests that the existing model will be recalibrated to reflect gross plan liabilities under IRA benefits. No other major methodological changes are expected in 2025.[8] This suggests that after the risk score model recalibration, plans could still experience revenue shortfalls for beneficiaries treated with the specialty therapies examined in this study. This can happen because the RxHCC risk score model, which will be recalibrated on a population-level basis, will still rely on HCC diagnosis representing a wide range of Part D plan costs. This dynamic would increase incentives for plans to implement formulary restrictions to manage exposure to claims incurred in the catastrophic coverage phase and adverse selection.

POTENTIAL PLAN RESPONSES TO MANAGE CATASTROPHIC SPENDING AND ADVERSE SELECTION RISK

Projected revenue shortfalls for specialty therapies, as shown in Figure 2, are likely to elicit Part D plan responses. According to a survey, plans expect formularies to narrow and utilization management to increase to give preference to products with lower net plan cost and to manage selection risk. [9,10] While plans have less flexibility in restricting access to drugs in protected classes, plans can deploy utilization management (UM) through stricter or additional step therapy (ST), prior authorization (PA), and quantity limits. The IRA could accelerate the formulary standardization that has occurred in recent years, as conformity in formularies reduces the risk of adverse selection.

CMS has several protections in place to help beneficiaries have access to their therapies. These include an exception and appeals process available when a prescription is rejected, an annual formulary review by CMS, limits on year-over-year changes in total beneficiary costs (TBC) for MAPDs, and mandated formulary inclusion for protected therapeutic classes.

A comparison of historical formularies in standalone PDPs and integrated MAPDs illustrates common strategies used by Part D plans to manage drug spending that could be deployed to address the revenue shortfall created by the IRA Part D benefit redesign in high-cost therapeutic classes. MAPD plans typically have more flexibility to provide richer formulary access due to their availability of additional sources of revenue (including medical "Part C" subsidies from CMS). TBC rules also limit the extent of formulary coverage reductions that MAPDs can make in any one year. Furthermore, MAPD plans need to balance managing catastrophic spending with beneficiary satisfaction and implications on star ratings, which affect revenue and enrollment retention. By contrast, PDPs often focus on adverse selection, do not have other sources of revenue to offset plan cost headwinds, and do not have a direct link between beneficiary satisfaction and revenue, and so tend to implement more formulary management.

Figure 3 shows the 2023 formulary coverage for PDPs and MAPDs for select therapeutic classes. The percentage of brand-name drugs not covered in the two non-protected specialty classes analyzed—multiple sclerosis and autoimmune—is 10% to 15% higher among standalone PDPs, at 62% and 26%, respectively, compared to 48% and 16% among MAPDs. Even then, most plans cover more than the minimum standard required by CMS, which is the inclusion of at least two therapies in each class.[11] This may suggest that, under financial pressure, both MAPDs and PDPs may opt for additional formulary restrictions of brand drugs.

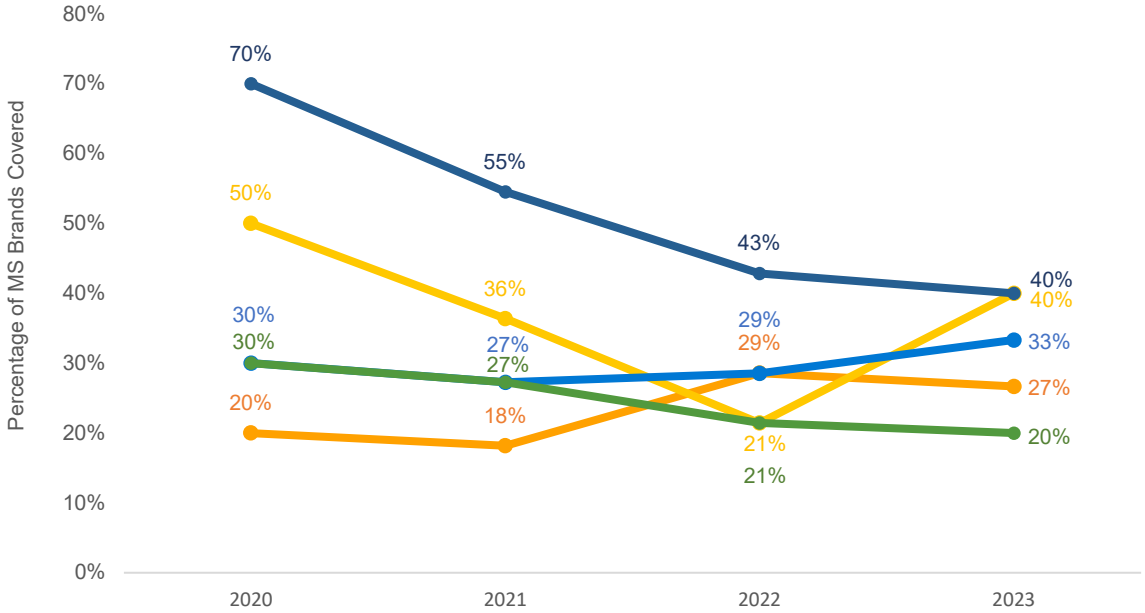
FIGURE 3: 2023 PDP AND MAPD FORMULARY COVERAGE (BENEFICIARY WEIGHTED) BY THERAPEUTIC CLASS AND OTHER CLASS CHARACTERISTICS

Therapeutic Class (Brand-Name Drugs Only)	Number of Brands in Class	2023 PDP Brand % Not Covered	2023 MAPD Brand % Not Covered	Protected Class	Specialty Class	Impacted by 2026 Price Negotiation[12]
Multiple Sclerosis	15	62%	48%		X	
Autoimmune	18	26%	16%		X	X
Diabetes (SGLT2 Inhibitors)	7	11%	14%			X
Breast and Ovarian Cancer	9	0%	0%	X	X	
HIV	9	0%	0%	X	X	

Source: Analysis of Part D Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information Files
Note: For consistency, this analysis includes only brand-name products in all therapeutic classes analyzed.

In addition to current formulary coverage, we also looked at the formulary coverage evolution from 2020 through 2023 for the largest PDPs by enrollment. For the non-protected classes analyzed, PDP formulary coverage has eroded or narrowed over time (see Figure 4) due to a variety of factors, which could include the introduction of new generics and financial pressures in the selected therapeutic classes. In 2023, among the largest PDPs, these plans covered at least three of the 15 MS drugs, but we could see that reduced in 2025 as plans are only required to cover at least two drugs in each class. In addition, formularies have trended toward higher standardization, with relatively less variation in the number of covered brands within a class in 2023 than in 2020. Given the formulary evolution over time, we expect that the trend toward narrower formularies for brand products could accelerate post-IRA as a strategy for plans to manage costs and selection risks.

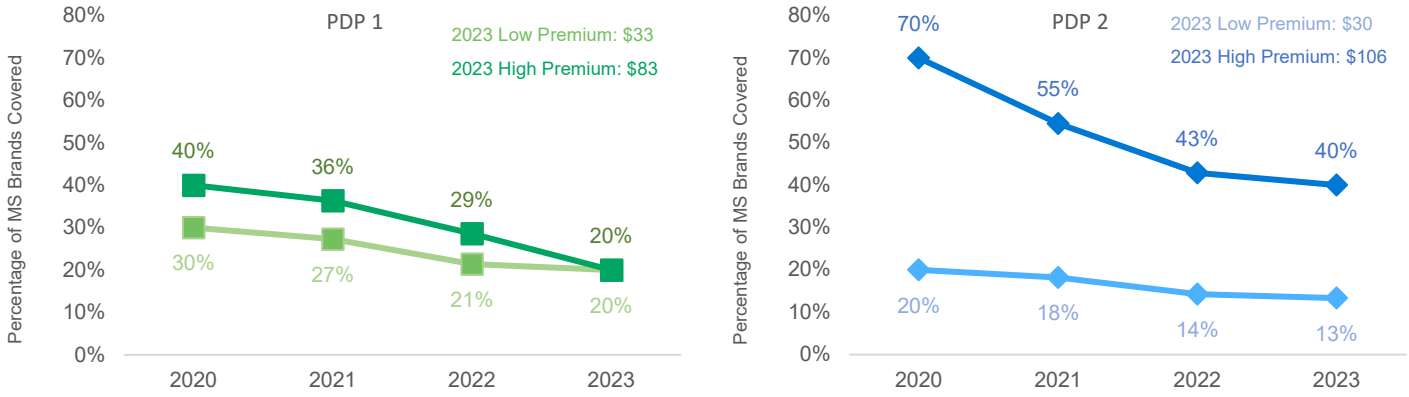
FIGURE 4: 2020-2023 PDP FORMULARY COVERAGE FOR MULTIPLE SCLEROSIS (MS) BRANDS



Another common practice for managing costs is the use of utilization management (UM) tools such as step therapy, prior authorization, and quantity limits. For the non-protected specialty therapeutic classes analyzed, autoimmune and multiple sclerosis, we observed some degree of UM, with step edits often embedded in a plan's PA policies. [13,14,15] As with formulary exclusion, plans may opt for additional UM in the future to respond to the increased plan drug liabilities posed by the IRA benefit redesign.

We examined the formulary coverage from 2020 through 2023 for enhanced PDPs offered to compare the number of MS brands covered on their low- and high-premium plans. In general, formulary coverage was leaner on the lower-premium plan and richer on the higher-premium plan, as illustrated in Figure 5. We note that other top PDPs do not differentiate between their lower- and higher-premium plans for formulary coverage of multiple sclerosis agents. Higher-premium plans that usually have broader formularies could potentially face adverse beneficiary selection risk with limited opportunity for cost management. Figure 5 shows the formulary coverage for lean and rich PDP formularies for MS brands. This figure suggests that higher-premium plans seem to have room for tightening formularies to mitigate risks while still meeting CMS formulary requirements. Post-IRA, we anticipate that plans will evaluate formulary levers to manage costs and selection risks.

FIGURE 5: 2020-2023 PDP LEAN VS RICH FORMULARY COVERAGE FOR MULTIPLE SCLEROSIS (MS) BRANDS AND 2023 PREMIUMS[16]



VARYING IRA IMPLICATIONS FOR MAPD AND PDPS AND FOR LOW-INCOME BENEFICIARIES

Given the financial differences between PDPs and MAPDs, there may be increased efforts to convert PDP enrollment to MAPD plan enrollment. MAPDs can leverage Part C subsidies and medical cost offsets from the use of Part D therapies to help offset the plan prescription drug liability increases, while PDPs cannot. MAPDs also tend to have richer formularies than PDPs, which may be a MAPD tactic to attract more beneficiaries to their plans over PDPs. Given that PDPs have fewer levers to manage costs than MAPDs, formulary will be a focal point for PDPs under the IRA, as we have observed in our analysis.

The impact to Part D plan financials under the IRA will depend on their beneficiaries' eligibility for the Part D low-income subsidy. Under the Part D program, low-income (LI) beneficiaries can be auto-enrolled in standalone Part D plans and are subject to nominal copays. LI beneficiaries typically have higher costs to Part D plans than non-LI beneficiaries, as they tend to use more and costlier drugs, in part because of their higher comorbidities and which is currently reflected in their risk scores. The IRA is expected to increase the plan liability differences by placing more of the liability incurred by high-spending beneficiaries on the plan, and the RxHCC model recalibration is expected to reflect these growing differences. In fact, CMS has projected the average annual plan liability to increase by 138% and 69% for LI and non-LI beneficiaries, respectively.[17] However, because these adjustments are made on a population-level basis, the RxHCC model recalibration is not anticipated to result in enough revenue to offset the increased costs of LI beneficiaries using high-cost drugs, based on our analysis, potentially adding to Part D plans' financial pressures and further incentivizing formulary scrutiny.

METHODOLOGY AND DATA SOURCES

We analyzed 2022 data from Milliman's Part D Consolidated Database to project prescription drug costs of beneficiaries treated with drugs in select therapeutic classes: autoimmune, HIV, multiple sclerosis, breast and ovarian cancer, and diabetes (specifically, SGLT2 inhibitors). This data source contains actual prescription drug event (PDE) data for more than 6 million Medicare-eligible beneficiaries. Beneficiaries are identified as low-income (LI) versus non-LI based on the corresponding flags in their Monthly Membership Report records from CMS. This data source includes beneficiaries in MAPD and PDPs, and beneficiaries in individual and employer group waiver plans (EGWPs). This data can be used to identify which benefit phase the beneficiary was in for each claim.

Therapeutic class study cohorts were identified as beneficiaries with at least one script of a drug belonging to the therapeutic class of interest from the 2022 PDCD claims. Beneficiaries were included in a therapeutic class cohort regardless of RxHCC diagnosis. Our analysis accounts for all drug spending among beneficiaries in these cohorts.

We trended 2022 data to 2025 expected levels, accounting for utilization and unit cost trends, and repriced the claims under pre- and post-IRA benefit designs and summarized gross plan liabilities. To obtain net plan liabilities (after rebates), we assumed prescription drug rebates as percentage of gross costs of 10% for protected classes (HIV and breast and ovarian cancer) and 35% for non-protected classes (autoimmune, HIV, and diabetes SGTL2 inhibitors), informed on Milliman's 2024 Part D contract survey and industry knowledge. We did not model the changes to 2025 risk scores in the post-IRA scenario.

In our formulary analysis, we obtain drug tier assignments and coverage from publicly available 2023 formulary files released by CMS in October 2022. This analysis includes MAPD and PDP formularies. The beneficiary weights to obtain total MAPD and PDP results are based on the September 2022 beneficiary file available from CMS, cross-walked to a 2023 plan ID basis. Specifically, we assume 100% of September 2022 beneficiary crosswalks from the 2022 plan to the corresponding 2023 plan, as applicable.

CONCLUSION

Under the IRA benefit redesign, we estimate Part D plans will face headwinds including increased net plan costs and revenue shortfalls among high-cost therapeutic classes. We expect plans to scrutinize their formularies and possibly put strategies in place to compensate for the expected revenue shortfall for beneficiaries using high-cost drugs. Consistent with historical trends, plans could implement additional formulary restrictions through narrowing coverage and/or implementing new utilization management to help effectively manage costs, protect against the risk of adverse selection, and incent behavior. These formulary restrictions may disrupt beneficiary access to their drugs, although existing protections may help mitigate some of this disruption.

CAVEATS AND LIMITATIONS

This report was commissioned by Novartis. The findings reflect the research of the authors. Milliman does not endorse any product or organization. Novartis did not author this paper or influence the findings.

This study has several limitations. Our analysis provides results for the five selected therapeutic classes, and results by other therapeutic classes will vary. There are other dynamics impacting therapeutic classes that could result in different approaches to formulary management than described here. It is important to note that even if a drug is not covered on a beneficiary's formulary, the beneficiary may obtain the drug through their plan's exception and appeals process. While only a small fraction of appeals are rejected, the number of denied prescriptions that go through the exception and appeals process is low.[18]

While we cannot predict plan behavior, we expect that plans will seek to preserve profitability, which requires sound financial decisions, including managing formularies to mitigate risks while attracting and retaining membership.

In addition, our analysis reflects nationwide results. We expect results to vary by health plan based on the population mix and risk profile of their beneficiaries, geographic area, and type of plan, among other factors.

There is a high degree of uncertainty in the 2025 direct subsidy due to the significant changes to the Part D benefit design implemented by the IRA. We estimated the 2025 direct subsidy in our analysis to project plan revenue; however, the actual 2025 direct subsidy will differ from our estimate. In addition, the 2025 RxHCC risk score model is unknown at this time. We did not model changes to risk scores in our analysis, and any changes to risk scores could have a material impact on the revenue shortfall that we estimated in this white paper.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Jennifer Carioto, Gabriela Dieguez, and Tushar Makhija are members of the American Academy of Actuaries and meet the qualification standards for performing the analyses in this report and rendering the actuarial opinions contained herein.

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