

MILLIMAN CLIENT REPORT

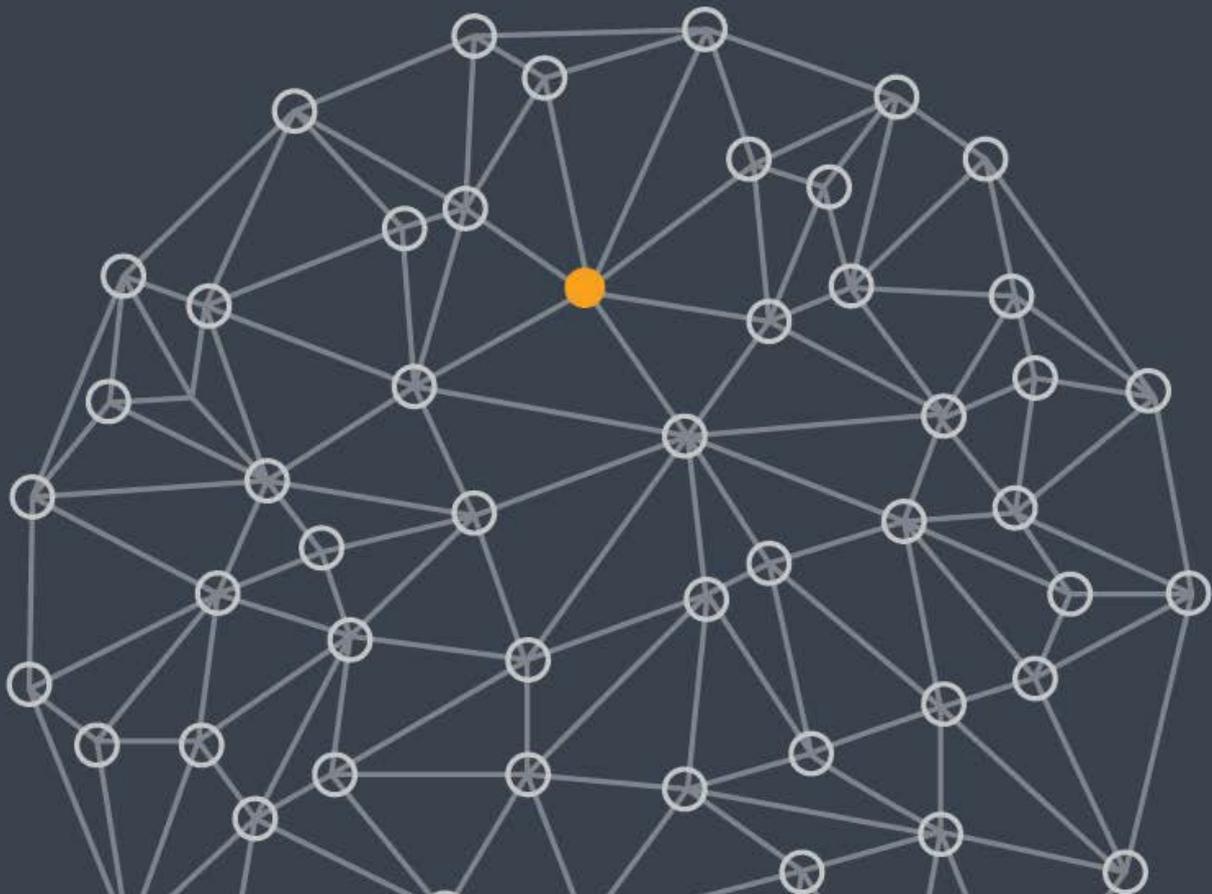
Mitigating out-of-pocket costs for prescription drugs

A discussion document

Prepared for Eli Lilly

December 2016

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Milliman is among the world's largest independent actuarial and consulting firms.

This report is intended to support a dialogue between stakeholders about how near-term relief could be delivered to members who have high cost-sharing exposure for prescription drugs.

This research was commissioned by Eli Lilly and Company (Lilly), and reflects the research of the authors.

Anne Jackson is a member of the American Academy of Actuaries and meets the qualification standards to perform the analyses in this report.

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Executive Summary

Although the uninsured rate in the United States is at a historical low as of 2016,¹ many insured adults find it difficult to afford the coverage they have.² Plan designs with high deductibles, high cost-sharing requirements, narrow provider networks, and strong utilization management controls have helped constrain the growth in premiums and employee contributions.^{3,4,5,6,7,8} Some of these tactics have contributed to growth in the out-of-pocket costs associated with healthcare services.⁹

A significant and growing number of commercially insured members have one or more chronic medical conditions that require multiple interactions with the healthcare system in a given year.^{10,11,12} For these members, avoiding care may exacerbate their condition(s) and lead to worse outcomes. That is, in order to protect their health, the medical services may be necessary and unavoidable.^{13,14}

Eli Lilly and Company (Lilly) commissioned this analysis to identify tactics plan administrators could adopt that would reduce the out-of-pocket costs for brand-name drugs. The scope of the research is the employer-sponsored group insurance market in the United States. The tactics we identified would have the largest impact to members of high-deductible plans and/or plans with coinsurance and a smaller impact to members of plans with copayments for prescription drugs. Plan administrators could vary the scope of implementation, but for purposes of illustrating the potential financial impact to patients and plan sponsors, we established specific parameters for the tactics described below. These tactics were selected because variations of them have an opportunity to achieve a meaningful reduction in patient out-of-pocket costs with minimum financial or operational disruption to plan administrators and the insured group.

Eliminate cost sharing for a subset of drugs

This tactic, which has been included in plan designs for years,¹⁵ is to reduce or eliminate the cost-sharing requirement for a subset of prescription drugs. We estimate that eliminating cost sharing for insulins (including short- and long-acting insulins) would save insulin users in plans with a coinsurance an average of approximately \$430 per patient per year in out-of-pocket costs, while increasing premium* by an estimated \$2.63 to \$5.23 per member per year (PMPY).

*Assumes an 85% medical loss ratio.

¹ Marken, S. (July 11, 2016). U.S. uninsured rate remains at historical low of 11.0%. Gallup. Retrieved December 14, 2016, from <http://www.gallup.com/poll/193556/uninsured-rate-remains-historical-low.aspx>.

² Collins, S.R., Gunja, M., Doty, M., & Beutel, S. (November 2015). How High Is American's Health Care Cost Burden? Findings From the Commonwealth Fund Health Care Affordability Tracking Survey, July-August 2015. The Commonwealth Fund.

³ Healthstat (February 5, 2016). The top 3 trends in healthcare cost reduction. Retrieved December 14, 2016, from <http://www.healthstatinc.com/the-top-3-trends-in-healthcare-cost-reduction>.

⁴ Miller, S. (April 17, 2014). Health plan cost-shifting trends highlighted. Society for Human Resource Management. Retrieved December 14, 2016, from <https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/health-cost-shifting-trends.aspx>.

⁵ Smart Business (October 1, 2016). How to use tiered and narrow networks to control health care costs. Retrieved December 14, 2016, from <http://www.sbnonline.com/article/tiered-narrow-networks-control-health-care-costs/>.

⁶ Miller, S. (October 1, 2015). Business trends to watch in 2016—and beyond. Society for Human Resource Management. Retrieved December 14, 2016, from <https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/benefit-trends-2016.aspx>.

⁷ Strategic Healthcare Alliance (2016). Payers increasing utilization management strategies to control drug costs, Retrieved December 14, 2016, from <http://www.shalliance.com/Payer-Trend-Watch/Payer-Increasing-Utilization/default.aspx>.

⁸ Lorenzetti, L. (June 21, 2016). Here's why you'll likely pay more for your employer-sponsored health insurance. Fortune. Retrieved December 14, 2016, from <http://fortune.com/2016/06/21/health-care-rising-costs/>.

⁹ Claxton, G. et al. (April 12, 2016). Payments for cost sharing increasing rapidly over time. Peterson-Kaiser Health System Tracker. Retrieved December 14, 2016, from <http://www.healthsystemtracker.org/insight/payments-for-cost-sharing-increasing-rapidly-over-time/>.

¹⁰ Agency for Healthcare Research and Quality. Number of People with Care for Selected Conditions by Type of Service: United States, 2014. Medical Expenditure Panel Survey Household Component Data. Generated interactively.

¹¹ Ornstein, Steve M., et al. (September-October 2013). Prevalence of chronic disease and multimorbidity in primary care practice: A PPRNet report. *Journal of the American Board of Family Medicine*, vol. 26 no. 5 518-524.

¹² Anderson, Gerard, *Chronic Care: Making the Case for Ongoing Care* (Princeton, NJ: Robert Wood Johnson Foundation, 2010), <http://www.rwjf.org/en/library/research/2010/01/chronic-care.html>.

¹³ <http://www.cdc.gov/chronicdisease/about/prevention.htm>

¹⁴ Anderson, Gerard (2010). Chronic care: Making the case for ongoing care. Robert Wood Johnson Foundation. Retrieved December 14, 2016, from <http://www.rwjf.org/en/library/research/2010/01/chronic-care.html>.

¹⁵ Edlin, M. (January 21, 2015). Value-based formularies take hold: Efficacy can off-set high drug costs. Managed Healthcare Executive. Retrieved December 14, 2016, from <http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/value-based-formularies-take-hold?page=fulltion>.

Reduce member cost sharing at the point of sale

For many in-network medical services, patients are provided with an explanation of benefits (EOB). This document reports the provider's billed amount for a service and then, typically, the discounted rate negotiated by the plan administrator. If a patient is in their deductible or has a coinsurance, the patient's cost is determined using the discounted amount.

Unlike many medical services, patient costs for pharmacy services are determined at the point of sale. Pharmacies are reimbursed according to a negotiated allowed amount, which reflects a discount from the full list price of the drug and may also include a dispensing fee. Member cost sharing is determined using the allowed amount. Additionally, plan administrators may earn rebates on some brand-name drugs. The rebates are credited on a quarterly basis and are not attributed to individual patients. Member cost sharing is not adjusted by the rebates earned on the product. We evaluated a tactic that would share a portion of the rebate with patients at the point of sale.

If rebates were shared only on insulin products, we estimate insulin users in high-deductible plans with a coinsurance would save an average of approximately \$276 per patient per year in out-of-pocket costs, while increasing premium* by an estimated \$1.59 PMPY to \$2.39 PMPY. If a rebate were shared on all rebate-generating products, we estimate the users of those products in high-deductible plans with a coinsurance would save an average of approximately \$89 per patient per year, while increasing premium* by an estimated \$10.02 PMPY to \$10.53 PMPY.

In addition to quantifying the costs associated with these tactics, we also tested the concepts with employee benefit consultants, pricing and product development actuaries, and former health plan and pharmacy benefit management (PBM) executives. The feedback and perspectives reflected the complexities of the U.S. health insurance market. Different components of the tactics resonated with stakeholders, but there was a consensus that mitigating out-of-pocket costs is administratively possible and could be financially feasible. This report is intended to support a dialogue between stakeholders about how near-term relief could be delivered to members who have high cost-sharing exposure for prescription drugs.

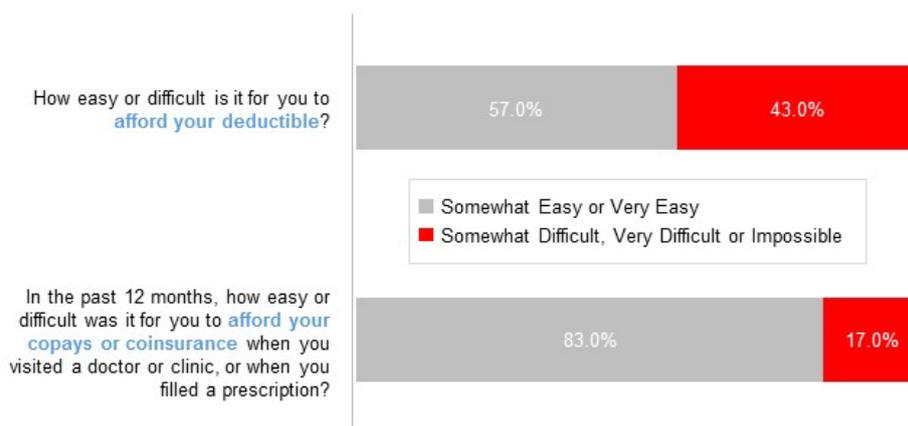
This research was commissioned by Eli Lilly and Company (Lilly), and reflects the research of the authors. Anne Jackson is a member of the American Academy of Actuaries and meets the qualification standards to perform the analyses in this report. Milliman does not endorse any policy or product.

*Assumes an 85% medical loss ratio.

Introduction

The Commonwealth Fund conducted a survey of 1,687 insured adults of ages 19 to 64 in July and August of 2015. Ninety percent of those surveyed had coverage through their employers. The remaining 10% of respondents had individual or marketplace coverage. Figure 1 summarizes the responses to questions about the affordability associated with key benefit design elements.

FIGURE 1: AFFORDABILITY



Source: How High Is America's Health Care Cost Burden? Findings from the Commonwealth Fund Health Care Affordability Tracking Survey, July-August 2015; Exhibits 4 and 5, all income groups.

NEED FOR MITIGATION SOLUTIONS

As seen in Figure 1 above, most members have prescription drug coverage with cost-sharing requirements they deem affordable. However, some members face high costs for prescription drugs that are due to the cost of the medication and the cost-sharing structure of their plan. If the trend toward higher deductibles and/or the greater use of coinsurance continues, an increasing number of patients may struggle to afford their medications.

For many conditions, the delay or avoidance of care can lead to worse outcomes, such that minimizing the resources used may ultimately lead to higher healthcare costs.^{17,18}

CHARACTERISTICS OF A SUCCESSFUL MITIGATION STRATEGY

For the purposes of this discussion, we narrowed the scope of proposals to those that will achieve the goal of reducing the patient out-of-pocket cost burden for patients with commercial insurance who use rebate-earning drugs. Within that narrowed focus, we evaluated proposals with the goal to achieve the following:

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 considerations. Plan

¹⁷ Eaddy, Michael T PharmD, PhD, et al. (January 2012). How patient cost-sharing trends affect adherence and outcomes: A literature review. *Pharmacy and Therapeutics*; 37(1): 45-55.

¹⁸ Snider, Julie Thornton PhD et al. (2016). Impact of Type 2 diabetes medication cost sharing on patient outcomes and health plan costs. *American Journal of Managed Care*;22(6):433-440.

administrators should be able to implement the approach within the existing adjudication systems. But also, the approach should be feasible without requiring any additional legislation or regulation.

If a proposed approach fails to meet any of these characteristics, it may be disruptive to the U.S. healthcare system and it is unlikely that it could be implemented successfully by any individual plan administrator. We wanted to consider only those approaches that appeared to meet all of these characteristics. There may be other important considerations against which the proposals should be evaluated.

TARGET PRODUCTS: INSULINS AS A CASE STUDY

Approximately 5% of the non-elderly population in the United States has been diagnosed with diabetes.¹⁹ Individuals with Type 1 diabetes cannot produce enough insulin and require insulin therapy to survive. The majority of people with diabetes have Type 2 diabetes, which is a chronic condition where a patient becomes resistant to insulin. Type 2 diabetes can often be managed with diet, exercise, and/or oral antidiabetic therapies. Some of these oral antidiabetic therapies are low-cost generic treatments, such as metformin. If the disease progresses, it is managed through an increasingly complex treatment regimen that often eventually leads to the requirement of insulin.²⁰ The regimen can include both short- and long-acting insulins.

Notably, given that insulin is a biologic medication, there are no generic equivalents available. Many of the insulins are already off-patent, but because of the biologic nature and requirements of manufacturing insulin, traditional generic market entrants are unlikely.

In this work, we included insulins in the analysis to recognize the unique aspects of the therapies:

- Individuals with Type 1 diabetes (approximately 6% of the population diagnosed with diabetes)²¹ require insulin to manage their condition.²² Often, this includes both short- and long-acting insulins.
- Although the prevalence of diabetes is relatively high, relatively few patients with Type 2 diabetes require treatment with insulin.²³
- Of those who do require treatment with insulin, compliance with the prescribed regimen is necessary to maintain glycemic control.²⁴ Insulin treatment often includes both short- and long-acting insulins. Complications associated with poorly managed diabetes include neuropathy, heart disease, and kidney disease.²⁵
- Patients who use insulin are often prescribed other products to treat diabetes or common comorbid conditions. Many of these products—including statins and antihypertensive agents—are available as generic products, but the cumulative cost-sharing requirement can be significant when considered in aggregate.²⁶

Finally, we included insulins in the analysis because the therapeutic area is a priority to the project sponsor. The therapeutic area (both short- and long- acting insulins) is highly competitive. As illustrated in the assumptions used in the analysis, the rebates paid by drug manufacturers for these products can be significant, and may exceed the typical rebate earned on primary care products for preferred formulary placement.

TREND IN VALUE OF MANUFACTURER PRICE CONCESSIONS

On a list price basis, double-digit price increases on brand-name drugs have been reported for three years.^{27,28} List prices are the basis for pharmacy reimbursement. Additionally, plan administrators may receive rebates and other price concessions that off-set a portion of the cost of the drug. After accounting for discounts, rebates, and

¹⁹ CDC (2014). National Diabetes Statistics Report, 2014. Retrieved December 14, 2016, from <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>.

²⁰ AACE/ACE comprehensive diabetes management algorithm. *Endocr Pract.* 2015;21(No.4)e6.

²¹ American Diabetes Association (December 12, 2016). Statistics About Diabetes. Retrieved December 14, 2016, from <http://www.diabetes.org/diabetes-basics/statistics/>.

²² American Diabetes Association (November 21, 2016). Living With Type 1 Diabetes. Retrieved December 14, 2016, from <http://www.diabetes.org/living-with-diabetes/recently-diagnosed/living-with-type-1-diabetes.html>.

²³ National Diabetes Statistics Report, 2014, *ibid*.

²⁴ AACE/ACE comprehensive diabetes management algorithm, *ibid*.

²⁵ American Diabetes Association (2016). Living With Diabetes: Complications. Retrieved December 14, 2016, from <http://www.diabetes.org/living-with-diabetes/complications/>.

²⁶ AACE/ACE comprehensive diabetes management algorithm, *ibid*.

²⁷ Dennis, B. (January 11, 2016). Prescription drug prices jumped more than 10 percent in 2015, analysis finds. *Washington Post*. Retrieved December 14, 2016, from https://www.washingtonpost.com/news/to-your-health/wp/2016/01/11/prescription-drug-prices-jumped-more-than-10-percent-in-2015/?utm_term=.c6587ac8cc9e.

²⁸ IMS Institute for Healthcare Informatics (April 2016). Medicines Use and Spending in the US; Chart 3.

other price concessions, the IMS Institute for Healthcare Informatics (IMS) estimates that the rate of growth in the net price of brand-name prescription drugs has slowed and is significantly lower than the growth in list prices.²⁹ Among insulins, IMS estimates that “all of the increase [in list prices] and more, was offset by rebates and price concessions.”³⁰

The lower rate of growth in net price suggests that rebates and price concessions between the drug manufacturers and plan administrators have grown more generous, especially related to insulins. One of the tactics included in this research shares a portion of those rebates with the patient at the point of sale.

Proposed approaches

We identify two approaches that are compatible with the evaluation criteria:

1. Insulins exempt from cost sharing.
2. Reduced member cost sharing at the point of sale.

Within this section, we introduce these approaches and discuss the key features of each. There are virtually unlimited ways the approaches (and others) could be implemented. We describe the specific benefit design and assumptions used for this analysis and recognize the opportunity for variation. Financial estimates of the proposed approaches are provided in the next section.

APPROACH 1: INSULINS EXEMPT FROM COST-SHARING

There are multiple regulations and terms that can convolute a discussion of cost-sharing exemptions. The Patient Protection and Affordable Care Act (ACA) requires that services or therapies that are recommended by the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Bright Futures Project of the Health Resources and Services Administration (HRSA), and an HRSA and Institute of Medicine (IOM) committee on women’s clinical preventive services be covered with no cost-sharing requirement.³¹ Insulins are not identified as preventive therapies under the ACA provision.

Section 223 of the Internal Revenue Code also addresses the coverage of preventive services, specifically related to high-deductible health plans (HDHPs) with tax-qualified health savings accounts (HSAs). Preventive services can be provided by an HDHP without satisfying the minimum deductible requirement. Note 2004-33³² (question 27) clarifies that “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.” Some plan administrators have asked for further clarification, but the Internal Revenue Service (IRS) has not reviewed specific formularies.³³

Value-based formularies have been used for years—even prior to the ACA’s provision for preventive services—and vary in breadth of included services and patient cost-sharing provisions. Some provide lower cost sharing (or no cost sharing) for maintenance drugs. Others include a variant of this and identify products that are particularly effective at preventing avoidable complications of chronic diseases.³⁴

Plan sponsors should consult with their tax accountants and/or legal counsel experts before implementing strategies that may be reviewed by the IRS. For the purposes of this proposed strategy, we assume that the benefit designs have the legal latitude to add insulins to a \$0 cost-sharing tier (or create such a tier) that is exempt from the deductible. Benefit designs that cover insulins on the generic tier (for example) or another low-cost tier with coverage exempt from the deductible would be a variation on this proposed strategy.

The approach that was tested in this research was to remove all cost sharing associated with insulins. By limiting the product list solely to insulins, we maintain the alignment between payers, prescribers, and patients as there are no generic alternatives in this class. Competition from manufacturers is preserved, because many plan sponsors

²⁹ IMS, Chart 3, *ibid*.

³⁰ IMS Institute for Healthcare Informatics (April 2016). *Medicines Use and Spending in the US*; page 17.

³¹ Patient Protection and Affordable Care Act. Sec. 2713, *Coverage of Preventive Services*.

³² Internal Revenue Bulletin No. 2004-33 (August 16, 2004). Retrieved December 14, 2016, from <https://www.irs.gov/pub/irs-irbs/irb04-33.pdf>.

³³ Wojcik, J. (November 9, 2014). *IRS' lack of definitive drugs list has firms fully covering maintenance meds*. *Business Insurance*. Retrieved December 14, 2016, from <http://www.businessinsurance.com/article/20141109/NEWS03/311099985/irs-lack-of-definitive-drugs-list-has-firms-fully-covering>.

³⁴ Edlin, M., *ibid*.

will manage relatively narrow formularies (i.e., only one or two products available in each insulin category) and earn substantial rebates from the manufacturer(s). Plan administrators may identify a different group of products that would be appropriate for reduced or eliminated cost sharing.

As illustrated in Figure 2, there is the potential for a patient to experience a significant reduction in out-of-pocket costs under this proposed approach. The actual reduction realized by any patient is dependent on their deductible amount, the cost-sharing requirement during the coverage phase, the cost of the insulin products, and the other services incurred during the year. Patients with higher out of pocket costs in the status quo are likely to experience a more significant change in out-of-pocket cost experience. Change may occur as lower annual out-of-pocket costs or a reallocation of expenses over the calendar year.

FIGURE 2: ILLUSTRATION OF PATIENT PERSPECTIVE OF INSULINS EXEMPT FROM COST-SHARING REQUIREMENTS

Illustration assumes 20% member cost sharing in the benefit phase (i.e., after deductible is satisfied, but before out-of-pocket maximum is reached).

MEMBER COST- SHARING EXAMPLES	DEDUCTIBLE PHASE*		
POINT-OF-SALE PRODUCT COST	\$400	\$600	\$1,000
STATUS QUO MEMBER COST SHARING (100%)	\$400	\$600	\$1,000
ALTERNATIVE MEMBER COST SHARING (0%)	\$0	\$0	\$0

MEMBER COST- SHARING EXAMPLES	COINSURANCE COVERAGE PHASE**		
POINT-OF-SALE PRODUCT COST	\$400	\$600	\$1,000
STATUS QUO MEMBER COST SHARING (20%)	\$80	\$120	\$200
ALTERNATIVE MEMBER COST SHARING (0%)	\$0	\$0	\$0

POS = Point of Sale

* Assumes the deductible has not yet been satisfied as the member is responsible for the full point-of-sale (POS) cost of the drug.

** Assumes, for illustration, that the member has a 20% cost-sharing requirement.

APPROACH 2: REDUCED MEMBER COST SHARING AT THE POINT OF SALE

Currently, there is not a direct relationship between the drug price, the rebate, and the patient's cost sharing. Typically, when a member has a coinsurance for a pharmacy transaction (including scripts filled in the deductible phase), that person's cost sharing is based on the cost at which a plan administrator (payer) will reimburse the pharmacy. Separately, the plan administrator may receive rebates from the drug manufacturer as an incentive to provide preferred formulary placement for brand-name drugs. The rebates lower the net cost of the drug for the plan administrator. Drugs with preferred formulary placement may be available to patients at lower cost-sharing levels, but, as stated above, there is not a direct relationship between the drug price, the rebate, and the patient's cost sharing.

Figure 3 illustrates the reduction in patient cost sharing associated with a specific rebate sharing arrangement. Any drug rebate that is retained by the plan administrator would continue to be shared across all members by lowering the net plan-paid amount and, therefore, the premium associated with the benefits. The cost-sharing reduction to a patient has the potential to be significant, but would still provide an incentive to seek lower-cost products if they are available and clinically appropriate. Drug manufacturers would continue to seek preferred formulary placement of their products.

The actual reduction in cost sharing realized by any patient is a function of the percentage value of the rebates shared, the magnitude of the deductible, the cost-sharing requirement during the coverage phase, the cost of the insulin products, and the other services incurred during the year. Patients with higher out of pocket costs in the status quo are likely to experience a more significant change in out-of-pocket cost experience. Change may occur as lower annual out-of-pocket costs or a reallocation of expenses over the calendar year.

FIGURE 3: ILLUSTRATION OF PATIENT PERSPECTIVE OF REBATES SHARED AT THE POINT OF SALE

Illustration assumes effective rebate percentage of 25% against point-of-sale (POS) drug price on rebate-eligible brand-name drugs. Illustration also assumes 20% member cost sharing in the benefit phase (i.e., after deductible is satisfied, but before out-of-pocket maximum is reached).

MEMBER COST-SHARING EXAMPLES	DEDUCTIBLE PHASE*		
POINT-OF-SALE PRODUCT COST	\$400	\$600	\$1,000
(A) STATUS QUO MEMBER COST SHARING (100%)	\$400	\$600	\$1,000
(B) DOLLAR VALUE OF REBATE SHARED (25%)	\$100	\$150	\$250
ALTERNATIVE MEMBER COST SHARING = (A) – (B)	\$300	\$450	\$750

MEMBER COST-SHARING EXAMPLES	COINSURANCE COVERAGE PHASE**		
POINT-OF-SALE PRODUCT COST	\$400	\$600	\$1,000
(C) STATUS QUO MEMBER COST SHARING (20%)	\$80	\$120	\$200
(D) DOLLAR VALUE OF REBATE SHARED (25%)	\$20	\$30	\$50
ALTERNATIVE MEMBER COST SHARING = (C) – (D)	\$60	\$90	\$150

* Assumes the deductible has not yet been satisfied as the member is responsible for the full point-of-sale cost of the drug.

** Assumes, for illustration, that the member has a 20% cost-sharing requirement.

If the drug manufacturers' rebates were shared with members at the point of sale, payments from the drug manufacturers would be used to directly benefit the patients who used the drugs. However, by diverting the rebate revenue to the patients, the cost to all members may increase.

It should be noted that not all brand-name drugs generate a rebate for the plan. Rebates are commonly associated with brand-name drugs that have preferred formulary placement, but there may be many other brand-name drugs available to members at higher cost sharing, or subject to prior authorization criteria, that do not generate rebates for the plan.

Manufacturer rebates are often highly competitive. Agreements between manufacturers and plan administrators are confidential. For the purposes of this proposed strategy, we have assumed that the products eligible for rebate sharing will be credited with a common percentage reduction in the cost sharing. This should streamline communication with patients and ease the administrative burden while preserving confidentiality. Therefore, within this proposed approach, we have assumed that plan administrators would continue to earn rebates on individual products according to the contractual provisions in place with the drug manufacturer. At the beginning of each plan year, the plan administrator would estimate the percentage rebate that is expected to be earned, on average, on the drugs that will be included in the rebate-sharing benefit. The plan administrator would also establish how much of that expected amount they will share with patients at the point of sale. After the effective rebate-sharing percentage is determined, that percentage amount would be applied at the point of sale to reduce the patient's cost sharing for those products.

Generic drugs (if available) often have the lowest cost sharing requirement—which is due to either lower copayment levels or their lower point-of-sale prices.³⁵ In 2015, 88% of all prescriptions were for generic drugs.³⁶ By reducing the patient's cost sharing for rebate-earning drugs by the expected rebate percentage, the patient's cost sharing is reduced, but there is still likely to be a strong financial incentive to use a generic drug if it is available and clinically appropriate.

³⁵ Pharmacy Benefit Manager Institute. 2014-2015 Prescription Drug Benefit Cost and Plan Design Report; Tables 8, 10, and 11.

³⁶ Generic Pharmaceutical Association (2015). Generic Drug Savings in the U.S., 7th ed. Retrieved December 14, 2016, from http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

LIST PRICE REDUCTION CONSIDERATIONS

Our analysis did not include list price reductions as a proposed approach. In the current commercial environment, there are many revenue streams associated with prescription drugs dispensed through a pharmacy (either a mail-order, specialty, or retail pharmacy).³⁷ The approaches we outlined to mitigate patient out-of-pocket costs for rebate-eligible drugs intentionally sought to preserve those revenue streams. Specifically, the list price of a brand-name drug is used as a basis for many transactions, including:

- **Manufacturer rebate payments:** Prescription drug formularies are often competitive. Not all clinically similar products may be covered by a formulary. Manufacturers enter rebate agreements with plan administrators in exchange for preferred formulary placement. The rebate revenue is paid as a function of list price. Specifically, rebate revenue is a function of the wholesale acquisition cost (WAC). For brand-name drugs, there is an established relationship between the WAC price and the average wholesale price (AWP) that is typically used by pharmacies as the starting list price.
- **Pharmacy reimbursement:** The reimbursement algorithm for pharmacies for brand-name drugs is a function of the list price and is typically described as list price less a discount plus a dispensing fee. A lower list price would result in lower revenue for a pharmacy, all else equal.
- **Plan administrator revenue:** Plan administrators may earn administrative fees from a manufacturer and may also retain a portion of the rebate revenue earned on drugs dispensed to plan members.³⁸

If the value of rebates were replaced by lower list prices, narrow formularies may disappear, because rebate revenue would not be available. A portion of the revenue that was a function of list price would be lost. If pharmacies and plan administrators wanted to maintain previous revenue levels, other fees would need to be increased to compensate. Lower list prices would have the greatest impact to the commercial and Medicare channels. Many other channels in the U.S. healthcare system have strong mechanisms in place already to constrain the cost of prescription drugs, such as federal supply schedule pricing, 340B pricing, and the federal Medicaid rebate program.

If one manufacturer were to replace rebates with a lower list price, and all other mechanisms remained in place, that manufacturer risks placing its products at a competitive disadvantage. It is likely that no single manufacturer has a large enough portfolio of products to impact the U.S. healthcare system in a material way.³⁹ When evaluating clinically comparable products in the existing profitability framework, the product with the lower list price will not have as many competitive levers to pull in order to secure preferred formulary placement.

³⁷ IMS Institute (November 2014). Understanding the Pharmaceutical Value Chain. Retrieved December 14, 2016, from https://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Understanding_Pharmaceutical_Value_Chain.pdf.

³⁸ Applied Policy (November 2015). Concerns Regarding the Pharmacy Benefit Management Industry. Retrieved December 14, 2016, from <http://www.ncpa.co/pdf/applied-policy-issue-brief.pdf>.

³⁹ Kaiser Family Foundation (March 2005). Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain. Retrieved December 14, 2016, from http://avalere.com/research/docs/Follow_the_Pill.pdf.

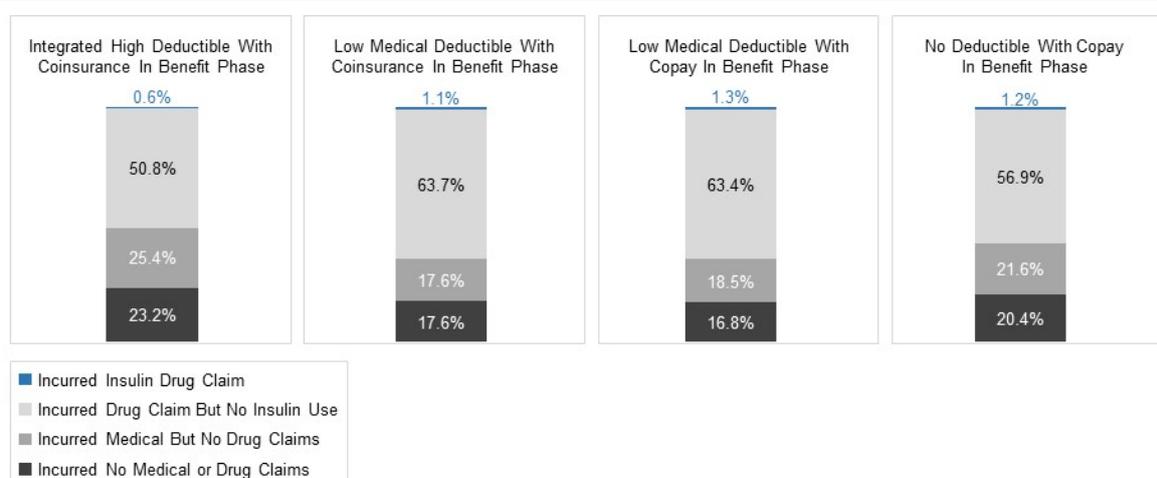
Results

For both of the proposed approaches, we generated exhibits to assess whether the approach: (a) provides a material reduction in out-of-pocket costs for the patients impacted by it, and (b) results in a relatively modest increase to the overall cost of care.

APPROACH 1: RESULTS FOR INSULINS EXEMPT FROM COST-SHARING

This mitigation strategy was applied to the integrated high-deductible health plans and also to plans with low or no deductibles on prescription drug services. Figure 4 stratifies the enrollment in each benefit design category. The members who had any insulin drug claims would benefit from this tactic.

FIGURE 4: INSULIN USERS BY BENEFIT DESIGN



Plans are categorized as having a high deductible if the deductible is at or above \$1,250 for single coverage.

Source: CY 2013 Truven MarketScan Commercial Claims and Encounters Data.

Based on a publication by the Centers for Disease Control and Prevention (CDC),⁴⁰ we expect that 4.9% of the non-elderly population in the United States has been diagnosed with diabetes. Further, approximately 29% of the non-elderly population with diabetes uses insulin (with or without an oral antidiabetic).⁴¹ Taken together, we would expect approximately 1.4% of the non-elderly population to use insulins. The values in Figure 4 are lower and may reflect the health status of actively-at-work employees and their dependents.

As seen in Figure 4, in the calendar-year 2013 experience, a lower percentage of insulin users were observed in the integrated high-deductible health plan. This may reflect a preference among the diabetes population (and insulin users specifically) for plans with lower or no deductibles. Employers who exclusively offer high-deductible health plans (also known as full replacement high-deductible plans) should expect to have a higher percentage of members who use insulin as compared with the level reported in Figure 4.

In all plan designs, most members (more than 98%) had no impact to their cost sharing under this approach, because they did not use an insulin product. Among members who used insulin, the reduction in out-of-pocket cost sharing in plans with a coinsurance benefit is around \$427 per year. Approximately 25% to 32% of members in plans with a coinsurance benefit who used insulin would have experienced a reduction of more than \$500 per year in out-of-pocket cost sharing under this approach.

⁴⁰ National Diabetes Statistics Report, 2014, *ibid*.

⁴¹ Selvin, E. et al. (March 2016). Trends in insulin use and diabetes control in the U.S.: 1988-1994 and 1999-2012. American Diabetes Association. Retrieved December 14, 2016, from <http://care.diabetesjournals.org/content/39/3/e33>.

FIGURE 5: IMPACT FROM REMOVING INSULIN COST SHARING: REDUCTION IN OUT-OF-POCKET COSTS

PLAN DESIGNS	INTEGRATED HIGH DEDUCTIBLE WITH COINSURANCE IN BENEFIT PHASE	LOW MEDICAL DEDUCTIBLE WITH COINSURANCE IN BENEFIT PHASE	LOW MEDICAL DEDUCTIBLE WITH COPAY IN BENEFIT PHASE	NO DEDUCTIBLE WITH COPAY IN BENEFIT PHASE
PERCENTAGE OF MEMBERS WHO USED INSULINS	0.6%	1.1%	1.3%	1.2%
PERCENTAGE OF MEMBERS WITH LOWER COST SHARING*	0.5%	1.1%	1.3%	1.2%
AVERAGE ANNUAL REDUCTION IN COST SHARING	\$434	\$423	\$214	\$182
DISTRIBUTION OF ANNUAL REDUCTION COST SHARING				

*A small number of members incurred their insulin claim(s) after meeting the out of pocket maximum

Source: CY 2013 Truven MarketScan Commercial Claims and Encounters Data

If the benefit administrator wants to preserve profitability (or maintain the same loss ratio target), the benefit that is accrued to the patients represented in Figure 5 must be collected through an increase in the group’s premium (or premium-equivalent for self-insured employers). The offsetting impact to premiums is estimated in Figure 6 on a per member per year (PMPY) basis. As shown in Figure 4 above, the percentage of members using insulin was lower in the integrated high-deductible health plan than we would expect for a non-elderly population. Figure 6 also estimates the increase in premium associated with removing the cost sharing on insulin if the number of users of insulin doubled within the high-deductible health plan. Note that we have not quantified the increase in the total claims costs; we have assumed that the insulin users are already covered under a plan offered by the plan administrator. If the expected costs increase in the high-deductible health plan, there should be an offsetting reduction in another plan. We did not increase the percentage of patients using insulin in the other plan types, because the prevalence of insulin users is already close to the reasonable utilization rate we should expect.

FIGURE 6: IMPACT FROM REMOVING INSULIN COST SHARING: INCREASE IN PLAN PREMIUM

PLAN DESIGNS	INTEGRATED HIGH DEDUCTIBLE WITH COINSURANCE IN BENEFIT PHASE	LOW MEDICAL DEDUCTIBLE WITH COINSURANCE IN BENEFIT PHASE	LOW MEDICAL DEDUCTIBLE WITH COPAY IN BENEFIT PHASE	NO DEDUCTIBLE WITH COPAY IN BENEFIT PHASE
ESTIMATED INCREASE IN PLAN PREMIUM				
MAINTAINING EXISTING LEVEL INSULIN USERS	\$2.63 PMPY	\$5.19 PMPY	\$3.18 PMPY	\$2.42 PMPY
WITH TWICE AS MANY INSULIN USERS	\$5.23	N/A	N/A	N/A

Assumes a target loss ratio of 85%. Increase in plan premium is associated with the removal of cost sharing for insulin only and does not reflect any increase (or decrease) in the baseline medical and prescription spending associated with insulin users.

Source: CY 2013 Truven MarketScan Commercial Claims and Encounters Data

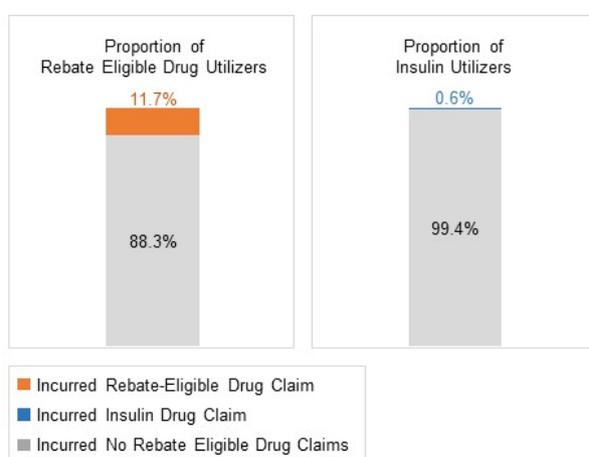
APPROACH 2: RESULTS FOR REBATE-SHARING

This mitigation strategy was applied only to integrated high-deductible health plans that have coinsurance. Other benefit design structures (including high-deductible health plans with a copayment and low- or no-deductible plans with a coinsurance) would be expected to generate a lower impact to the beneficiaries who are directly affected as well as to the aggregate cost of care. Other combinations of included products and the level of rebate sharing can be considered by plan administrators. We provide these estimates as a starting point for the discussion.

We evaluated two versions of the proposed approach that provides for proportional rebate sharing at the point of sale. One version provides rebate sharing for all rebate-eligible brand-name drugs, including specialty drugs. The other version provides rebate sharing for insulins only. We used the calendar year 2013 Truven MarketScan Commercial Claims and Encounter data to quantify the number of members in integrated high-deductible health plans with coinsurance who could be impacted by the rebate-sharing approaches. As shown in Figure 7, during calendar year 2013, an estimated 12% of members used any rebate-eligible drugs and fewer than 1% of members used any insulins.

FIGURE 7: MEMBERS OF HIGH-DEDUCTIBLE HEALTH PLANS UTILIZING REBATE ELIGIBLE DRUGS IN THE STUDY

Limited to members in integrated high-deductible health plans with coinsurance in the benefit phase.



Note that the patients who used an insulin drug are a subset of the patients who used any rebate-eligible brand-name drug.

Source: CY 2013 Truven MarketScan Commercial Claims and Encounters Data

Next, we examined the extent to which the out-of-pocket cost sharing would be reduced for the patients who used one of the rebate-eligible drugs. For the “all rebate-eligible” brand-name drug approach, we identified the highest volume brand-name drugs that account for 80% of brand-name drug pharmacy costs. We assumed that rebate-earning specialty drugs earn an average 35% rebate. For all other rebate-earning brand-name drugs, we assumed they earn an average 20% rebate. Individual products may generate rebates higher or lower than this amount, and the effective rebate may fluctuate from quarter to quarter, but we have assumed the average amount will be shared with the members and that the average amount is earned by the plan administrator. For the insulins-only approach, we used an assumption of a 45% rebate. There are no public sources for the typical value of a rebate. Actual rebates earned by plan administrators will vary depending on many factors. Figure 8 shows the distribution of the impact to member cost sharing under the two proposed approaches using the assumptions outlined above.

As seen in Figure 8, a small number of patients used an in-scope product but have no cost-sharing reduction. They are members who will reach their out-of-pocket maximum under the current benefit design and the alternative that is under consideration.

FIGURE 8: IMPACT FROM PROPORTIONAL REBATE SHARING AT THE POINT OF SALE: REDUCTION IN OUT-OF-POCKET COSTS

Limited to enrollees in integrated high-deductible plans with coinsurance in the benefit phase.

SCOPE OF PRODUCTS	ALL REBATE-ELIGIBLE	INSULINS ONLY																				
REBATE PERCENTAGE AVAILABLE TO SHARE	35% FOR SPECIALTY PRODUCTS 20% FOR ALL OTHER	45%																				
PERCENTAGE OF MEMBERS WHO USED THE ELIGIBLE PRODUCTS	11.7%	0.6%																				
PERCENTAGE OF MEMBERS WITH LOWER COST SHARING*	9.4%	0.5%																				
AVERAGE ANNUAL REDUCTION IN COST SHARING	\$89	\$276																				
DISTRIBUTION OF ANNUAL REDUCTION IN COST SHARING	<table border="1"> <caption>Distribution of Annual Reduction in Cost Sharing - All Rebate-Eligible</caption> <thead> <tr> <th>Reduction Range</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>\$1 - \$100</td> <td>78.0%</td> </tr> <tr> <td>\$101 - \$500</td> <td>19.2%</td> </tr> <tr> <td>\$501 - \$750</td> <td>1.1%</td> </tr> <tr> <td>\$750+</td> <td>1.7%</td> </tr> </tbody> </table>	Reduction Range	Percentage	\$1 - \$100	78.0%	\$101 - \$500	19.2%	\$501 - \$750	1.1%	\$750+	1.7%	<table border="1"> <caption>Distribution of Annual Reduction in Cost Sharing - Insulins Only</caption> <thead> <tr> <th>Reduction Range</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>\$1 - \$100</td> <td>30.8%</td> </tr> <tr> <td>\$101 - \$500</td> <td>52.1%</td> </tr> <tr> <td>\$501 - \$750</td> <td>10.0%</td> </tr> <tr> <td>\$750+</td> <td>7.1%</td> </tr> </tbody> </table>	Reduction Range	Percentage	\$1 - \$100	30.8%	\$101 - \$500	52.1%	\$501 - \$750	10.0%	\$750+	7.1%
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*A small number of members incurred their insulin claim(s) after meeting the out of pocket maximum

Source: CY 2013 Truven MarketScan Commercial Claims and Encounters Data

If the benefit administrator wants to preserve profitability (or maintain the same loss ratio target), the benefit that is accrued to the people represented in Figure 8 must be collected through an increase in the group's premium. Figure 9 estimates the increase in the premium required to maintain the same profitability. It may be that the rebate-sharing solution would encourage more users of high-cost brand-name drugs to enroll in the high-deductible health plan. We also estimate the increase in the premium if the number of users of these products increased by 50%. Note that we have not quantified the increase in the total claims costs; we have assumed that the brand-name drug users are already covered under a plan offered by the plan administrator. If the expected costs increase in the high-deductible health plan, there should be an offsetting reduction in another plan.

FIGURE 9: IMPACT FROM PROPORTIONAL REBATE SHARING AT THE POINT OF SALE: INCREASE IN PLAN PREMIUM

Limited to enrollees in integrated high-deductible health plans with coinsurance in the benefit phase.

SCOPE OF PRODUCTS	ALL REBATE-ELIGIBLE	INSULINS ONLY
REBATE PERCENTAGE AVAILABLE TO SHARE	35% FOR SPECIALTY PRODUCTS 20% FOR ALL OTHER	45%
ESTIMATED INCREASE IN PLAN PREMIUM		
MAINTAINING EXISTING LEVEL OF IN-SCOPE DRUG USERS	\$10.02 PMPY	\$1.59 PMPY
WITH 50% MORE IN-SCOPE DRUG USERS	\$14.19	\$2.39

Assumes a target loss ratio of 85%. Increase in plan premium is associated with the proportional rebate sharing only and does not reflect any increase (or decrease) in the baseline medical and prescription spending associated with users of the in-scope products.

Source: CY 2013 Truven MarketScan Commercial Claims and Encounters Data

Methodology

SOURCE DATA

We used the calendar year 2013 Truven MarketScan Commercial Claims and Encounters (Truven) data set. The Truven database reflects the healthcare experience of employees and dependents covered by the health benefit programs of large employers. The data reflects claims and membership information from approximately 100 different insurance companies, Blue Cross Blue Shield plans, and third-party administrators. The data represents the medical experience of active employees, early retirees, and COBRA continuations. No Medicare Supplemental, Medicaid, or workers' compensation experience is included.

BENEFIT DESIGN IDENTIFICATION

Approximately 69% of the plan data contributed to Truven includes detailed plan design information, such as deductible and cost-sharing requirements. In order to have a robust sample of plans to use in our estimates, we created an algorithm to derive the benefit design structure for each reported plan. We confirmed that the algorithm was reasonable by comparing the derived benefit design characteristics with the reported characteristics for plans with the detailed information available. In this way, we were able to identify 3.1 million members enrolled in integrated high-deductible health plans.

REBATE-ELIGIBLE DRUGS

Formulary information was not available for the plans included in the analysis. Moreover, we did not want to assess whether each individual drug was likely to be rebate-eligible within each plan. Instead, we assumed that the highest-volume brand-name drugs, accounting for 80% of the allowed costs, would qualify as "rebate-eligible."

Within the subset of drugs classified as rebate-eligible, the list of specialty products was created from the Centers for Medicaid and Medicare Services (CMS) Network and Pharmacy Public Use Files. Products that were covered on the specialty tier for more than 20% of the Medicare Part D enrollment as of July 2016 were categorized as specialty products.

AVERAGE REBATE ASSUMPTIONS

Drug manufacturer rebate agreements are confidential. The values assumed in this research were chosen by the authors as reasonable placeholders. Any plan administrator who evaluates the rebate-sharing alternatives should consider the rebates they earn as well as the percentage of those rebates they wish to share with the patients at the point of sale (or through some other mechanism).

LOSS RATIO TARGETS

The premium impact these tactics was estimated assuming an 85% loss ratio. For insured large group commercial business, this is the lowest loss ratio allowed under the ACA.⁴² Small group insured business must meet an 80% loss ratio. The premium estimates shown in the exhibits would be 6% higher for small group insured business at an 80% loss ratio. Self-insured employers establish budget expectations or premium equivalents. The loss ratio for self-insured employers would not include a profit margin and may reflect different expectations for administrative expense and risk margin. At any loss ratio higher than 85% (e.g., 88% or 90%), the premium estimates shown in the exhibits would be lower by a factor of $[85\%] \text{ divided by } [\text{loss ratio target}]$. For example, a 90% target loss ratio would result in premium equivalents 6% lower than the values shown in the exhibits.

⁴² 45 CFR 158.210

Discussion of Stakeholder Perspectives

We tested the two mitigation tactics with industry experts including employee benefit consultants, pricing and product development actuaries, and former health plan and pharmacy benefit management (PBM) executives. We met with nine stakeholder representatives in person or on the phone for challenge sessions of either one or three hours in length. There was a shared knowledge that a subset of plans include high deductibles and/or coinsurance and that this subset is growing. The industry experts note that many plan administrators want to balance cost containment techniques and affordability. Plan administrators may provide contributions to Health Savings Accounts, for example. Others have unique plan designs for lower income workers.

There was less consensus about the extent to which rebates reduce the net cost of a plan administrator's pharmacy benefit. Particularly for self-insured employer plans, the visibility to rebate volume may be limited. PBM contracts exist along a spectrum of transparency, consistent with the priorities of the plan administrator: some contracts may include lower fees in lieu of rebates, while other contracts may require all rebates to be credited to the plan administrator on a quarterly basis. Plan administrators also have flexibility with respect to how the rebate credited from the PBM is used. We heard one anecdote that the plan administrator used the rebate to off-set administrative expenses. Other plan administrators may apply the rebate as an off-set to the pharmacy benefit budget.

Components of the mitigation tactics resonated more strongly with some stakeholders. We simplify two themes of the feedback we received:

- **Patient budgeting and cost predictability.** The reduced or eliminated cost-sharing approach provides a simple and predictable cost sharing structure for members when they use products that are in-scope for the mitigation tactic. Even for members who may still meet their out-of-pocket maximum, the tactic may ease some cash flow burden. The plan administrator may consider whether there is a subset of drugs for which cost sharing could better align to the plan's goals for improved adherence and outcomes.
- **Improved transparency to net costs.** Health plan and PBM stakeholders had more familiarity with the manufacturer rebate mechanism. They acknowledged that the traditional preferred and non-preferred copayment tiers effectively passed on the value of the rebate by reducing the cost sharing for preferred drugs. Particularly for plans with a single coinsurance percentage, the rebate does not provide a direct financial benefit to the patient.

Some experts framed the rebate sharing as an opportunity to provide greater equity to the users of those products. Others observed that the rebate sharing approach had similarities to a "copay card" offered by the manufacturer, but using a mechanism that better aligns the plan sponsor and manufacturer. All emphasized that the approach needs some simplifying assumptions to be operationally feasible.

In particular, it is unlikely that the rebate shared would be equal in value to the amount earned by the plan. Drug rebate contracts can be complex and include contingent payments that cannot be determined at the start of the plan year. Plan administrators could determine a target percentage to share, anticipating that actual rebates earned during the year will be above that amount. Plan administrators may choose to recognize the cost sharing off-set through a number of mechanisms at the point of sale. Some mechanisms may not itemize the source of the lower member cost sharing.

We also note that the rebate-sharing approach may lead to lower out-of-pocket costs for the impacted patients, but it may not lower them enough to be affordable. Moreover, the amount the patient may be required to pay from prescription to prescription may vary as:

- the patient moves through the plan design coverage phases and,
- the list price of the drug(s) they take changes.

In our expert review sessions, we found that stakeholders with a clinical background or a pharmacy benefit focus were able to compare and contrast therapeutic areas. This group was more likely to contemplate the appropriate scope of products that would be addressed by the tactics. People with a stronger benefits background requested additional information about diabetes and the insulin therapeutic class. Their familiarity with specific therapeutic areas was often linked to categories with costs that were increasing unexpectedly. Across all experts, though, the estimated premium increase associated with the insulin only tactics were compelling.

Limitations

The financial estimates were based on calendar year 2013 data from the Truven Commercial Claims and Encounters database. Benefit design features were identified for each plan and included an estimate of the deductible (single and family) level, cost sharing requirement for medical and pharmacy benefits, and the out-of-pocket maximum level. Service limits, exceptions to cost sharing for certain services, and other specific features were not considered in the analysis. We also did not derive the formulary for each plan. We assumed that the highest volume brand-name drugs that accounted for 80% of total brand-name drug costs were rebate-eligible. On a plan-by-plan basis, the list of products that would be rebate-eligible may be different from the list of products we assumed. In practice, plan administrators should consider their own specific formulary, rebate arrangements and circumstances.

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.

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