

Prescription Medicines: Insulin Costs in Context

May 2022

Medical Innovation Has Transformed the Lives of Patients with Diabetes

A century ago, patients were treated with insulins from pigs and cattle.

Today, patients have access to insulins that operate at the molecular level which more closely resemble insulin released naturally in the body.

More recent advances have driven much of this transformation.

Maintenance of stable and consistent blood

sugar levels is better than ever before, helping to

avoid serious complications and reduce weight



gain.

Longer-acting insulins provide coverage for over 24 hours and enable greater flexibility in dosing and reduced risk of dangerous blood sugar drops.

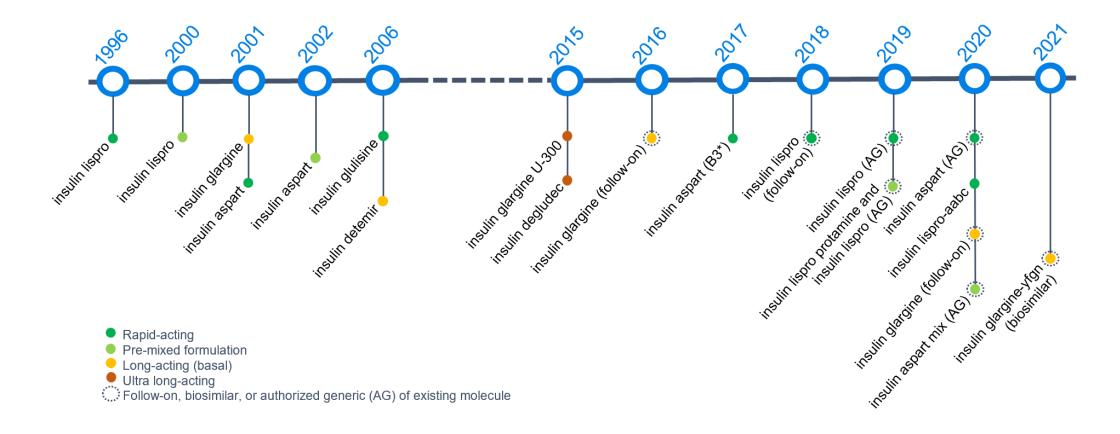


Rapid-acting insulins—including an inhaled form—enable dosing directly before or even after meals, rather than in anticipation of meals.



Insulin pens offer greater convenience, including some that reduce injections for high doses or ease of use in children.

Market Launches of Insulin Analogs, 1996-2021





**Following the transition date, authorized generics may be regarded as unbranded biologics.

Better Diabetes Management Saves Money and Improves Health Outcomes

Improving Medication Adherence Among Patients with Diabetes Could:



million

Americans live with **uncontrolled** diabetes.



Result in 1 million fewer ER visits and hospitalizations annually



Save \$8.3 billion for the U.S. health care system each year



SOURCES: American Diabetes Association.; Jha, et al. "Greater Adherence to Diabetes Drugs is Linked to Less Hospital Use and Could Save Nearly \$5 Billion Annually." Health Affairs

Private Sector Negotiations Hold Down Medicine Costs

Negotiating power is increasingly concentrated among fewer pharmacy benefit managers (PBMs).

Insurers & PBMs determine:

IF MEDICINE IS COVERED on the formulary

PATIENT OUT-OF-POCKET COST

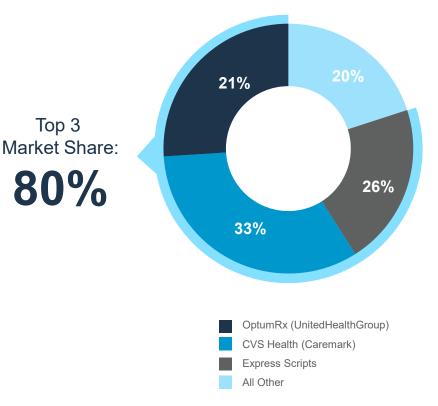
based on tier placement

ACCESS BARRIERS

like prior authorization or fail first

PROVIDER INCENTIVES

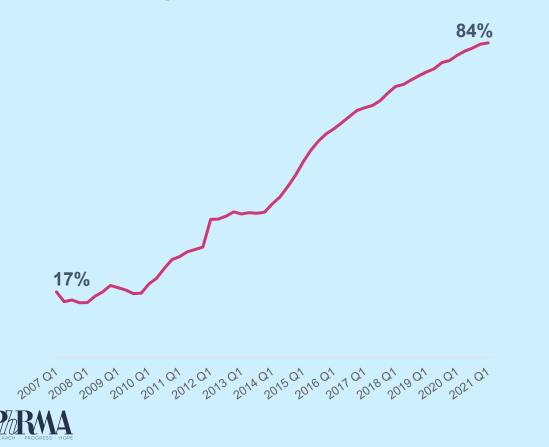
through preferred treatment guidelines and pathways

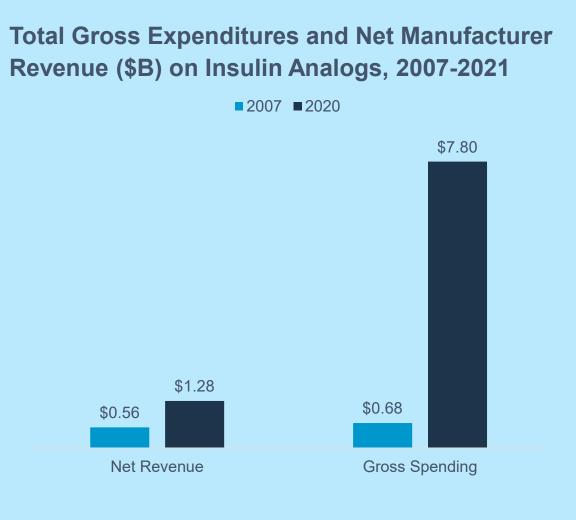




Discounts, Rebates and Other Payments Lowered the Cost of The Most Commonly Used Insulins by 84% in 2021

Average Gross-to-Net Difference for Insulin Analogs, 2007-2021

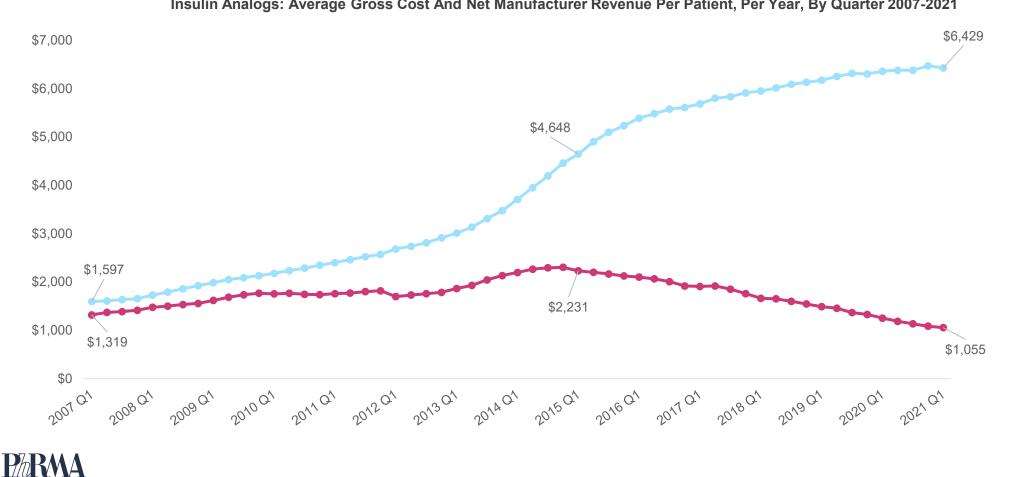




SOURCE: Milliman, Analysis of Insulin Competition and Costs in the United States, December 2021.

Health Plans Pay Less Today for Insulin Than 15 Years Ago

The average annual net costs for the most commonly used insulins have declined by 20% since 2007.



Insulin Analogs: Average Gross Cost And Net Manufacturer Revenue Per Patient, Per Year, By Quarter 2007-2021

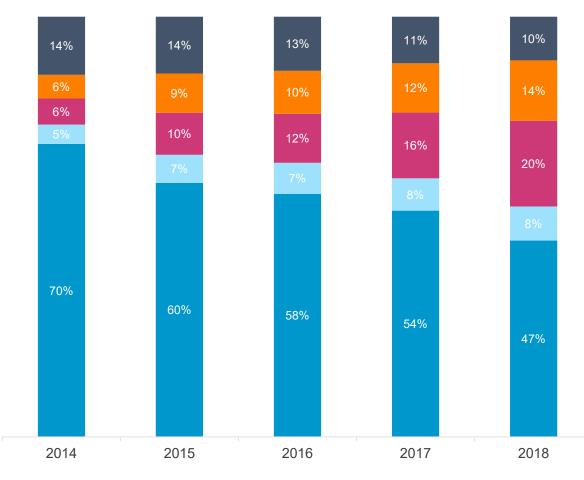
SOURCE: Milliman, Analysis of Insulin Competition and Costs in the United States, December 2021.

Others in the supply chain, such as PBMs, have received a growing share of total spending on insulins.

Between 2014 and 2018, the share of total spending on insulins retained by PBMs increased 155%. At the same time, the share going to manufacturers decreased by 33%.

Share of Net Expenditures on Insulin Captured by Manufacturers, Wholesalers, PBMs, Pharmacies, and Health Plans

Manufacturer Wholesaler Pharmacy PBM Health Plan

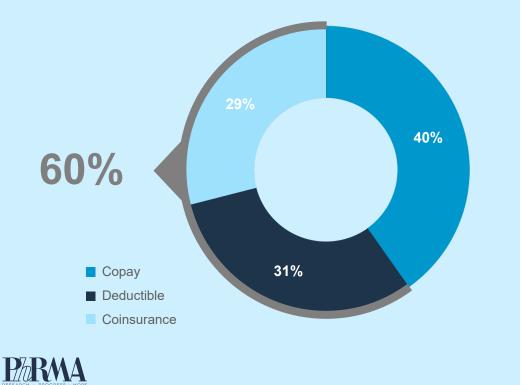




SOURCE: Van Nuys K, Ribero R, Ryan M, Sood N. Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018. JAMA Health Forum. 2021;2(11):e213409

Insurers Use of Deductibles and Coinsurance Shift the Cost of Medicines onto Vulnerable Patients

More than half of patient out-of-pocket spending on brand diabetes medicines is attributable to deductibles and coinsurance.

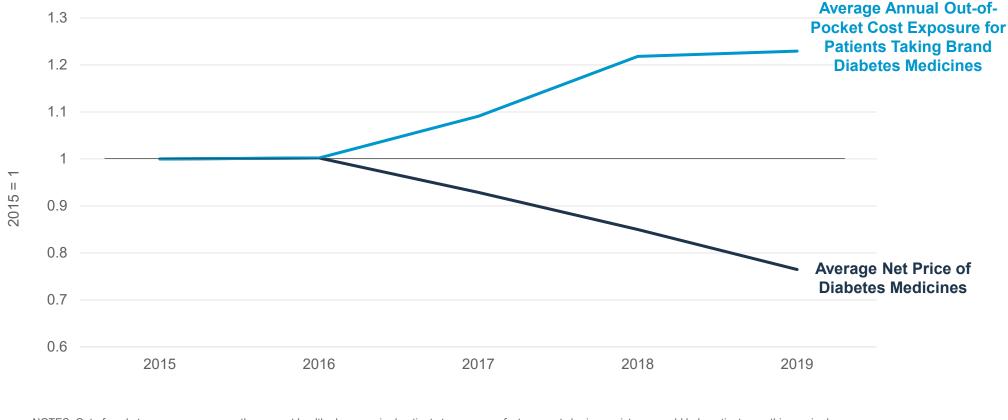


1 in 4 patients taking brand diabetes medicines are exposed to deductibles or coinsurance, which is typically based off of a medicine's undiscounted list price.



Insurers and Middlemen Expose Patients with Diabetes to Increasing Out-of-Pocket Costs

Patients taking brand diabetes medicines are forced to pay an increasing amount out of pocket, even though prices health plans pay have gone down.



NOTES: Out-of-pocket exposure measures the amount health plans required patients to pay; manufacturer cost sharing assistance could help patients pay this required amount. Diabetes net price data includes both brand and generic medicines.

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Patients with Coinsurance and Deductibles Pay More on Average for Diabetes Medicines

Patients who filled prescriptions for brand diabetes medicines while in the deductible spent



out of pocket than patients with only fixed copays.

Patients with coinsurance cost sharing who filled prescriptions for brand diabetes medicines spent



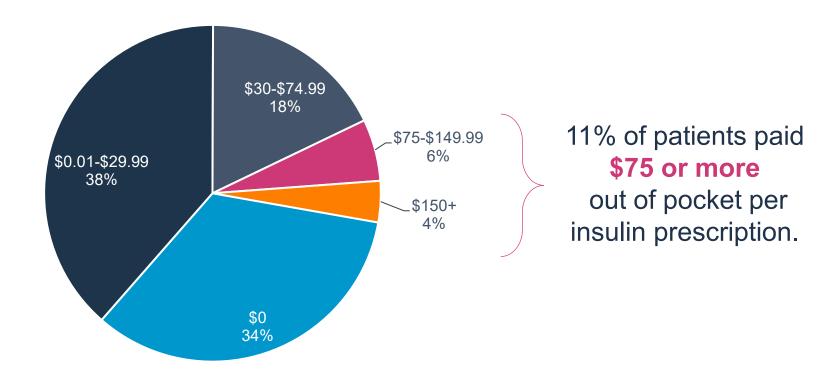
out of pocket than patients with fixed copays.



SOURCE: IQVIA. US Market Access Strategy Consulting analysis. 2020.

Insurer Practices Have Led to High Out-of-Pocket Costs for Some Patients with Diabetes

Final Out-Of-Pocket Cost Per Insulin Prescription, All Payers, 2019

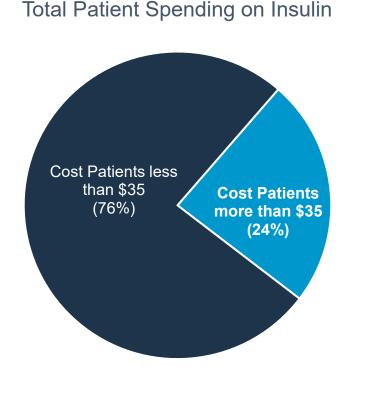




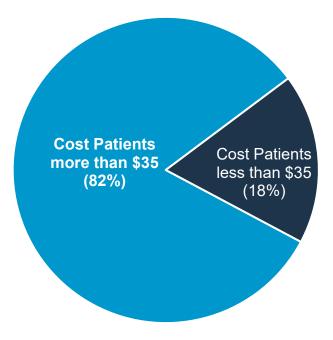
NOTES: Includes insulins only, all payers SOURCES: IQVIA, Medicine Spending and Affordability in the United States, August 2020.; IQVIA, Diabetes Costs and Affordability in the United States, June 2020.

A Small Share of Insulin Scripts Account for the Majority of Total Spending – The Opposite of How Insurance Should Work

While just 24% of insulin prescriptions cost patients more than \$35 out of pocket, these prescriptions account for 82% of total patient spending on insulin.



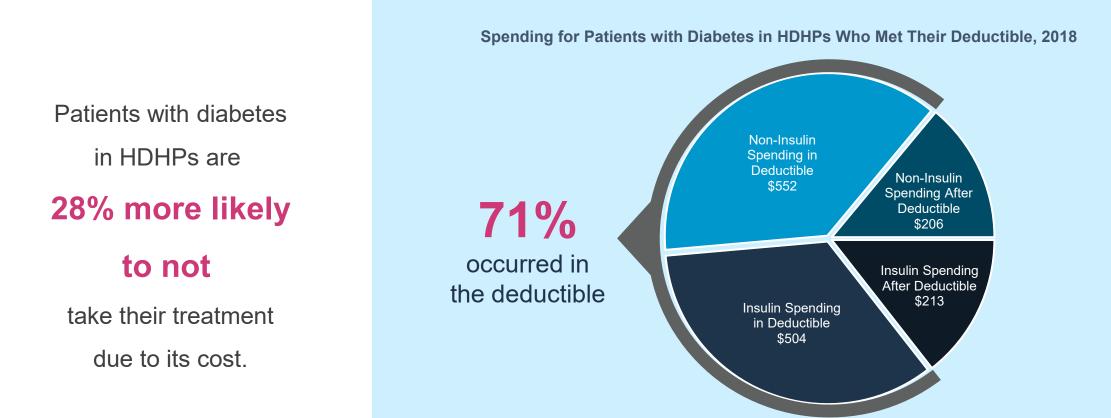
Total Insulin Prescriptions





Patients with Diabetes in High-Deductible Health Plans Face High Out-of-Pocket Costs at the Start of Each Year

For patients with diabetes whose insulin is subject to the deductible, it takes nearly half a year, on average, to meet that deductible.



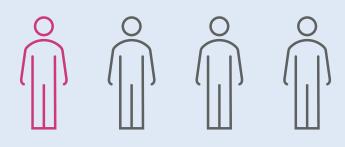


NOTE: For patients with diabetes who had at least 1 insulin claim in the deductible. In 2018, 88% of patients with diabetes in HDHPs met their deductible.

SOURCES: Xcenda, Impact of First Dollar Coverage for Insulin, October 2020.; Rastas, C., Bunker, D., Gampa, V. et al. Association Between High Deductible Health Plans and Cost-Related Non-adherence to Medications Among Americans with Diabetes: an Observational Study. J GEN INTERN MED (2021). https://doi.org/10.1007/s11606-021-06937-9

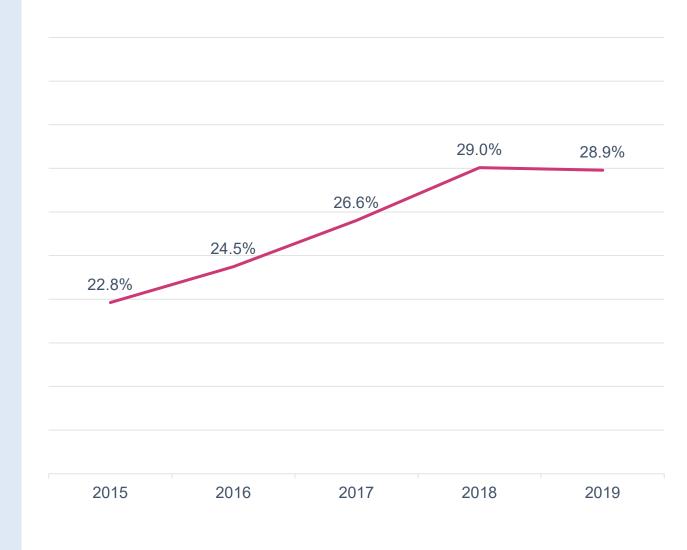
Patient Assistance Programs Have Become a Crucial Lifeline for Many Patients with Diabetes

More than **1 in 4 patients** taking brand diabetes medicines used cost-sharing assistance to help them pay for their medicines in 2019.



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Share of Patients Taking Brand Diabetes Medicines Using One or More form of Cost-Sharing Assistance



Patient Spending On Brand Diabetes Medicines Would Have Been Twice As High Without Cost-Sharing Assistance

Patients just beginning treatment with brand medicines are nearly

3X

more likely to abandon their treatment at the pharmacy if they don't use costsharing assistance. Average Cost Sharing Requirement and Final Annual Out-of-Pocket Spending for Patients Taking Brand Diabetes Medicines Who Used Cost-Sharing Assistance, 2019



NOTES: Includes out-of-pocket spending for condition-specific brand medicines only. Out-of-pocket cost sharing requirement measures the amount health plans required patients to pay. Difference between cost sharing requirement and final out-of-pocket spending represents the savings from use of cost sharing assistance.

SOURCES: IQVIA, Patient Affordability, Part 2, 2018.; IQVIA U.S. Market Access Strategy and Consulting analysis, July 2020.

The Regulatory Framework Governing Insulins has Not Allowed For Generics

There are commonly used insulins that have not had patent protection for many years. But a regulatory pathway to bring biosimilar insulins to market did not exist until March 23, 2020.

Prior to that time, a range of follow-on and authorized generic insulins drove competition and now two biosimilar insulins have been approved.

	Long-Acting insulin analogs	Rapid-Acting insulin analogs
Total Products in Class (including brands)	8	9
Follow-ons	2	1
Authorized Generics		3
Biosimilars	1	
Interchangeable Biosimilars	1	

Interchangeable products may be automatically substituted at the pharmacy counter in many states and hold tremendous potential to further fuel competition and drive savings in the years ahead.

* Each class is available in a variety of dosage forms and delivery methods (e.g. vials, injections, etc.) ‡ Short-acting human insulins, intermediate insulins and pre-mixed formulations are not included here ** Following the transition date, authorized generics may be regarded as unbranded biologics.

Current System Can Lead Middlemen to Favor Medicines with High List Prices and Large Rebates

While follow-on, authorized generic and biosimilar insulins drive competition across the market, misaligned incentives mean PBMs may block patient access to these lower list-priced products in favor of products with large rebates.

Follow-on insulins launched in 2016 and 2018 have been found to capture just 2-17% of the market share in Medicare by 2019. In 2019, just 1 in 4 Medicare Part D beneficiaries and 1 in 5 patients with commercial insurance could access lower-list priced authorized generics.

None of the nation's 3 largest PBMs included the low-list priced interchangeable biosimilar on 2022 formularies.

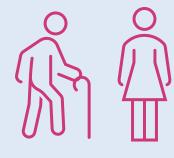


* Following the transition date, authorized generics may be regarded as unbranded biologics.

SOURCES: HHS, OIG "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 Pharmaceuticals and Certain Pharmaceuticals and Creation Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmaceuticals and Creation Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmaceuticals and Creation Pharmaceuticals and Creation Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmaceuticals and Creation Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Creation Pharmaceuticals and Pharmaceutic

Sharing Negotiated Savings Could Lower Patient Costs in Medicare Part D

For a typical Part D patient with diabetes taking five medicines, including insulin:





Out-of-pocket spending could **decrease nearly \$900 a year**



Premiums could increase \$3 to \$6 a month, **as little as a dime a day**

Sharing Negotiated Savings Would Help Lower Out-of-Pocket Costs for Patients with Commercial Insurance

Example: High-Deductible Health Plan with a Copay



Mary has diabetes and spends \$1,000 each year on medical and pharmacy expenses



She would save \$359 a year

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Her premium would increase less than 1%

His premium would increase less than 1%

He would save about \$800 a year



Kevin has diabetes and several other health conditions and spends \$5,000 each year on medical and pharmacy expenses

Example: High-Deductible Health

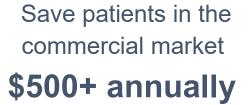
Plan with Coinsurance



SOURCE: Milliman Analysis, October 2017.

Sharing Rebates Can Save Americans with Diabetes \$500 Each Year, Especially For Black and Hispanic Americans

Sharing negotiated rebates directly with patients in commercial health plans taking brand oral antidiabetic drugs could:



on average

Have large adherence improvements for patients of color

- Asian patients: 9%
- Black patients: 11%
- Hispanic patients: 16%

Avoid nearly 700

premature deaths each year and reduce overall health care spending by **\$8B**

over 10 years



SOURCE: GlobalData, "Sharing rebates can save Americans with diabetes \$500 each year and improve adherence, especially for Black and Hispanic Americans." March 2022.

First Dollar Coverage for Insulin Could Improve Affordability for Patients with Diabetes in High-Deductible Health Plans

Exempting insulin from the deductible could significantly lower patients' annual outof-pocket costs.

Annual out-of-pocket costs could be:

2.4x to 3.7x Less

If all patients taking insulin in highdeductible health plans had first dollar coverage. And could save certain patients with diabetes:

\$1,500 in annual out-of-pocket costs

Allowing patients to more evenly spread out-of-pocket costs throughout the year.



SOURCE: Xcenda, Impact of First Dollar Coverage for Insulin, October 2020.

Policy Solutions to Address Insulin Affordability Challenges

SUPPORT REBATE PASS-THROUGH AND PROVIDE FIRST DOLLAR COVERAGE

Insurers and PBMs should pass through negotiated rebates and discounts and provide first dollar coverage of insulin, to help lower out-of-pocket costs for insulin and allow patients to spread costs throughout the year.

ADDRESS INCENTIVES THAT HARM PATIENTS, BENEFIT MIDDLEMEN

Advance reforms that prevent PBMs and other supply chain entities from having their compensation calculated as a percent of the price of a medicine and instead support policies that require compensation as a flat fee based on the value their services provide.

REQUIRE THAT PATIENTS WITH STATE-REGULATED INSURANCE BENEFIT FROM REBATES

Support legislation at the state level that could help reduce patients' out-of-pocket costs by requiring insurers to share discounts and rebates with patients at the pharmacy counter or to cap certain out-ofpocket costs.

MODERNIZE PART D COVERAGE

Establish an annual cap on out-of-pocket costs and allow patients to spread costs throughout the year.

COUNT COST-SHARING ASSISTANCE AND THIRD-PARTY DISCOUNT PLANS

Support policies that require health plans to count costs incurred on prescriptions purchased with cost-sharing assistance or through third-party discount programs, like Blink Health and GoodRx, towards deductibles and out-of-pocket limits.

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