Medicare Evaluating the potential out-of-pocket cost impact of the Senior Savings Model on Medicare Part D members who use insulin

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The Centers for Medicare and Medicaid Services (CMS) recently announced the Part D Senior Savings Model, a new Medicare Part D initiative created to reduce beneficiary cost sharing for insulin products.[1]

The Model, set to begin January 1, 2021, is designed to make insulin product cost sharing more affordable and predictable for Medicare beneficiaries. Plans opting to participate in this voluntary Model are required to provide insulin at a maximum $35 copay per 30-day supply in the first three phases of coverage under Medicare Part D (i.e., deductible, initial coverage phase, and coverage gap). Low-income subsidy (LIS) beneficiaries and employer group waiver plans (EGWPs) are not eligible to participate in the Model.

The Model also modifies how supplemental benefits, such as a $35 copay, are applied in the coverage gap. Under the current Part D benefit design, if a plan sponsor provides supplemental benefits on applicable drugs in the coverage gap, the manufacturer coverage gap discount of 70% applies only to the beneficiary cost sharing. This increases the plan's liability in the coverage gap and may discourage a plan from offering supplemental gap benefits for applicable drugs. Through the Model, however, the 70% discount paid by the manufacturer will apply prior to any supplemental benefits.

A previous Milliman white paper focused on plan sponsors considering participation in the Model.[2] In this paper, we explore the impact of the Model on patient out-of-pocket costs. Using Milliman's Part D Claims Database (PDCD) we apply the Model benefits to observed experience of non-low-income beneficiaries on insulins.

Background

Participation in the Model is voluntary for both manufacturers and plan sponsors. For sponsors, participation is limited to enhanced alternative (EA) plans, which offer benefits that exceed the value of the defined standard benefit such as reduced cost sharing or expanded coverage for drugs. CMS recently announced that over 1,750 individual Medicare Advantage Prescription Drug (MA-PD) and standalone Prescription Drug Plan (PDP) plans offered by 88 different plan sponsors have applied to participate in the program. Part D sponsors that applied must submit their calendar year 2021 plan benefits to CMS by June 1, 2020 to designate their participation in the model.[3]

Eligible manufacturers opting to participate were required to apply by March 18, 2020.[4] CMS announced that the three main insulin manufacturers in the United States, Eli Lilly and Company, Novo Nordisk, and Sanofi-Aventis, will be participating in the Model. As a result, a wide range of insulin products, including rapid-acting, short-acting, intermediate-acting, long-acting, and combination or mixed insulins will be eligible for coverage through the Model. For a full list of Model drugs and National Drug Codes (NDCs) covered, visit the CMS Part D Senior Savings website.[5]

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[1] CMS. Part D Senior Savings Model. Retrieved May 20, 2020, from https://innovation.cms.gov/innovation-models/part-d-savings-model.

[2] D'Anna, S. et al. (March 2020). Reducing Insulin Costs for Seniors: Thoughts for Plan Sponsors Considering Participation in the Medicare Part D Senior Savings Model. Milliman White Paper. Retrieved May 20, 2020, from https://milliman-cdn.azureedge.net/-/media/milliman/pdfs/articles/reducing_insulin_costs_for_seniors.ashx.

[3] President Trump Announces Lower Out of Pocket Insulin Costs for Medicare's Seniors. Retrieved May 28, 2020, from https://www.cms.gov/newsroom/press-releases/president-trump-announces-lower-out-of-pocket-insulin-costs-medicares-seniors

[4] CMS. Part D Senior Savings Model Request for Applications for Pharmaceutical Manufacturers. Retrieved May 20, 2020, from https://innovation.cms.gov/files/x/partd-seniorsav-manufacturer-rfa.pdf.

[5] CMS (March 23, 2020). Model Drug National Drug Code (NDC) List. Retrieved May 20, 2020, from https://innovation.cms.gov/files/x/partd-seniordav-ndclist.pdf.

This article provides analysis to answer the following research questions:

1. What is the expected reduction in insulin out-of-pocket costs for beneficiaries enrolled in plans that participate in the Model?
2. How do patient savings vary for insulin patients enrolled in plans offering different benefit designs (deductible, copay, or coinsurance)?
3. How do patient savings vary with the total annual drug spend of the insulin patient?

Beneficiary impact

Higher out-of-pocket costs are associated with higher rates of medication abandonment for insulin users.[6] In Medicare Part D, this may be exacerbated by the complex benefit structure for many Medicare Part D plans. The benefit structure in Medicare Part D includes four distinct benefit phases: the deductible, the initial coverage phase, the coverage gap, and the catastrophic phase. Patient cost sharing for the same medication with the same dosing filled at the same pharmacy can and often does vary across each of these benefit phases. The Model aims to make these costs affordable and predictable for a broad set of insulins.[7]

In the Model, patients will pay the same copay amount every month for insulin products at no more than $35 per 30-day script, up to the catastrophic phase. In contrast, out-of-pocket costs for a patient in a plan not participating in the Model can range from $25 to nearly $250 for claims not subject to a deductible. The out-of-pocket cost can reach the full cost of the deductible ($445 in 2021), although many EA plans offer no deductible or reduced deductibles.

There are two potential trade-offs to consider associated with the Model. First, all members in participating plans, even those not taking insulin, may be subject to higher premiums to cover the modest additional cost that plans will bear to participate in the Model. However, we expect Part D premium increases will be nominal for plans participating in the Model. This is driven by several factors:

1. Non-LIS beneficiaries who are diabetic and insulin-dependent tend to be small portions of a plan's total enrollment and plan premiums are calculated based on plan averages for its total enrollment. However, participation in the Model may attract more Model-eligible members.

2. MA-PD plans often target a $0 premium for their Part D benefits, with about 55% of members selecting these $0 premium plans.[8] This is achieved by using "Part C savings," also known as "Part C rebates," to buy down the Part D premiums. MA-PD plans wishing to continue to target a $0 premium for their Part D benefits will likely use more Part C rebates to offset any incremental change in Part D premiums. PDP-only sponsors do not have this revenue source.

3. Plans may demand additional manufacturer rebates or price concessions to offset the expected increase in cost from participation in the Model. Additionally, we note that the portion of manufacturer rebates retained by the plan may increase slightly due to less spending (on average) in the catastrophic phase, as patients on insulins will accumulate true out-of-pocket (TrOOP) costs at slower rates.

Second, patients on insulins in the Model will accumulate TrOOP costs more slowly and may spend more time in the coverage gap before reaching the catastrophic phase. Because these patients are spending less out-of-pocket on insulins, some non-insulin prescriptions that would have otherwise been subject to the 5% catastrophic coinsurance will instead be subject to the standard coverage gap coinsurance of 25%. This would only impact patients who spend enough to hit the catastrophic phase, and these additional out-of-pocket costs would be more than offset by the patient's savings on insulin, as illustrated in the results below.

Results

In order to evaluate the impact of the Model across various patient groups, we look at the modeled impact on four different benefit design scenarios. These benefit designs were selected to evaluate the impact of the Model on patients enrolled in plans with and without a deductible as well as different levels of cost sharing for insulins in the initial coverage phase.

- Deductible of $445 and $47 insulin copay
- No deductible and $47 insulin copay
- Deductible of $445 and 25% coinsurance for insulins
- No deductible and 25% coinsurance for insulins

Each of these scenarios is compared to the Model benefit design ($35 insulin copay in the deductible, initial coverage phase, and coverage gap). Figure 1 shows a summary of the average out-of-pocket cost reductions for patients who use insulin for each of the four benefit design scenarios.

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[6] Bibeau, W.S. et al. (November 2016). Impact of out-of-pocket pharmacy costs on branded medication adherence among patients with type 2 diabetes. JMCP. Retrieved May 20, 2020, from https://www.jmcp.org/doi/full/10.18553/jmcp.2016.22.11.1338.

[7] CMS (March 11, 2020). Fact Sheet: Part D Senior Savings Model. Retrieved May 20, 2020, from https://www.cms.gov/newsroom/fact-sheets/part-d-senior-savings-model.

[8] Piper, B.J. & Gabe, M.L. (April 2019). Hang on Tight! Why Maintaining a Zero-Dollar MA-PD Premium Plan Is Worth the Effort. Milliman White Paper. Retrieved May 20, 2020, from http://assets.milliman.com/ektron/zero-dollar-ma-pd-premium-plan.pdf.

In Figure 1, we see that insulin patients under all of the benefit design scenarios have reductions in average out-of-pocket cost. Patients who are currently subject to a 25% coinsurance for their insulins would have higher savings than patients with a $47 copay for insulin due to lower costs in the initial coverage phase. Patients with a deductible would benefit more from the Model because insulins that would have been subject to the deductible under standard EA plan benefits now only cost the patient $35.

FIGURE 1: AVERAGE OUT-OF-POCKET COST REDUCTIONS

DRUG CATEGORY	PATIENT OOP (EA)	PATIENT OOP (MODEL)	PATIENT SAVINGS	TOTAL PATIENT SAVINGS
EA BENEFIT: DEDUCTIBLE AND $47 COPAY				
Non-Insulin Rx	$935	$1,012	$(77)	$488
Insulin Rx	$918	$353	$565	
EA BENEFIT: NO DEDUCTIBLE AND $47 COPAY				
Non-Insulin Rx	$838	$848	$(10)	$315
Insulin Rx	$678	$353	$325	
EA BENEFIT: DEDUCTIBLE AND 25% COINSURANCE				
Non-Insulin Rx	$954	$1,047	$(93)	$669
Insulin Rx	$1,115	$353	$762	
EA BENEFIT: NO DEDUCTIBLE AND 25% COINSURANCE				
Non-Insulin Rx	$859	$878	$(20)	$548
Insulin Rx	$920	$353	$567	

For all four scenarios, we see some degree of non-insulin cost offset. This is due to an aggregate downshift in costs resulting in more costs falling under the deductible, initial coverage, and coverage gap phases. As a result, fewer beneficiaries may reach the catastrophic phase.

To further explore how the Model potentially reduces the out-of-pocket cost of patients who use the Part D program, we also looked at the different levels of patient savings based on the patients' total annual Part D allowed cost. By separating patients into 10 segments based on total allowed cost, we can see how the Model impacts patient cohorts differently and infer how the Model affects their exposure to the benefit phases of Part D.

Figure 2 shows the benefit design scenario for patients with a deductible and $47 copayment for insulins and preferred brand drugs. A summary of other benefit design scenarios by allowed decile can be found in the appendix. For this benefit design scenario, we see that all decile groups would have lower out-of-pocket costs under the Model. We can also see that in the top

two decile groups, the total savings is lower than the eighth decile group. Very high utilizers of the Part D program will likely meet the TrOOP threshold relatively early in the year compared to other patients. Once a patient is in the catastrophic phase of Part D, the Model insulin copayment structure no longer applies.

FIGURE 2: EA BENEFIT: DEDUCTIBLE AND $47 COPAY

ALLOWED DECILE	ALLOWED RANGE	PATIENT OOP (EA)	PATIENT OOP (MODEL)	TOTAL PATIENT SAVINGS
1st	$0 - $1,957	$734	$475	$260
2nd	$1,957 - $3,021	$1,013	$700	$314
3rd	$3,021 - $3,827	$1,148	$800	$348
4th	$3,827 - $4,579	$1,269	$901	$368
5th	$4,579 - $5,527	$1,466	$1,033	$433
6th	$5,527 - $6,738	$1,708	$1,190	$518
7th	$6,738 - $8,361	$2,041	$1,430	$611
8th	$8,361 - $11,188	$2,490	$1,769	$721
9th	$11,188 - $16,435	$2,800	$2,100	$700
10th	>$16,435	$3,852	$3,242	$610

Impact on manufacturers, payers, and the government

We anticipate the Model having some impact on manufacturers. While manufacturers would have to pay the same amount of coverage gap payments for insulin fills in the coverage gap under the Model, they will pay slightly more coverage gap payments due to patients taking longer to reach the catastrophic threshold. This increase in coverage gap payments will impact all brand manufacturers, not only the participating insulin manufacturers. However, insulin manufacturers may see increased revenue if the Model induces utilization, as patients may become more adherent and thus fill more scripts. As noted previously, all major insulin manufacturers opted to participate in the Model.

Payers may anticipate increased premiums in plans where they are participating in the Model, though they could mitigate those increases with reduced margin or reduced supplemental benefits in Part C. While the Part D portion of insulin-taking members is typically profitable for plans, Medicare Advantage payers will need to understand their ability to efficiently manage the medical costs for these members, especially because risk corridor programs offer protection on Part D claims only.

Government costs may decrease due to fewer members reaching the catastrophic threshold. If beneficiary premiums increase, this would only affect the supplemental premium and not increase direct subsidy payments.

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Methodology

This analysis was performed on a calendar year 2018 sample of Part D beneficiaries from the Milliman PDCD. The beneficiaries were aged, non-LIS members enrolled in a Part D plan for the entire calendar year, who filled at least two insulin prescriptions covered under the Model during 2018. Observed price increases as of January 1, 2020, were applied to the drug cost of all scripts used in the analysis. Additionally, price change factors for brands, generics, and specialty products were calculated and used to adjust drug costs an additional year to reflect projected 2021 drug costs.

The Part D benefit design scenarios were applied to the claims. This process uses the projected allowed cost of each patient's claims and applies the Part D benefit design scenarios for each patient. The four scenarios hold all parts of the benefit design constant except for the presence of a deductible and the preferred brand tier (tier 3) cost-sharing amount. Other assumptions include:

- Deductible (when present): $445
- Allowed threshold: $4,130
- TrOOP threshold: $6,550
- Tier 1 cost share in the ICL: $2
- Tier 2 cost share in the ICL: $10
- Tier 3 cost share in the ICL: $47 or 25%
- Tier 4 cost share in the ICL: 35%
- Tier 5 cost share in the ICL: 33%
- Tier 6 cost share in the ICL: $10

These four baseline scenarios are compared to modeled patient experience under the Model where the insulin copay is assumed to be $35 for patients in the deductible, initial coverage limit (ICL), and coverage gap.

Caveats

The modeled values do not take into account any changes to patient behavior between 2018 and 2021 such as increased adherence to insulins or other medications as a result of the Model. The analysis relies on projected drug prices to evaluate the expected impact of the benefit design change for 2021. Results will vary to the extent that these price increases differ from the projected amounts. The impact of the Model will vary based on specific plan benefits, plan membership, and changes to laws and regulations. The results reflect the average expected impact and will vary for any individual plan or member.

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Appendix

EA BENEFIT: DEDUCTIBLE AND $47 COPAY

ALLOWED DECILE	ALLOWED RANGE	PATIENT OOP (EA)	PATIENT OOP (MODEL)	TOTAL PATIENT SAVINGS
1st	$0 - $1,977	$734	$475	$260
2nd	$1977 - $3,067	$1,013	$700	$314
3rd	$3,067 - $3,900	$1,148	$800	$348
4th	$3,900 - $4,676	$1,269	$901	$368
5th	$4,676 - $5,655	$1,466	$1,033	$433
6th	$5,655 - $6,908	$1,708	$1,190	$518
7th	$6,908 - $8,599	$2,041	$1,430	$611
8th	$8,599 - $11,522	$2,490	$1,769	$721
9th	$11,522 - $16,970	$2,800	$2,100	$700
10th	>$16,970	$3,852	$3,242	$610

DEDUCTIBLE AND 25% COINSURANCE

ALLOWED DECILE	ALLOWED RANGE	PATIENT OOP (EA)	PATIENT OOP (MODEL)	TOTAL PATIENT SAVINGS
1st	$0 - $1,977	$700	$455	$245
2nd	$1,977 - $3,067	$1,036	$665	$371
3rd	$3,067 - $3,900	$1,298	$778	$520
4th	$3,900 - $4,676	$1,501	$904	$597
5th	$4,676 - $5,665	$1,725	$1,055	$670
6th	$5,655 - $6,908	$1,996	$1,236	$760
7th	$6,908 - $8,599	$2,353	$1,501	$852
8th	$8,599 - $11,522	$2,799	$1,857	$943
9th	$11,522 - $ 16,970	$3,099	$2,193	$907
10th	>$16,970	$4,169	$3,345	$824

NO DEDUCTIBLE AND $47 COPAY

ALLOWED DECILE	ALLOWED RANGE	PATIENT OOP (EA)	PATIENT OOP (MODEL)	TOTAL PATIENT SAVINGS
1st	$0 - $1,977	$444	$394	$50
2nd	$1,977 - $3,067	$689	$599	$91
3rd	$3,067 - $3,900	$801	$687	$114
4th	$3,900 - $4,676	$909	$764	$145
5th	$4,676 - $5,655	$1,100	$876	$224
6th	$5,655 - $6,908	$1,337	$1,016	$321
7th	$6,908 - $8,559	$1,668	$1,230	$438
8th	$8,599 - $11,522	$2,138	$1,548	$591
9th	$11,522 - $16,970	$2,503	$1,885	$619
10th	>$16,970	$3,561	$3,005	$556

NO DEDUCTIBLE AND 25% COINSURANCE

ALLOWED DECILE	ALLOWED RANGE	PATIENT OOP (EA)	PATIENT OOP (MODEL)	TOTAL PATIENT SAVINGS
1st	$0 - $1,977	$417	$341	$76
2nd	$1,977 - $3,067	$738	$536	$202
3rd	$3,067 - $3,900	$993	$642	$351
4th	$3,900 - $4,676	$1,192	$752	$440
5th	$4,676 - $5,655	$1,414	$889	$525
6th	$5,655 - $6,908	$1,685	$1,059	$626
7th	$6,908 - $8,599	$2,042	$1,306	$735
8th	$8,599 - $11,522	$2,515	$1,650	$865
9th	$11,522 - $16,970	$2,854	$1,995	$859
10th	>$16,970	$3,927	$3,129	$798