## Overview

An economic model was constructed to estimate the impact of passing through a share of negotiated manufacturer rebates and discounts on brand diabetes medicines to patients with commercial insurance at the point of sale (POS). (Exhibit 1) The goal of the study is to estimate how the beneficiaries' adherence to diabetes drugs changes with the reduced out-of-pocket (OOP) drug expense and the subsequent budget impact due to improved population health. Patients are assumed to have higher adherence to diabetes medications due to lower OOP expense. Because of the higher adherence, their overall health condition is expected to improve, leading to lower disease management cost.

The model was populated using state-level data on commercially insured adults with diabetes aged 18 to 64 from the Center for Disease Control and Prevention (CDC) [1]. The subpopulation of interest for the study – beneficiaries with type 2 diabetes taking brand diabetes medicines eligible for rebates -- was derived using multiple sources[1,2,3,4,& 5] (Exhibit 2 and Exhibit 3).

Exhibit 1 Model schematic diagram
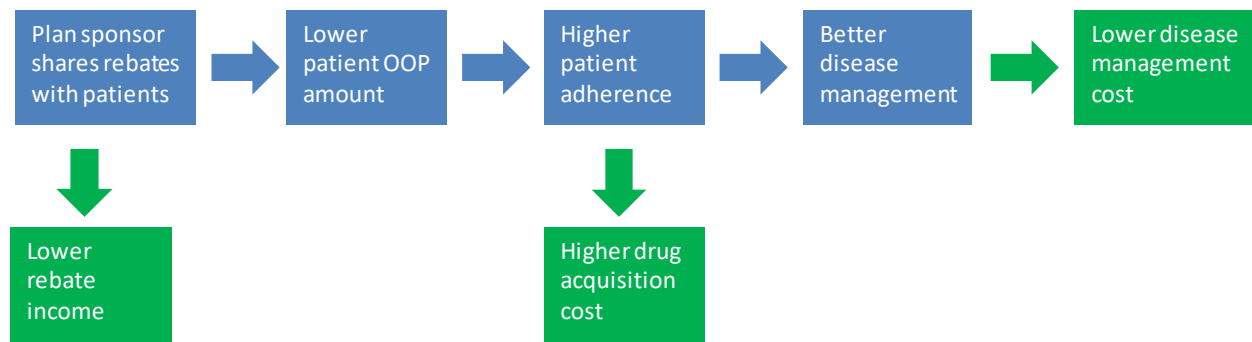
The commercial health plans included in the analysis are high-deductible health plans (hereafter, HDHPs; meeting IRS definitions regardless of HSA option) and preferred provider organization (PPO) plans. Three treatment regimens are considered and then aggregated: brand oral antidiabetic (OAD) only; brand insulin only; and both types of treatments in combination. Key model inputs were derived from peer-reviewed literature, public survey databases, and a review of approximately 9,000 insurance plans[17].

A sensitivity analysis was performed to verify the robustness of the model. The following parameters were varied for the sensitivity analysis: rebate passed through; rebate size; coinsurance size; price elasticity of demand; and offset effect (impact of adherence on medical expense).

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[1] IHSM estimation using state-level projections of demographic/insurance/residential status distribution on underlying data of diabetes population from CDC (2015), available at: https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html

[2] Xu, Guifeng, et al. "Prevalence of diagnosed type 1 and type 2 diabetes among US adults in 2016 and 2017: population based study." *bmj* 362 (2018): k1497.

[3] Centers for Disease Control and Prevention. "Number (in millions) of adults with diabetes by diabetes medication status, United States, 1997–2011." (2013).

[4] Su, Wayne, and Timothy Dall. "Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare." (2018).

[5] Milliman report (2018): *Prescription Drug Rebates and Part D Drug Costs Analysis of historical Medicare Part D drug prices and manufacturer rebates*. Available at: https://www.ahip.org/prescription-drug-rebates-and-part-d-drug-costs/.

Study Population

Exhibit 2 How the study population is derived

Commercially insured population with diabetes

Step 1
Type 2 diabetes (T2DM)
91.2% of the diabetes population

Step 2
T2DM patients on branded medication
61% of the T2DM population

Step 3
T2DM patients on branded medication w/ rebates
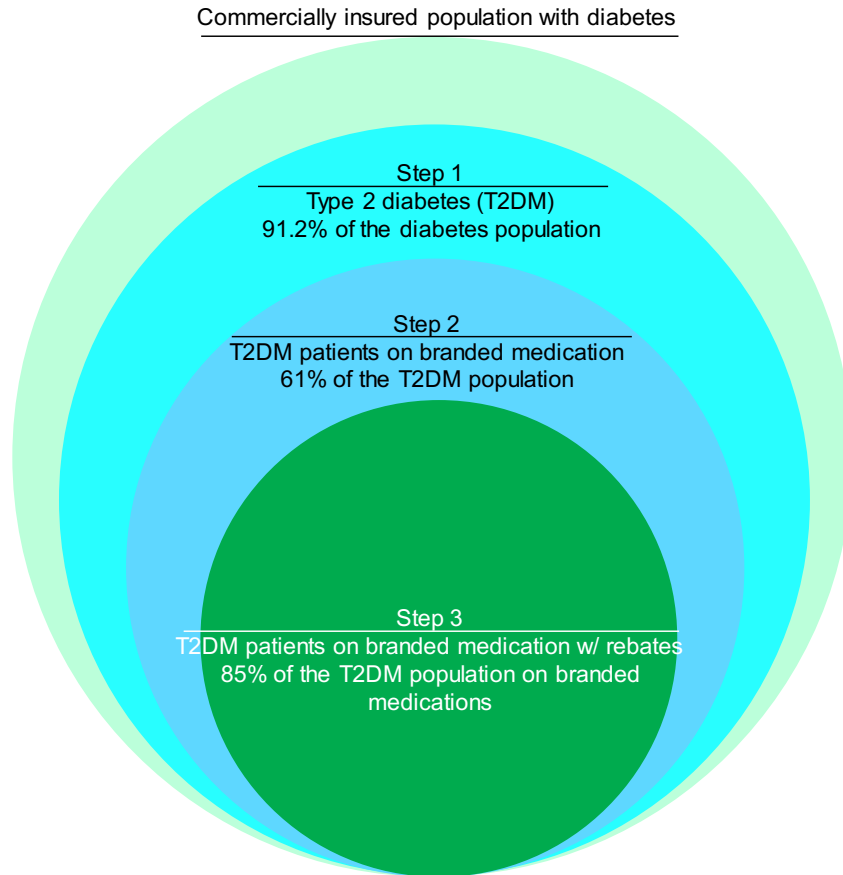85% of the T2DM population on branded
medications

Exhibit 3 Detailed calculation steps of the study population

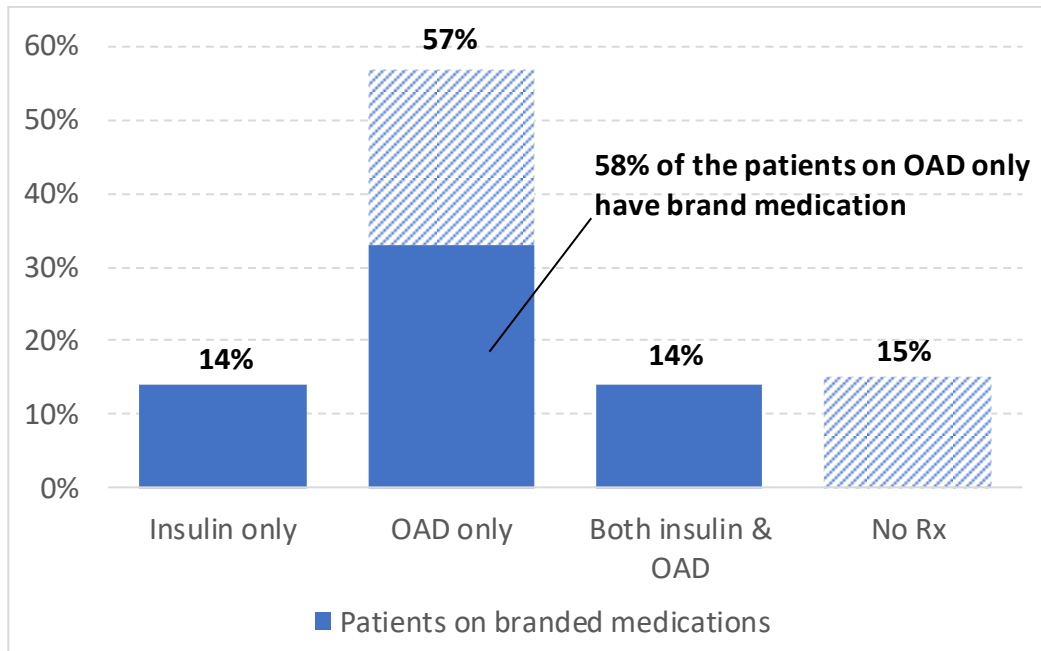| Commercially insured population with diabetes	Based on CDC data of commercially insured state-level data of adults with diabetes (Type 1 & Type 2) aged 18 to 64. Extrapolated to 2018 figures with IHSM estimation using state-level projections of demographic/insurance/residential status distribution[1]
Step 1: Type 2 diabetes (T2DM)	Patients with T2DM population consists of 91.2% of the overall diabetes population[2]
Step 2: T2DM patients on branded medication	61% of the T2DM population has at least one branded medication. This is a weighted average calculated from insulin, OAD, and both insulin & OAD populations (Exhibit 4)
Step 3: % branded medication with rebates	85% of brand medication are eligible for rebates[5]

For step 2, we calculated the percentage of patients on brand medication per weighted average across the three populations – insulin only, OAD only, and both insulin and OAD. (Exhibit 4) Because the vast majority of insulin prescriptions currently are for brand medication, it is assumed that 100% of patients

on insulin only, or on both insulin and OAD have at least one brand medication. Per a Medicare claims data analysis, 58% of the OAD-only population has at least one brand medication.[4] Among all the T2DM patients, the percentage of those on brand medication can thusly be calculated as follows:

*% of insulin-only patients * 100% + % of OAD-only patients*% patients on brand OAD + % of patients on both insulin and OAD * 100% = 14% * 100% + 57% * 58% + 14% * 100% = 61%*

Exhibit 4 Percentage of T2DM patients on different types of medications [3,4]

The study population is the commercially-insured T2DM population on brand diabetes medicines eligible for rebates. Combining all 3 steps above, it is estimated to be 91.2% * 61% * 85% = 47% of the total commercially insured population with type 2 diabetes.

A summary of key population inputs can be found below in Exhibit 5. These inputs represent national averages across the different treatment types (i.e. OAD only, insulin only, or combination OAD and insulin). The model also included state-specific population projections that are not described in this document.

Exhibit 5 Summary of key population inputs

Economic inputs	HDHP	PPO
Share of diabetes patients with type 2[2]	91.2%	91.2%
Share of patients on OAD only with at least one brand diabetic drug[4]	58%	58%
Share of brand drug scripts with rebates[5]	85%	85%
Share of the total commercial diabetes population with T2DM patients receiving brand drugs eligible for rebate[6]	47%	47%
Total number of patients[7]	1,786,048 (US total: 4,115,319)	2,329,270 (US total: 4,115,319)
Total number of fills[8]	10,232,762 (US total: 23,577,792)	13,345,030 (US total: 23,577,792)
Population growth (yearly rate)[1]	0.9%	0.9%
Share of fills in each insurance phase[9]	Deductible: 64%, Coinsurance: 11%, Over OOP maximum: 25%	Deductible: 26%, Coinsurance: 41%, Over OOP maximum: 33%

Other Model Inputs

The number of fills in each insurance phase (deductible, coinsurance, or reaching out-of-pocket (OOP) maximum) was estimated using a report of the distribution of healthcare spending across the population[10]. By combining this distribution and the estimates from the literature review on medical costs, averages number of fills, deductibles and max OOP, the percentage of fills in each insurance phase was extrapolated.

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[6] IHSM estimation based on data from sources: 2, 3, 4 & 5. See Exhibit 2 for detailed overview.

[7] IHSM estimation based on source 1 and source 17.

[8] IHSM calculation based on number of fills per patient from source 4 and population data from source 1.

[9] IHSM calculation, see methodology section for in-depth description.

[10] Kaiser Family Foundation (2017)" How do health expenditures vary across the population". Available at:

(https://www.healthsystemtracker.org/chart-collection/health-expenditures-vary-across-population/#item-pocket-spending-health-services-almost-concentrated-overall-health-spending_2015).

Exhibit 6 Summary of econmic and plan-related inputs

Economic inputs	HDHP	PPO
Rebate size (%)[4]	OAD:40%, Insulin:70%, Both:40%, Overall: 47%	OAD: 40%, Insulin:70%, Both: 40 %, Overall: 47%
Total average medical cost (excluding drugs)[11]	$15671	$15671
Price elasticity of demand (drug adherence change from 1% change in OOP cost)[12,]	-0.23%	-0.23%
Offset effect (medical savings) from better adherence/glycemic control reducing diabetes-related complications[13, 14, 15, 16]	OAD: 0.94%, Insulin: 0.72%, Both: 0.83%, All:0.83%	OAD: 0.94%, Insulin: 0.72%, Both: 0.83%, All:0.83%
Total negotiated gross price per fill[4]	OAD: $466, Insulin: $487, Both: $446, ALL: $474	OAD: $466, Insulin: $487, Both: $446, ALL: $474
Health expenditure cost growth (yearly rate)[11]	2.6%	2.6%
Rebate pass through (%)	100%	100%
Plan-related inputs		
Cost share percentage ("coinsurance" input in the model)[4,17,18] for pharmacy benefit	36%	43%
Cost share percentage for medical benefit[18]	17%	20%
Max OOP (combined from pharmacy and Medical benefits)[17]	$5811	$4013
Deductible overall (combined from pharmacy and Medical benefits) [17]	$3290	$482
Share of patients with each plan[19]	43%	57%

Notes: All dollar-denominated values are in 2018 USD.

[11] American Diabetes Association. "Economic Costs of Diabetes in the US in 2017." *Diabetes care* 41.5 (2018): 917.

[12] Goldman, Dana P., et al. "Pharmacy benefits and the use of drugs by the chronically ill." *Jama* 291.19 (2004): 2344-2350.

[13] Kennedy-Martin, Tessa, Kristina S. Boye, and Xiaomei Peng. "Cost of medication adherence and persistence in type 2 diabetes mellitus: a literature review." *Patient preference and adherence* 11 (2017): 1103.

[14] Kleinman, Nathan L., Justin L. Schaneman, and Wendy D. Lynch. "The association of insulin medication possession ratio, use of insulin glargine, and health benefit costs in employees and spouses with type 2 diabetes." *Journal of occupational and environmental medicine* 50.12 (2008): 1386-1393.

[15] Encinosa, William E., Didem Bernard, and Avi Dor. "Does prescription drug adherence reduce hospitalizations and costs? The case of diabetes." *Pharmaceutical Markets and Insurance Worldwide.* Emerald Group Publishing Limited, 2010. 151-173.

[16] Sokol, Michael C., et al. "Impact of medication adherence on hospitalization risk and healthcare cost." *Medical care* (2005): 521-530.

[17] Based on report prepared by Leverage Global Consulting LLC. "Fully Insured plans from AETNA & ANTHEM" (2018)

[18] Kaiser Family Foundation 2018 Employer Health Benefits Survey (2018) Available at: https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/

[19] Cohen, R. A., and E. P. Zammitti. "High-deductible Health Plan Enrollment Among Adults Aged 18-64 With Employment-based Insurance Coverage." *NCHS data brief* 317 (2018): 1-8.

Key Assumptions

This economic model estimates the potential impact of sharing diabetes drug rebates directly with the patients who take them on overall medical spending, and utilizes the following assumptions:

- The study population consists of the commercially insured (HDHP and PPO) with T2DM, as HDHP and PPO are the most common insurance plans and represent most of the commercially insured population[19].
- The 10-year state-level population growth of the commercially insured with T2DM is estimated indirectly by stratifying the overall population trend by demographics/insurance/geography[1].
- The study only includes beneficiaries who receive brand diabetes medicine that are eligible for rebates.
- The insurance phases in which the costs are distributed between the beneficiaries and the health plans are: deductible phase, cost sharing phase, and over out-of-pocket (OOP) maximum phase.
- Rebate is calculated as a percentage of list price.
- Rx and medical cost are combined and counted towards deductible and OOP maximum
- Copayments and premiums are assumed to be constant and thus are not modelled.
- The rebate amounts are confidential and may differ within each category (e.g., within the insulin class), from product to product and between health insurance plan. The rebate level is assumed to be the same as the IHSM Medicare study and the aggregated rebate level is weighted with number of patients of the commercial population within each formulary category[4].
- The study assumes that beneficiaries on insulin or a combination of insulin and oral antidiabetic medication receive at least on branded medicine.