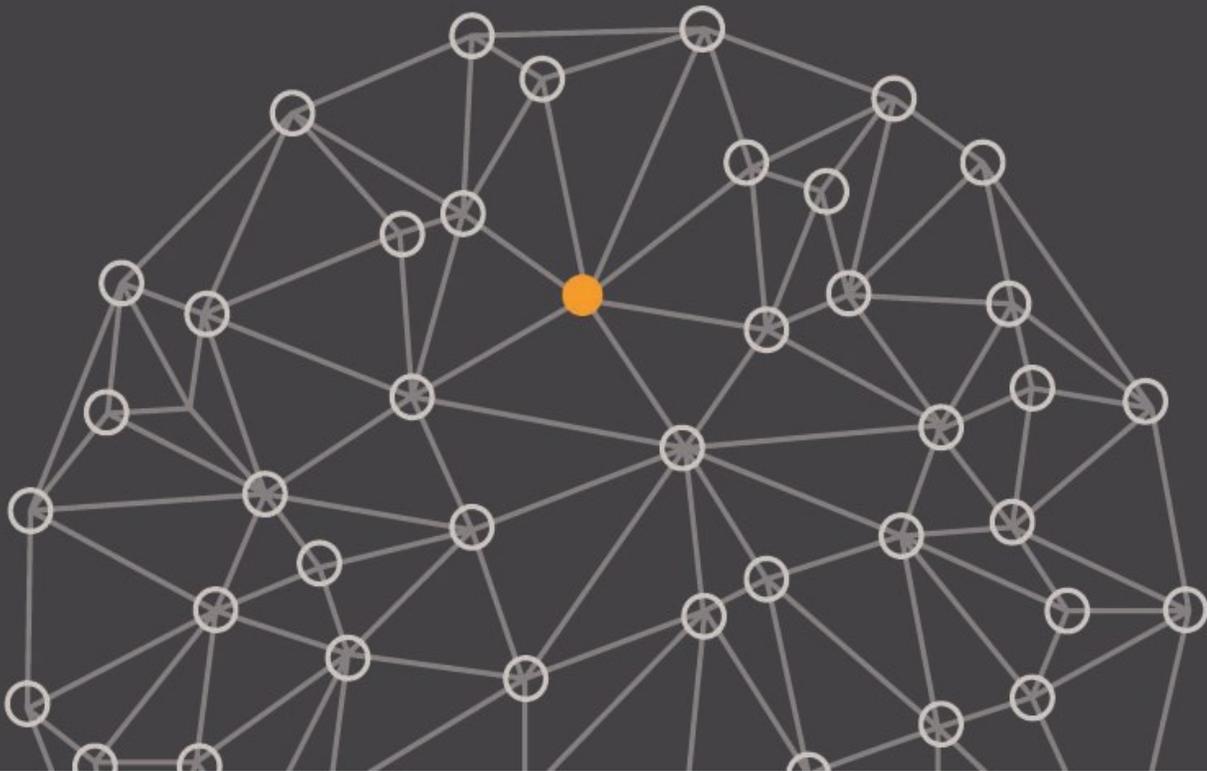


Mitigating out-of-pocket costs for insulin users

Commissioned by Eli Lilly

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Executive Summary

In 2016, Eli Lilly and Company (Lilly) commissioned Milliman to perform an analysis of approaches that plan administrators could use to reduce member out-of-pocket costs for brand-name drugs. The approaches included in that analysis were selected because they were expected to create a meaningful reduction in patient out-of-pocket costs without creating substantial financial and operational disruptions to plan administrators and insured groups. The discussion document resulting from that analysis, titled "Mitigating out-of-pocket costs for prescription drugs," reviewed the following:

- The need for cost-mitigating solutions
- Why insulins can be used as a case study
- Trends in the value of manufacturer price concessions
- Summary of out-of-pocket mitigation approaches considered and analyzed
- Results from the out-of-pocket mitigation approaches analyzed, including insulins exempt from cost sharing and reduced member cost sharing at the point of sale
- A discussion of stakeholder perspectives

In 2019, Lilly commissioned Milliman to refresh the analysis.

The scope of this analysis is focused on high-deductible health plans (HDHPs) in the employer-sponsored group insurance (commercial) market in the United States. HDHPs are the focus of this analysis because these plans are expected to consistently result in high out-of-pocket cost exposure at the beginning of the plan year for members who use insulin. In addition, HDHPs are increasingly utilized, resulting in higher out-of-pocket cost exposure for members seeking the lower premiums typically offered by these plans. Since 2013, a 50% increase in HDHP enrollment has helped drive a 53% increase in the average deductible for single coverage among all workers.¹ Insulin users were the sub-cohort of interest in this analysis due to their high cost burden on users² and their special interest to Lilly.

Three scenarios were modeled in this analysis. Each scenario modeled was intended to reduce out-of-pocket costs for insulin users while fitting within the current healthcare framework and creating minimal increases in the total cost of benefits for members. Estimates for the scenario impact were produced by re-adjudicating claims based on member benefit designs and scenario-specific changes in patient cost sharing on insulin claims. The re-adjudication methodology allows actual member experience to reflect hypothetical benefit designs, often shifting patient cost exposure between the deductible and coverage phase. We note that out-of-pocket costs for other services may have greater exposure to the deductible and/or coverage phase as a result of reducing cost sharing for insulins. An overview of the scenarios included in this analysis and their impact on member out-of-pocket costs and premiums is provided below.

SCENARIO 1: PROPORTIONAL REBATE SHARING ON INSULIN

In this modeled scenario, manufacturer rebates on insulins are passed through to patients at the point of sale. Under our assumptions, this results in a 50% reduction to member deductible and coinsurance out-of-pocket costs for insulin transactions. Modeling results include the following:

- Insulin users would save an estimated \$142 per year on total out-of-pocket costs and \$396 per year on insulin out-of-pocket costs, on average.
 - Insulin savings are higher than total savings for the following reason: Member savings on insulin claims often shift which phase of coverage subsequent claims are adjudicated in. As medical and other pharmacy claims shift from the benefit phase to the deductible, they typically face higher member cost sharing. Higher member cost sharing on these medical and other pharmacy claims offsets insulin out-of-pocket savings, resulting in total out-of-pocket savings that are lower than insulin out-of-pocket savings.
- An estimated 19% of insulin users would save over \$250 on total out-of-pocket costs per year, while an estimated 32% of insulin users would save over \$500 on insulin out-of-pocket costs per year.
 - As mentioned above, insulin out-of-pocket savings are greater than total out-of-pocket savings due to shifting member cost sharing on non-insulin claims.

¹ Kaiser Family Foundation. Employer Health Benefits: 2018 Summary of Findings. Retrieved May 17, 2019, from <http://files.kff.org/attachment/Summary-of-Findings-Employer-Health-Benefits-2018>.

² American Diabetes Association (May 2018). Economic Costs of Diabetes in the U.S. in 2017. *Diabetes Care*. Retrieved May 17, 2019, from <http://care.diabetesjournals.org/content/diacare/41/5/917.full.pdf>.

- Premiums for all members would increase an estimated \$0.13 per member per month (PMPM), or \$1.51 per member per year (PMPY), assuming an 85% medical loss ratio.
 - Premium increases are relatively small because insulin users, which are the only members with the potential for out-of-pocket savings in this scenario, make up 1.1% of all HDHP members.

SCENARIO 2: PROPORTIONAL REBATE SHARING ON BRAND-NAME PRODUCTS

In this modeled scenario, for rebate-eligible products, manufacturer rebates would be passed through to patients at the point of sale. The scope of this scenario includes members taking insulin and members taking other rebate-eligible brand-name drugs. Modeling results include the following:

- Insulin users would save an estimated \$176 per year on total out-of-pocket costs, \$379 per year on insulin out-of-pocket costs, and \$26 per year on other rebate-eligible drug out-of-pocket costs, on average.
 - Similar to scenario 1, total savings are lower than insulin savings because savings on rebate-eligible claims shift subsequent claims into the deductible, where they experience higher member cost sharing, thus offsetting out-of-pocket savings on insulin claims. Unlike scenario 1, where insulin claims could only move from the benefit phase to the deductible when there was an insulin claim in the deductible, the rebate-sharing cost-sharing reduction in scenario 2 insulin claims can move from the benefit phase to the deductible based on reduced cost sharing on prior non-insulin claims. This results in lower insulin out-of-pocket savings relative to scenario 1, but increased total out-of-pocket savings as members save on other brand-name drugs.
- An estimated 26% of insulin users would save over \$250 on total out-of-pocket costs per year, while an estimated 31% of insulin users would save over \$500 on insulin out-of-pocket costs per year.
- Brand-name drug users would save an estimated \$55 per year on total out-of-pocket costs and \$84 per year on drug out-of-pocket costs, on average.
- Premiums for all members would increase an estimated \$1.43 per member per month (PMPM), or \$17.16 per member per year (PMPY), assuming an 85% medical loss ratio.
 - Premium increases are larger in scenario 2 because 31.2% of all HDHP members have the potential to save, compared to just 1.1% in scenario 1.

SCENARIO 3: INSULINS EXEMPT FROM PATIENT COST SHARING

In this modeled scenario, patient cost sharing for insulin transactions is reduced to \$0. This is similar to the treatment of products on the Patient Protection and Affordable Care Act (ACA) preventive drug list. Modeling results include the following:

- Insulin users would save an estimated \$481 per year on total out-of-pocket costs and \$1,162 per year on insulin out-of-pocket costs, on average.
 - While scenario 3 does not involve rebate sharing like scenarios 1 and 2, the reasoning for greater insulin savings than total savings is similar. If insulin has \$0 member cost sharing, subsequent claims can shift into the deductible where member cost sharing is typically higher, partially offsetting the out-of-pocket savings on insulin.
- An estimated 51% of insulin users would save over \$250 on total out-of-pocket costs per year, while an estimated 69% of insulin users would save over \$500 on insulin out-of-pocket costs per year.
- Premiums for all members would increase an estimated \$0.43 per member per month (PMPM), or \$5.12 per member per year (PMPY), assuming an 85% medical loss ratio.
 - As with scenario 1, only insulin users, who make up 1.1% of all HDHP members, have the potential for out-of-pocket savings in this scenario.

Background

The purpose of this analysis is to identify potential approaches that plan administrators could take in an effort to reduce out-of-pocket costs for insulin-taking members. Milliman was initially commissioned by Lilly to perform analysis on this topic in 2016. In that analysis, two scenarios were analyzed:

- Insulins exempt from member cost sharing
- Utilizing manufacturer rebates to reduce the point-of-sale drug cost

These scenarios were identified because they meet the following criteria:

- 1) **Provide material relief.** The approach should provide a material reduction in out-of-pocket costs for the beneficiaries impacted by it.
- 2) **Produce modest increase.** The approach should result in a relatively small impact to the total cost of benefits (e.g., premiums).
- 3) **Preserve alignment.** The approach should continue to align the payer, prescriber, and patient to a preference for lower-cost generic therapies when they are available.
- 4) **Promote competition.** The approach should continue to encourage competition among clinically comparable products.
- 5) **Be feasible.** It should be possible to implement the proposal within the existing framework for reimbursement of prescription drugs. This characteristic addresses both operational and legislative consideration. Plan administrators should be able to implement the approach within the existing adjudication systems, and the approach should be feasible without any changes to legislation or regulation.

In 2019, Milliman was commissioned by Lilly to refresh the 2016 analysis, with a heightened focus on insulin users in HDHPs. Key metrics resulting from this analysis include total member savings, reduction of insulin out-of-pocket costs, and increases in plan premiums.

The three scenarios modeled in this update are:

- Scenario 1: Proportional rebate sharing on *insulin*
- Scenario 2: Proportional rebate sharing on rebate eligible *brand-name drugs*
- Scenario 3: *Insulins* exempt from patient cost sharing

The remainder of this paper will review the methodology used in this analysis, additional information on how scenarios were implemented, and the estimated financial impact of each scenario.

Methodology

DATA SOURCE

We used the calendar year 2016 IBM MarketScan Commercial Claims and Encounters database as the basis for this analysis. The Commercial Claims and Encounters database is a robust sample of medical and prescription drug claims associated with employer group health plans. For this analysis, we identified plans with a high-deductible health plan (HDHP) benefit design. Further, we excluded any plans that appeared to have already implemented scenario 3 above (i.e., where insulin cost sharing was \$0).

COHORTS

Members with the following characteristics were included in the HDHP cohort:

- Individual deductible level according to MarketScan's Benefit Plan Design (BPD) database was greater than the minimum of \$1,300 for a qualifying HDHP
- Individual maximum out-of-pocket level was available in the BPD database
- Full 12 months of plan enrollment according to MarketScan's enrollment tables

Within the HDHP cohort, there are two sub-cohorts:

- 1.1% of HDHP members in our sample met the inclusion criteria for the insulin user cohort, relevant in all three scenarios. These members met the HDHP cohort criteria and had one or more insulin claims in 2016. Members who reached their out-of-pocket maximums before experiencing an insulin claim were not included in this cohort as they already had zero out-of-pocket costs for insulins and thus did not have the potential for savings on insulin (this removed 5.2% of all insulin users). Insulins were defined at the National Drug Code (NDC) level using the product list seen in Figure 1.

FIGURE 1: INSULINS INCLUDED IN SCENARIO ANALYSIS		
AFREZZA	HUMULIN N KWIKPEN	NOVOLIN N U-100
APIDRA	HUMULIN N U-100 PEN	NOVOLIN R
APIDRA SOLOSTAR	HUMULIN R	NOVOLIN R RELION
BASAGLAR KWIKPEN	HUMULIN R U-500 (CONCENTRATED)	NOVOLOG
HUMALOG	HUMULIN R U-500 KWIKPEN	NOVOLOG FLEXPEN
HUMALOG KWIKPEN	LANTUS	NOVOLOG MIX 70/30
HUMALOG MIX 50/50	LANTUS SOLOSTAR	NOVOLOG MIX 70/30 PREFILLED FLEXPEN
HUMALOG MIX 50/50 KWIKPEN	LEVEMIR	NOVOLOG PENFILL
HUMALOG MIX 75/25	LEVEMIR FLEXPEN	RELION 70/30
HUMALOG MIX 75/25 KWIKPEN	LEVEMIR FLEXTOUCH	RELION N
HUMULIN 70/30	NOVOLIN 70/30	RELION R
HUMULIN 70/30 KWIKPEN	NOVOLIN 70/30 RELION	SOLIQUA 100/33
HUMULIN 70/30 PEN	NOVOLIN N	TOUJEO SOLOSTAR
HUMULIN N	NOVOLIN N RELION	TRESIBA FLEXTOUCH

Note: Products listed often have multiple associated NDCs.

- 31.2% of HDHP cohort members in our sample met the inclusion criteria for the brand user cohort, specific to scenario 2. These members met the HDHP cohort criteria and had at least one claim for a rebate eligible brand drug in 2016. Members who reached their out-of-pocket maximum before experiencing a rebate eligible drug claim were not included in this cohort as they already had zero out-of-pocket costs for rebate eligible drugs and thus did not have the potential for savings on rebate eligible claims (this removed 4.5% of all brand users).

BASELINE EXPERIENCE

We identified 1.2 million members who met the criteria for the HDHP cohort. Benefit designs of these members varied widely, but were required to have a minimum individual deductible of \$1,300. We observed plans with copayments, coinsurance, and mixes of cost-sharing requirements. For all members, we restated the calendar year 2016 experience to consistently represent the individual benefit design parameters (i.e., deductible and out-of-pocket maximum), assuming an integrated benefit design. The out-of-pocket amounts for each service were applied consistently with the observed experience for the member. When a member did not have experience in the coverage phase from which to observe service cost sharing, the most frequent copay or coinsurance amount for the service from the member's plan group was used. If the plan group did not have experience for a particular service in the coverage phase, we assumed a 20% coinsurance requirement.

Based on the baseline calendar year experience, the average premium for the HDHP plans included in the analysis was \$352.88, assuming an 85% medical loss ratio. We note that the study reflects the experience of multiple data contributors. We did not trend the experience, nor restate the experience to a common benefit design or provider fee schedule. The results in this analysis are expected to be reasonable but may not represent the actual results any particular plan would experience if the scenarios were implemented.

SCENARIOS

Patient out-of-pocket costs and impact on premium were developed by re-adjudicating the baseline calendar year 2016 experience under each of the three scenarios. Behavioral changes, included adherence changes, were not modeled in any scenario. For members of the insulin cohort or brand-name drug cohort (for scenario 2 only), member out-of-pocket costs were restated consistent with the assumptions for the scenario. When patient cost is removed from insulin transactions it also impacts how quickly patients satisfy their deductibles or reach their out-of-pocket maximums. If a patient benefits from one of the outlined scenarios, but overall resource use still exceeds the out-of-pocket maximum, then it would be expected they would not experience a change in annual out-of-pocket cost despite reducing the insulin out-of-pocket costs.

Scenario 1: Implementation and results

IMPLEMENTATION

Insulins have been identified as a drug class where patients may face high cost when enrolled in high-deductible health plans,³ despite manufacturer rebates that can be in excess of 50% of the list price.⁴ One approach to reducing the high patient cost burden is passing these manufacturer rebates through to patients at the point of sale. There are two primary approaches to model rebate sharing:

- A “dollar-for-dollar” rebate-sharing approach would reduce member out-of-pocket cost by the dollar amount of the rebate. If a \$100 claim had a 30% rebate, the member would receive an effective \$30 reduction in out-of-pocket cost.
 - If the claim fell in the deductible, then the member would pay \$70 rather than paying \$100 in the status quo.
 - If the claim fell in the benefit phase, where there is a 20% coinsurance, then the member would have \$0 out-of-pocket costs rather than paying \$20 in the status quo.
- A proportional rebate-sharing approach reduces the point of sale drug cost by the rebate percentage, effectively reducing deductible and coinsurance payments by the rebate proportion (note that in real-world applications the out-of-pocket reduction proportion could be based on an average rate across a set of rebate earning products to protect rebate level confidentiality). If a \$100 claim had a 30% rebate, the member would receive an effective 30% reduction in out-of-pocket cost.
 - If the claim fell in the deductible, then the member would pay \$70 rather than paying \$100 in the status quo.
 - If the claim fell in the benefit phase, where there is a 20% coinsurance, then the member would pay \$14 rather than \$20 in the status quo.
 - Note that proportional rebate sharing has no impact on copays, as copays are not directly related to point of sale drug costs.

The scenario modeled uses proportional rebate sharing and an assumed 50% insulin rebate to effectively reduce member deductible and coinsurance payments on insulin claims by half. The implementation of proportional rebate sharing used in this analysis is illustrated in Figure 2.

³ Kaiser Family Foundation, op cit.

⁴ Eli Lilly and Company (2018). 2018 Integrated Summary Report. Retrieved May 17, 2019, from <https://www.lilly.com/2018-integrated-summary-report>.

FIGURE 2: PROPORTIONAL REBATE SHARING: MEMBER OUT-OF-POCKET IMPACT

Illustrations assume a 50% manufacturer rebate and 20% member cost sharing in the benefit phase (i.e., after deductible is satisfied, but before out-of-pocket maximum is reached).

MEMBER OUT-OF-POCKET COST ILLUSTRATION	DEDUCTIBLE PHASE*		
Point of sale product cost	\$400	\$600	\$1,000
Reduced point of sale product cost after 50% rebate	\$200	\$300	\$500
Status quo member out-of-pocket (100% of original cost)	\$400	\$600	\$1,000
Scenario member out-of-pocket (100% of reduced cost)	\$200	\$300	\$500
	BENEFIT PHASE**		
Point of sale product cost	\$400	\$600	\$1,000
Reduced point of sale product cost after 50% rebate	\$200	\$300	\$500
Status quo member out-of-pocket (20% of original cost)	\$80	\$120	\$200
Scenario member out-of-pocket (20% of reduced cost)	\$40	\$60	\$100

* Assumes entire claim falls into the deductible and claim has a 50% manufacturer rebate.

** Assumes entire claim falls into the benefit phase with a 20% coinsurance and claim has a 50% manufacturer rebate.

AVERAGE OUT-OF-POCKET SAVINGS

Insulin users are the only members with the potential for savings in this scenario. On average, insulin cohort members saved \$396 per year on insulin, and \$142 overall (Figure 3). As members experience savings on insulin claims, they progress through their deductibles more slowly. This can expose subsequent claims to higher cost sharing if they move from the benefit phase to the deductible. Likewise, members who reach their out-of-pocket maximums regardless of the cost-sharing changes will experience savings on insulin claims but no overall savings. In this scenario, the average savings of \$396 on insulin claims is offset by an average increase of \$254 on medical and other pharmaceutical claims, resulting in \$142 of net savings.

FIGURE 3: PROPORTIONAL REBATE SHARING ON INSULIN: AVERAGE TOTAL OUT-OF-POCKET SAVINGS

CLAIM TYPE	INSULIN USER COHORT* (1.1% OF TOTAL HDHP COHORT)			
	STATUS QUO OOP	SCENARIO OOP	PMPY SAVINGS	PMPM SAVINGS
Insulin	\$1,161.74	\$765.26	\$396.47	\$33.04
All Other**	\$2,402.71	\$2,657.02	-\$254.31	-\$21.19
Total	\$3,564.45	\$3,422.28	\$142.16	\$11.85

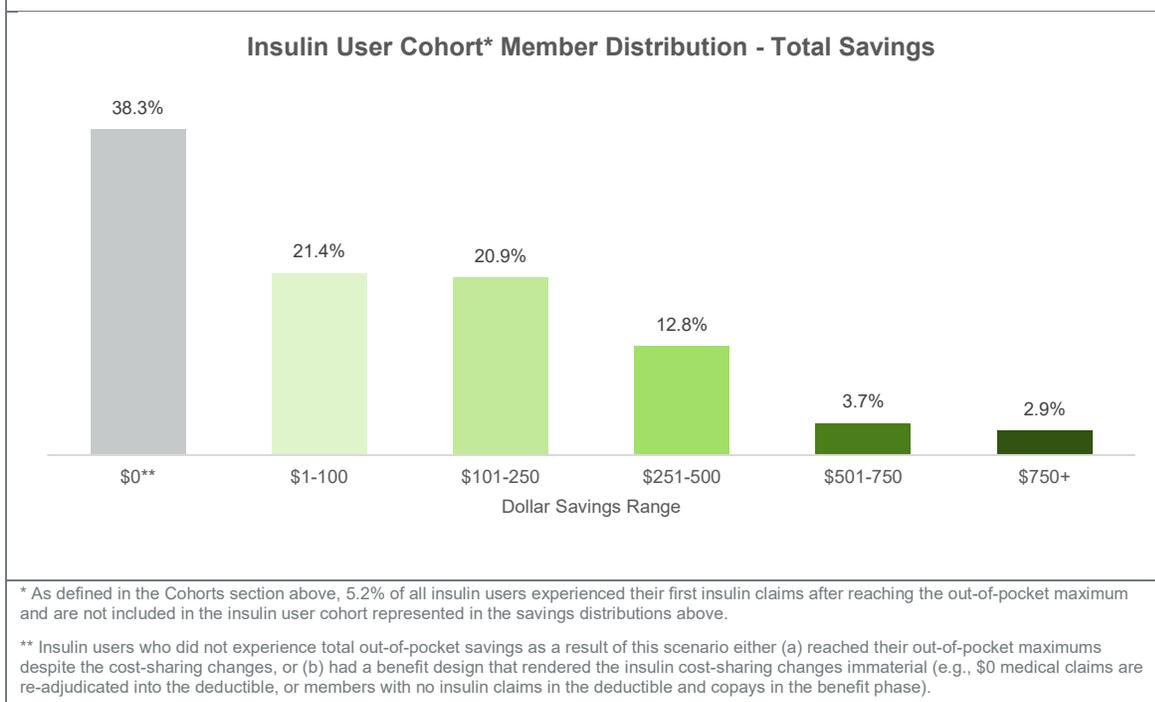
* As defined in the Cohorts section above, 5.2% of all insulin users experienced their first insulin claims after reaching the out-of-pocket maximum and are not included in the insulin user cohort represented in the savings calculations above.

** As members save on insulin claims, medical claims and other pharmaceutical claims can be subject to higher member cost sharing, leading to negative out-of-pocket savings (i.e. increased out-of-pocket costs).

IMPACT ON INSULIN USERS' TOTAL OUT-OF-POCKET COSTS

Our modeling estimates that 62% of insulin users experienced a lower annual out-of-pocket cost in this scenario. Figure 4 provides a distribution of the percentage of insulin users at each band of total annual out-of-pocket savings. Insulin users who did not experience total out-of-pocket savings as a result of this scenario either (a) reached the out-of-pocket maximum despite the cost-sharing changes (29% of insulin users in this scenario, see Appendix A6 for the full distribution by coverage phase), or (b) had a benefit design that rendered the insulin cost-sharing changes immaterial (e.g., medical claims with no member cost sharing are re-adjudicated into the deductible, or members with no insulin claims in the deductible and copays in the benefit phase).

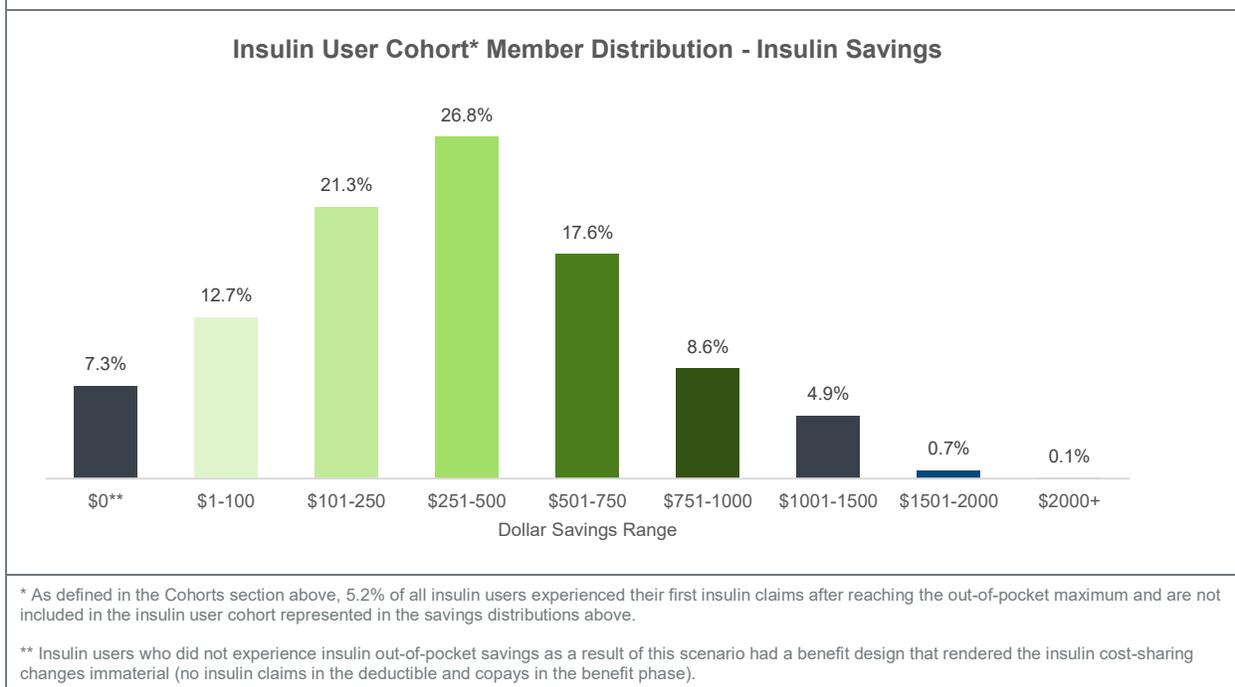
FIGURE 4: PROPORTIONAL REBATE SHARING ON INSULIN: TOTAL SAVINGS INSULIN COHORT MEMBER DISTRIBUTION



IMPACT ON INSULIN USERS’ INSULIN OUT-OF-POCKET COSTS

Ninety-three percent of insulin users experienced savings on the out-of-pocket costs for their insulin prescriptions, but the level of savings varies. Figure 5 provides a distribution of the percentage of insulin users at each band of insulin annual out-of-pocket savings.

FIGURE 5: PROPORTIONAL REBATE SHARING ON INSULIN: INSULIN SAVINGS INSULIN COHORT MEMBER DISTRIBUTION



ESTIMATED IMPACT ON PREMIUM

This scenario results in a PMPM premium increase of \$0.13, or \$1.51 PMPY. This is a 0.04% premium increase assuming an 85% medical loss ratio.

Scenario 2: Implementation and results

IMPLEMENTATION

At the time this analysis was conducted, the U.S. Department of Health and Human Services (HHS) has proposed a rule to share rebates through the point of sale in the Medicare and Medicaid channels.⁵ Scenario 2 adopts the proposed rule from HHS and applies it to HDHPs in the commercial channel. Some stakeholders in the commercial market, such as UnitedHealthcare, have implemented plan designs that utilize rebate pass-through.⁶

Scenario 2 uses the proportional rebate-sharing logic used on insulins in scenario 1 above (example shown in Figure 2), and applies it to all rebate-eligible drugs. The rebate assumptions applied varied by drug type: insulins (50%), specialty products (35%), and other brand-name drugs (20%).

AVERAGE OUT-OF-POCKET SAVINGS

Scenario 2 differs from scenario 1 because it impacts both insulin users and other brand-name users. For that reason, summaries for the brand-name cohort are also included in this section.

On average, insulin cohort members saved \$379 per year on insulin, \$26 per year on other rebate-eligible pharmaceutical claims, and \$176 overall (Figure 6). In the larger brand-name user cohort (33% of the total HDHP cohort), members saved \$92 per year on rebate-eligible pharmaceutical claims and \$53 per year total, on average.

FIGURE 6: PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS: AVERAGE OUT-OF-POCKET SAVINGS

CLAIM TYPE	INSULIN USER COHORT* (1.1% OF TOTAL HDHP COHORT)				BRAND USER COHORT** (31.2% OF TOTAL HDHP COHORT)			
	STATUS QUO OOP	SCENARIO OOP	PMPY SAVINGS	PMPM SAVINGS	STATUS QUO OOP	SCENARIO OOP	PMPY SAVINGS	PMPM SAVINGS
Insulin	\$1,161.74	\$783.05	\$378.68	\$31.56	\$39.64	\$26.73	\$12.91	\$1.08
Other Rebate Eligible	\$744.42	\$718.54	\$25.88	\$2.16	\$636.52	\$552.65	\$83.87	\$6.99
All Other***	\$1,658.29	\$1,887.24	-\$228.95	-\$19.08	\$1,603.29	\$1,645.06	-\$41.77	-\$3.48
Total	\$3,564.45	\$3,388.84	\$175.61	\$14.63	\$2,279.45	\$2,224.44	\$55.02	\$4.58

* As defined in the Cohorts section above, 5.2% of all insulin users experienced their first insulin claims after reaching the out-of-pocket maximum and are not included in the insulin user cohort represented in the savings calculations above.

** As defined in the Cohorts section above, 4.5% of all brand-name users experienced their first brand-name drug claim after reaching the out-of-pocket maximum and are not included in the brand-name user cohort represented in the savings calculations above.

*** As members save on brand-name drug claims, medical claims and other pharmaceutical claims can be subject to higher member cost sharing, leading to negative out-of-pocket savings (i.e., increased out-of-pocket costs).

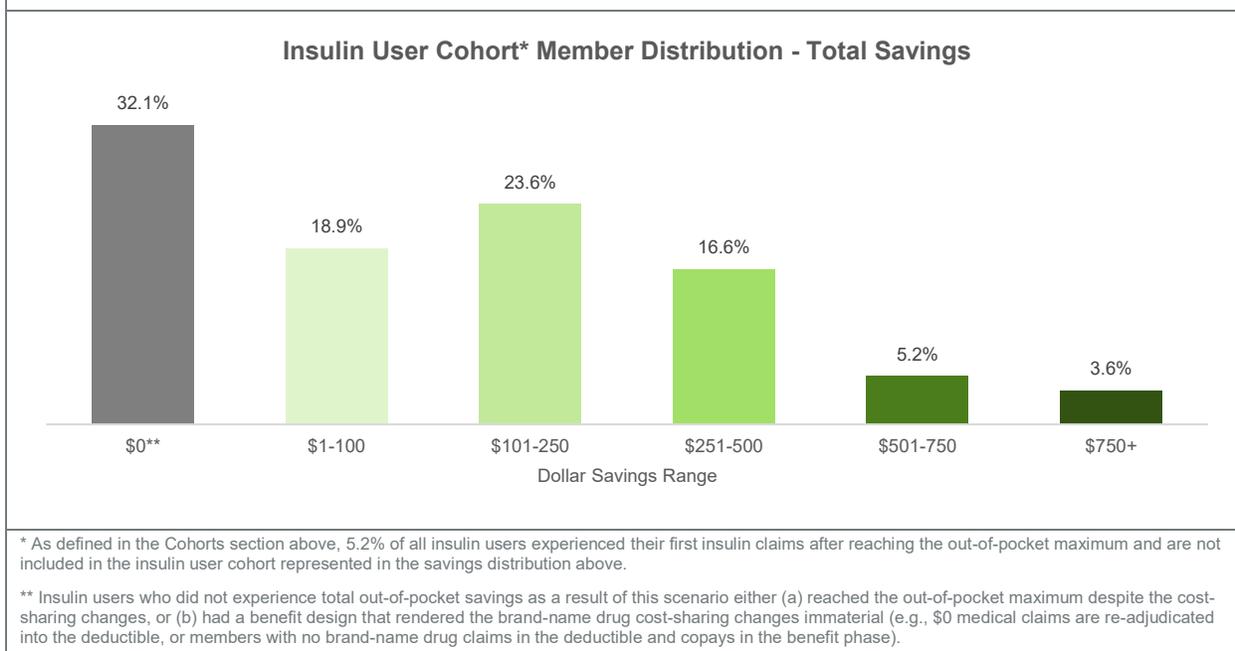
IMPACT ON INSULIN USERS' TOTAL OUT-OF-POCKET COSTS

Figure 7 provides the distribution of total out-of-pocket cost savings for the insulin cohort. Sixty-eight percent of the insulin cohort saved in this scenario, a six-point increase from scenario 1.

⁵ Federal Register (February 6, 2019). Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Retrieved May 17, 2019, from <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.

⁶ UnitedHealthcare (March 12, 2019). UnitedHealthcare and OptumRx expand successful point-of-sale prescription drug discount program. Retrieved May 17, 2019, from <https://www.uhc.com/employer/news/brokers/unitedhealthcare-and-optumrx-expand-successful-point-of-sale-pre>.

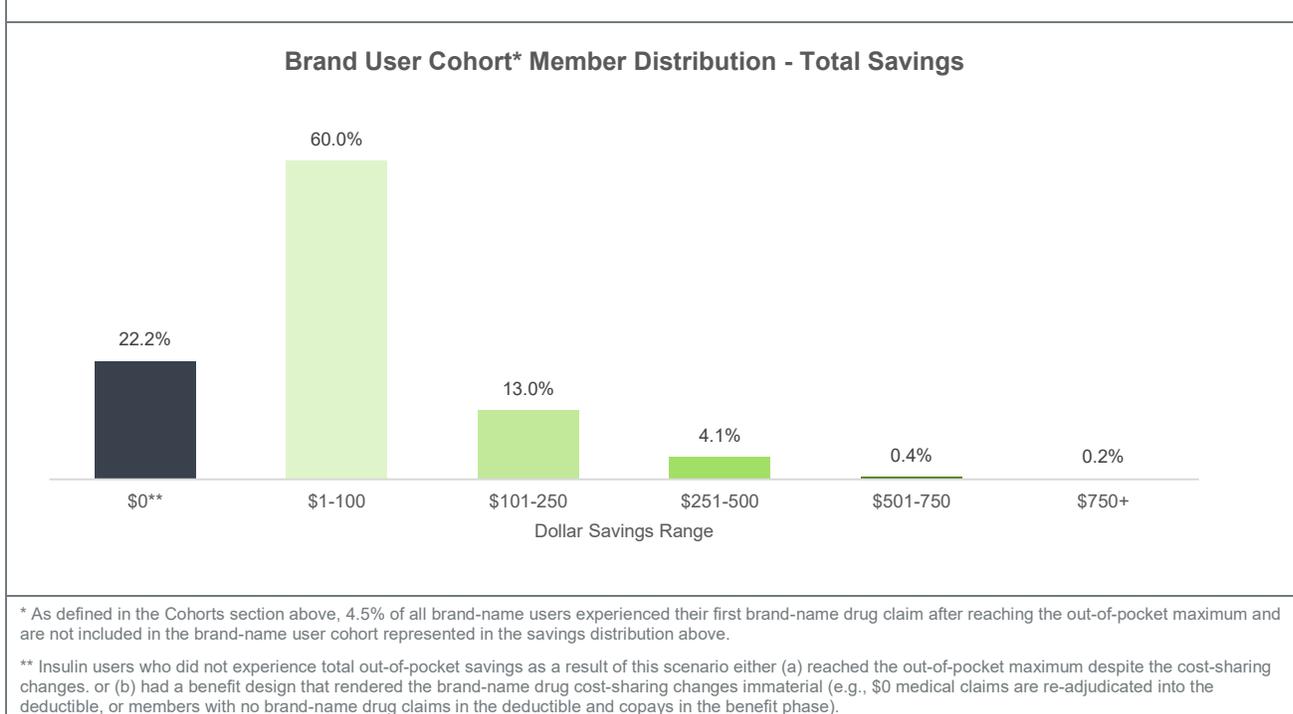
FIGURE 7: PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS: TOTAL SAVINGS INSULIN COHORT MEMBER DISTRIBUTION



IMPACT ON BRAND-NAME USERS' TOTAL OUT-OF-POCKET COSTS

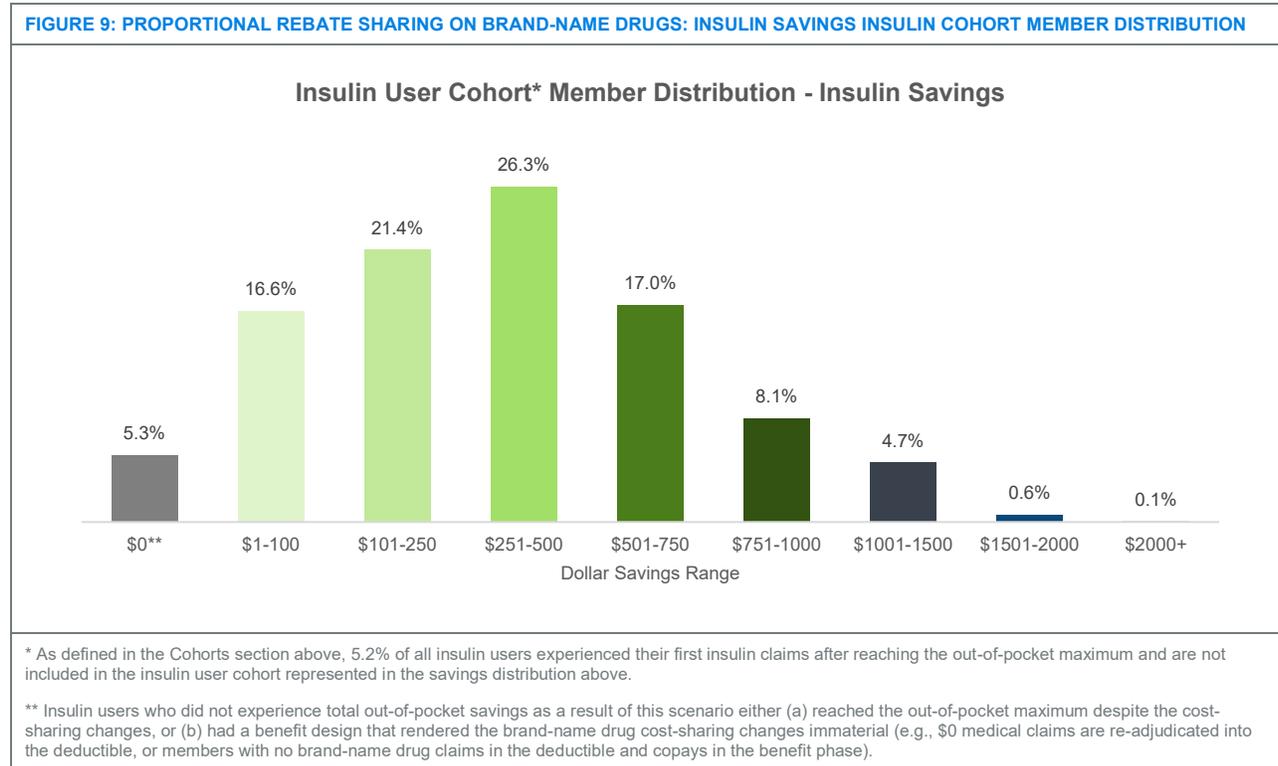
Figure 8 provides the distribution of total out-of-pocket cost savings for the broader cohort of members who used any brand-name drugs in the year. While the savings per member is significantly lower than the savings for the insulin cohort, there are many more members in the brand-name drug cohort.

FIGURE 8: PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS: TOTAL SAVINGS BRAND-NAME COHORT MEMBER DISTRIBUTION



IMPACT ON INSULIN USERS' INSULIN OUT-OF-POCKET COSTS

Figure 9 provides the distribution of out-of-pocket cost savings on insulins for the insulin cohort. When compared to scenario 1 (see Figure 5 above), the distribution of member savings on insulins is very similar.



ESTIMATED IMPACT ON PREMIUM

By implementing rebate sharing on all rebate-eligible drugs, scenario 2 impacts a larger population and has a more substantial PMPM premium increase relative to scenario 1, which is limited to insulin users. This scenario results in a PMPM premium increase of \$1.43, or \$17.16 PMPY. This is a 0.41% premium increase assuming an 85% medical loss ratio.

Scenario 3: Implementation and results

IMPLEMENTATION

As part of the 2010 implementation of the ACA, preventive services and medicines were mandated to be covered at no cost to members.⁷ Preventive services and medicines related to HDHPs are described in Section 223 of the Internal Revenue Code, and clarified in Note 2004-33 question 27:⁸

“...drugs or medications are preventive care when taken by a person who has developed risk factors for a disease that has not yet manifested itself or not yet become clinically apparent (i.e., asymptomatic), or to prevent the reoccurrence of a disease from which a person has recovered... However, the preventive care safe harbor under section 223(c)(2)(C) does not include any service or benefit intended to treat an existing illness, injury, or condition, including drugs or medications used to treat an existing illness, injury or condition.”

This definition of preventive drugs does not include insulins, though it could provide a framework for expanding the definition of preventive drugs.

Independent of regulations expanding the definition of preventive drugs, health plans have discretion to provide coverage above and beyond the drugs and services identified by the United States Preventive Services Task Force.⁹ A recent publication from CVS Health advocated for a broad interpretation of preventive drugs and more robust \$0 coverage.¹⁰

“We recommend this wider “preventive” drug list for clients with any kind of HDHP, and believe that the government should broaden the definition of what is considered a preventive drug. Research we recently completed indicates that expanding preventive drug lists to the five most chronic diseases – diabetes, hypertension, hyperlipidemia, asthma/COPD, and depression – could substantially improve care and lower costs.”

In this modeled scenario, we have added \$0 coverage for only insulins (see the Methodology section above for a full list). Inclusions of the other categories mentioned above would produce different results. An illustration of member out-of-pocket cost for this scenario is shown in Figure 10.

FIGURE 10: INSULINS EXEMPT FROM PATIENT COST SHARING: MEMBER OUT-OF-POCKET IMPACT

Illustrations assume a 20% member cost share in the benefit phase (i.e., after deductible is satisfied, but before out-of-pocket maximum is reached).

MEMBER OUT-OF-POCKET COST ILLUSTRATION	DEDUCTIBLE PHASE*		
	\$400	\$600	\$1,000
Point of sale product cost	\$400	\$600	\$1,000
Status quo member out-of-pocket (100%)	\$400	\$600	\$1,000
Scenario member out-of-pocket (0%)	\$0	\$0	\$0
BENEFIT PHASE**			
Point of sale product cost	\$400	\$600	\$1,000
Status quo member out-of-pocket (20%)	\$80	\$120	\$200
Scenario member out-of-pocket (0%)	\$0	\$0	\$0

* Assumes entire claim falls into the deductible.
 ** Assumes entire claim falls into the benefit phase with a 20% coinsurance.

⁷ HealthCare.gov. Preventive Care Benefits for Adults. Retrieved May 17, 2019, from <https://www.healthcare.gov/preventive-care-adults/>.

⁸ IRS (August 16, 2004). Internal Revenue Bulletin No. 2004-33. Retrieved May 17, 2019, from <https://www.irs.gov/pub/irs-irbs/irb04-33.pdf>.

⁹ Express Scripts (September 2018). Preventive Medicine List. Retrieved May 17, 2019, from https://www.express-scripts.com/art/open_enrollment/PreventiveMedDL_KEYCORP.pdf.

¹⁰ CVSHealth (August 2018). Current and New Approaches to Making Drugs More Affordable. Retrieved May 17, 2019, from <https://cvshhealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf>.

AVERAGE OUT-OF-POCKET SAVINGS

Insulin users are the only members with the potential for savings as a result of this scenario. On average, insulin cohort members saved \$1,162 per year on insulin, and \$481 overall (Figure 11).

FIGURE 11: INSULINS EXEMPT FROM PATIENT COST SHARING: AVERAGE OUT-OF-POCKET SAVINGS

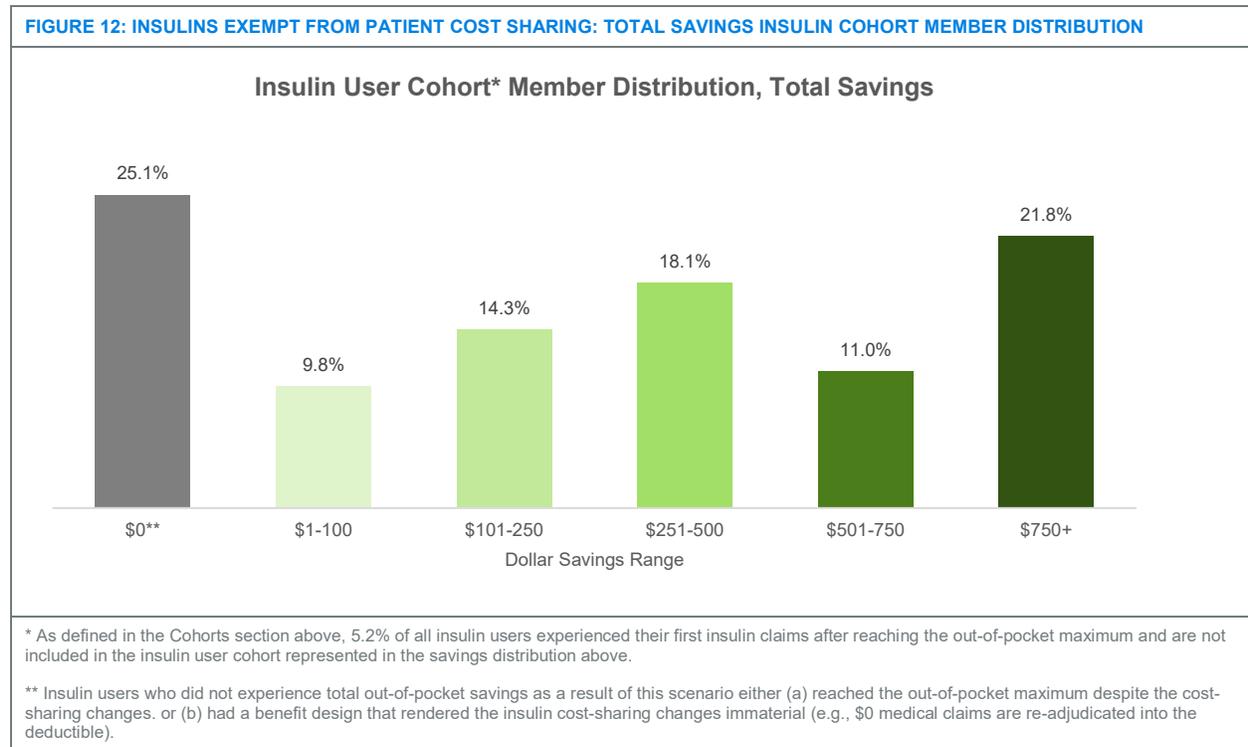
CLAIM TYPE	INSULIN USER COHORT* (1.1% OF TOTAL HDHP COHORT)			
	STATUS QUO OOP	SCENARIO OOP	PMPY SAVINGS	PMPM SAVINGS
Insulin	\$1,161.74	\$0.00	\$1,161.74	\$96.81
All Other**	\$2,402.71	\$3,083.15	-\$680.44	-\$56.70
Total	\$3,564.45	\$3,083.15	\$481.29	\$40.11

* As defined in the Cohorts section above, 5.2% of all insulin users experienced their first insulin claims after reaching the out-of-pocket maximum and are not included in the insulin user cohort represented in the savings calculations above.

** As members save on insulin claims, medical claims and other pharmaceutical claims can be subject to higher member cost sharing, leading to negative out-of-pocket savings (i.e., increased out-of-pocket costs).

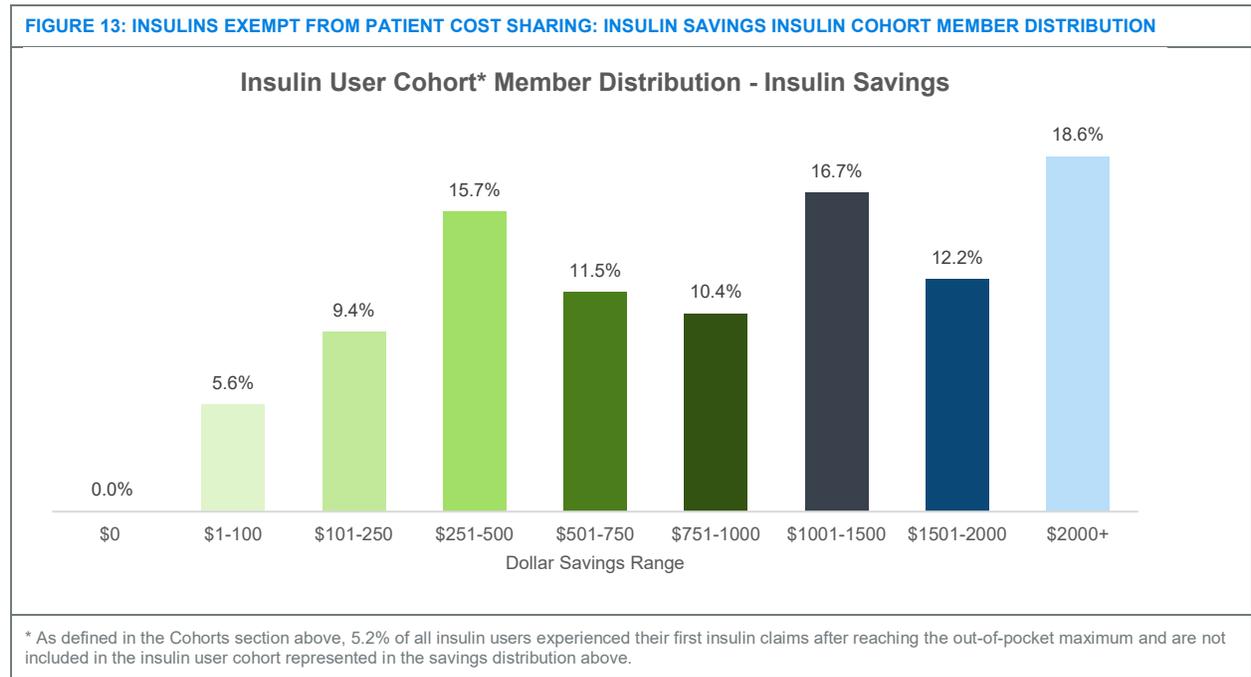
IMPACT ON INSULIN USERS' TOTAL OUT-OF-POCKET COSTS

A comparison between Figure 11 and Figure 3 above indicates that scenario 3 (which eliminates insulin out-of-pocket costs) produces more than twice the savings as scenario 1 (which reduces insulin out-of-pocket costs by half). Driving this disparity is that, under scenario 3, fewer members reach their out-of-pocket maximums (see Appendix A6) so more of the insulin savings are realized. As seen in Figure 12, more insulin users experience greater levels of overall out-of-pocket savings relative to scenario 1.



IMPACT ON INSULIN USERS' INSULIN OUT-OF-POCKET COSTS

All insulin users experience savings on insulin in this scenario, as the \$0 cost sharing impacts copays along with the deductible and coinsurance payment reductions relevant to proportional rebate sharing. As seen in Figure 13, a higher percentage of members reach the larger insulin savings ranges when compared to the other scenarios (seen in Figures 5 and 9 above).



ESTIMATED IMPACT ON PREMIUM

This scenario results in a PMPM premium increase of \$0.43, or \$5.12 PMPY. This is a 0.12% premium increase assuming an 85% medical loss ratio.

Scenario results summary

Key results from all three scenarios are displayed in Figure 14.

FIGURE 14: SCENARIO COMPARISON

METRIC	PROPORTIONAL REBATE SHARING ON INSULIN	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS	INSULINS EXEMPT FROM PATIENT COST SHARING
PMPY Average Total OOP Savings (Insulin User Cohort*)	\$142	\$176	\$481
PMPY Average Insulin OOP Savings (Insulin User Cohort*)	\$396	\$379	\$1,162
Total Savings Distribution (Insulin User Cohort*)	<p>Dollar Savings Range</p>	<p>Dollar Savings Range</p>	<p>Dollar Savings Range</p>
Insulin Savings Distribution (Insulin User Cohort*)	<p>Dollar Savings Range</p>	<p>Dollar Savings Range</p>	<p>Dollar Savings Range</p>
PMPM Premium Increase (Insulin User Cohort*)	\$0.13 (\$1.51 PMPY)	\$1.43 (\$17.16 PMPY)	\$0.43 (\$5.12 PMPY)

* As defined in the Cohorts section above, 5.2% of all insulin users experienced their first insulin claims after reaching the out-of-pocket maximum and are not included in the insulin user cohort represented in the savings calculations and distributions above.

Scenario application

The estimates provided in this analysis reflect the application of the scenarios as described. In real-world application, many reasonable variations could be implemented, and it is likely that plan administrators would differ in their approaches. The scope of the approaches when implemented will impact the magnitude of the savings, which could be higher or lower than the amounts we have illustrated.

The purpose of this research is to propose potential approaches and provide an estimate for the associated impact on the patients' out-of-pocket costs and member premium. The actual decision to implement any of these scenarios would require the coordination of all stakeholders and analysis specific to the employer group.

Application of these scenarios may result in behavioral changes. For example, as out-of-pocket costs are reduced for insulin users, adherence for this cohort may improve. Beyond a direct impact to pharmacy claims for these patients, improved adherence could lead to reduced PMPY medical and total costs.

There does appear to be an increased urgency to reduce the out-of-pocket costs for insulin-taking members. Express Scripts recently announced its proposal to allow affiliated plans to offer a monthly \$25 cap on insulin spending.¹¹ Other plans will be monitoring the success of this approach, as well as the proposed rebate-sharing policy for Medicare and Medicaid from HHS, should it go into effect. These recent developments suggest the healthcare landscape is trending toward some means of reducing patient out-of-pocket costs on brand-name products.

Limitations

Eli Lilly commissioned Milliman to refresh this project with updated data, methodology, and scenarios in an effort to better understand how reduced patient cost sharing on insulins will impact both insulin users and all covered members enrolled in high-deductible health plans (HDHPs).

In performing this analysis, we relied on the 2016 IBM MarketScan Commercial Claims and Encounters databases. We have not audited or verified this data or other information. If the underlying data or information is inaccurate or incomplete, the results of our analysis may likewise be inaccurate or incomplete. The database is expected to be representative of HDHP claims experience but does not represent a single benefit design, nor a single health plan or employer group.

We performed a limited review of the data used directly in our analysis for reasonableness and consistency and have not found material defects in the data. If there are material defects in the data, it is possible that they would be uncovered by a detailed, systematic review and comparison of the data to search for data values that are questionable or for relationships that are materially inconsistent. Such a review was beyond the scope of our assignment.

Actual rebate rates will vary by plan administrator and will depend on the subset of products included in the benefit design. Rebate agreements can be complex and may include contingent payments that have an unknown value to the plan administrator at the beginning of a plan year. In this analysis, we assumed “perfect” information; that is, the percentage value of the rebates shared with members was equal to the percentage value of the rebates received by the plan administrator. In practice, the plan administrator may share a lower percentage with the members. The impact to the premium would be lower than what we have estimated in the exhibits, all else equal.

There is a relationship between lower cost sharing and increased utilization. For prescription drug benefits, increased utilization may result in improved adherence or compliance with a treatment regimen. Increased utilization may lead to higher prescription drug costs for the plan administrator, which we have not reflected in the exhibits. Improved adherence may lead to lower overall medical costs, which we have not reflected in the exhibits. Plan sponsors should consider the potential impact to medical and pharmacy budgets, the time horizon associated with those impacts, and whether to establish any metrics for monitoring emerging results.

Milliman does not intend to benefit or create a legal duty to any third-party recipient of its work. Any distribution of the information should be in its entirety. Third parties receiving this report must rely upon their own experts to draw any conclusions. It is certain actual experience will deviate from the estimates produced. Any user of this information should be familiar with the U.S. healthcare system or be advised by someone who is familiar with it.

¹¹ New York Times. (April 3, 2019). Express Scripts offers diabetes patients a \$25 cap for monthly insulin. Retrieved May 17, 2019, from <https://www.nytimes.com/2019/04/03/health/drug-prices-insulin-express-scripts.html>.



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Appendix

A1. INSULIN USER COHORT* (1.1% OF HDHP COHORT), AVERAGE OUT-OF-POCKET SAVINGS							
CLAIM TYPE	AVERAGE OOP				AVERAGE OOP SAVINGS		
	STATUS QUO	PROPORTIONAL REBATE SHARING ON INSULIN	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS	INSULINS EXEMPT FROM PATIENT COST SHARING	PROPORTIONAL REBATE SHARING ON INSULIN	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS	INSULINS EXEMPT FROM PATIENT COST SHARING
Insulin	\$1,161.74	\$765.26	\$783.05	\$0.00	\$396.47	\$378.68	\$1,161.74
Other Rx	\$995.71	\$1,093.88	\$1,000.60	\$1,261.93	-\$98.18	-\$4.89	-\$266.23
Medical	\$1,407.00	\$1,563.14	\$1,605.18	\$1,821.22	-\$156.13	-\$198.18	-\$414.22
Total	\$3,564.45	\$3,422.28	\$3,388.84	\$3,083.15	\$142.16	\$175.61	\$481.30

* As defined in the Cohorts section above, 5.2% of all insulin users experienced their first insulin claims after reaching the out-of-pocket maximum and are not included in the insulin user cohort represented in the savings calculations above.

A2. INSULIN USER COHORT* (1.1% OF HDHP COHORT), AVERAGE OUT-OF-POCKET SAVINGS			
CLAIM TYPE	AVERAGE OOP		AVERAGE OOP SAVINGS
	STATUS QUO	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS
Insulin	\$1,161.74	\$783.05	\$378.68
Rebate Eligible	\$744.42	\$718.54	\$25.88
Other Rx	\$251.28	\$282.06	-\$30.77
Medical	\$1,407.00	\$1,605.18	-\$198.18
Total	\$3,564.45	\$3,388.84	\$175.61

* As defined in the Cohorts section above, 5.2% of all insulin users experienced their first insulin claims after reaching the out-of-pocket maximum and are not included in the insulin user cohort represented in the savings calculations above.

A3. BRAND USER COHORT* (31.2% OF HDHP USERS), AVERAGE OUT-OF-POCKET SAVINGS			
CLAIM TYPE	AVERAGE OOP		AVERAGE OOP SAVINGS
	STATUS QUO	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS
Insulin	\$39.64	\$26.73	\$12.91
Rebate Eligible	\$636.52	\$552.65	\$83.87
Other Rx	\$213.69	\$219.60	-\$5.91
Medical	\$1,389.61	\$1,425.46	-\$35.85
Total	\$2,279.45	\$2,224.44	\$55.02

* As defined in the Cohorts section above, 4.5% of all brand-name users experienced their first brand-name drug claims after reaching the out-of-pocket maximum and are not included in the brand-name user cohort represented in the savings calculations above.

A4. INSULIN USER COHORT*, TOTAL SAVINGS DISTRIBUTION

SAVINGS BUCKET	PERCENT OF MEMBERS		
	PROPORTIONAL REBATE SHARING ON INSULIN	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS	INSULINS EXEMPT FROM PATIENT COST SHARING
\$0	38.3%	32.1%	25.1%
\$1-100	21.4%	18.9%	9.8%
\$101-250	20.9%	23.6%	14.3%
\$251-500	12.8%	16.6%	18.1%
\$501-750	3.7%	5.2%	11.0%
\$750+	2.9%	3.6%	21.8%
	100.0%	100.0%	100.0%

* As defined in the Cohorts section above, 5.2% of all insulin users experienced their first insulin claims after reaching the out-of-pocket maximum and are not included in the insulin user cohort represented in the savings calculations above.

A5. INSULIN USER COHORT*, INSULIN SAVINGS DISTRIBUTION

SAVINGS BUCKET	PERCENT OF MEMBERS		
	PROPORTIONAL REBATE SHARING ON INSULIN	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS	INSULINS EXEMPT FROM PATIENT COST SHARING
\$0	7.3%	5.3%	0.0%
\$1-100	12.7%	16.6%	5.6%
\$101-250	21.3%	21.4%	9.4%
\$251-500	26.8%	26.3%	15.7%
\$501-750	17.6%	17.0%	11.5%
\$751-1000	8.6%	8.1%	10.4%
\$1001-1500	4.9%	4.7%	16.7%
\$1501-2000	0.7%	0.6%	12.2%
\$2000+	0.1%	0.1%	18.6%
	100.0%	100.0%	100.0%

* As defined in the Cohorts section above, 5.2% of all insulin users experienced their first insulin claims after reaching the out-of-pocket maximum and are not included in the insulin user cohort represented in the savings calculations above.

A6. END-OF-YEAR COVERAGE PHASE: PERCENTAGE OF INSULIN USER COHORT* MEMBERS BY SCENARIO

COVERAGE PHASE	SCENARIO			
	STATUS QUO	PROPORTIONAL REBATE SHARING ON INSULIN	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS	INSULINS EXEMPT FROM PATIENT COST SHARING
Deductible	8.1%	12.2%	12.9%	21.9%
Benefit Phase	59.0%	59.0%	59.4%	55.6%
OOP Max	32.9%	28.8%	27.7%	22.5%
Total	100.0%	100.0%	100.0%	100.0%

* As defined in the Cohorts section above, 5.2% of all insulin users experienced their first insulin claims after reaching the out-of-pocket maximum and are not included in the insulin user cohort represented in the savings calculations above.

A7. ALL MEMBERS: PMPM PREMIUM CHANGES

MEDICAL LOSS RATIO LEVEL / PMPM PREMIUM METRICS	SCENARIO			
	STATUS QUO	PROPORTIONAL REBATE SHARING ON INSULIN	PROPORTIONAL REBATE SHARING ON BRAND-NAME DRUGS	INSULINS EXEMPT FROM PATIENT COST SHARING
100% MLR				
Baseline Premium	\$299.95	\$299.95	\$299.95	\$299.95
Change in Premium	\$0.00	\$0.13	\$1.43	\$0.43
New Premium	\$299.95	\$300.08	\$301.38	\$300.38
Percent Change in Premium	0.00%	0.04%	0.48%	0.14%
90% MLR				
Baseline Premium	\$333.28	\$333.28	\$333.28	\$333.28
Change in Premium	\$0.00	\$0.13	\$1.43	\$0.43
New Premium	\$333.28	\$333.40	\$334.71	\$333.71
Percent Change in Premium	0.00%	0.04%	0.43%	0.13%
85% MLR				
Baseline Premium	\$352.88	\$352.88	\$352.88	\$352.88
Change in Premium	\$0.00	\$0.13	\$1.43	\$0.43
New Premium	\$352.88	\$353.01	\$354.31	\$353.31
Percent Change in Premium	0.00%	0.04%	0.41%	0.12%