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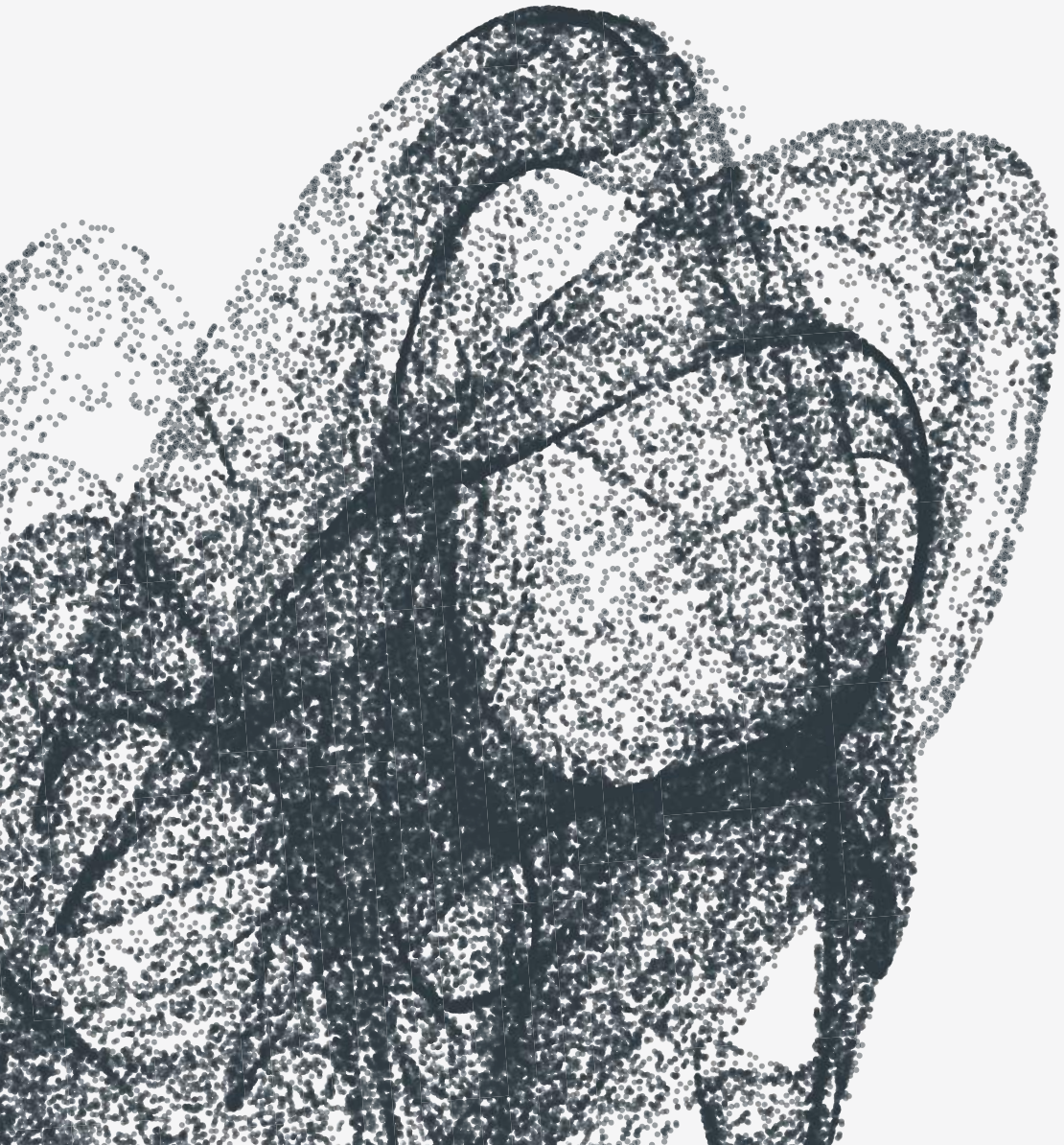
INSTITUTE
FOR HUMAN DATA SCIENCE

Diabetes Costs and Affordability in the United States



JUNE
2020

Introduction

In the current healthcare climate, particularly during the social and economic disruptions related to COVID-19, healthcare and medicine costs are very important to patients, payers and policymakers. Diabetes is a high-profile therapy area often considered a driver of financial challenges for payers and patients. Diabetes has a large and growing patient population, ranks among the top three therapy classes in terms of both utilization and drug spend for both Commercial and Medicare, and contributes significantly to CMS costs due to high volumes dispensed moreso than prices. Diabetes is a highly competitive and heavily contracted category where discounts and rebates lower net prices to levels much lower than list prices. As policymakers consider significant changes to U.S. drug pricing, including rules potentially impacting diabetes pricing, this report provides useful facts and context to inform those decisions.

This report has been designed to provide information of interest to patients, payers, providers, legislators and regulators to help better understand the complex dynamics surrounding diabetes medicines.

The study was produced independently by the IQVIA Institute for Human Data Science as a public service, with funding from Novo Nordisk. The contributions to this report of Katie Devane, Marcella Vokey, Elyse Muñoz, and dozens of others at IQVIA are gratefully acknowledged.

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MURRAY AITKEN
Executive Director
IQVIA Institute for Human Data Science

Overview

Diabetes costs have been a focus for stakeholders but several key misunderstandings persist around the prices of these critical medicines. Overall spending on diabetes is a function of the number of people suffering and the price of treatments. Changes in list price, net manufacturer price and out-of-pocket costs are trending differently and the price 'to whom' is often the most important issue to study. Net prices realized by manufacturers have been declining for the last three years but reductions have not been uniformly observed in patient out-of-pocket costs. For a subset of patients, costs fall outside their ability to afford them but the overwhelming majority of patients have low costs that are trending flat or declining. These observations may inform policies that target patients with the most pressing affordability challenges.

+ Diabetes prices have risen significantly in the past five years on a list-price basis though manufacturer net revenues have been declining and patient out-of-pocket costs have been flat or have risen only slightly.

+ The various discounts and rebates that lower manufacturer net revenues are not uniform even for products in the same class.

+ There are significant variations in initial cost exposure and final out-of-pocket costs by patient insurance type with initial copays substantially higher for Commercial patients, though their final out-of-pocket costs are similar to that of Medicare patients.

+ As patients face higher costs, more patients abandon prescriptions and are less adherent, which could lead to poorer clinical outcomes in the diabetes population, but relatively few patients have faced these high costs overall. Notably patient sensitivity to cost has been largely unchanged during COVID-19.

+ Commercially-insured patients have higher initial cost exposure than Medicare patients, but can use coupons to offset costs and a significant proportion are doing so. Medicare patients cannot use coupons but do benefit from mandated manufacturer subsidies in the coverage gap.

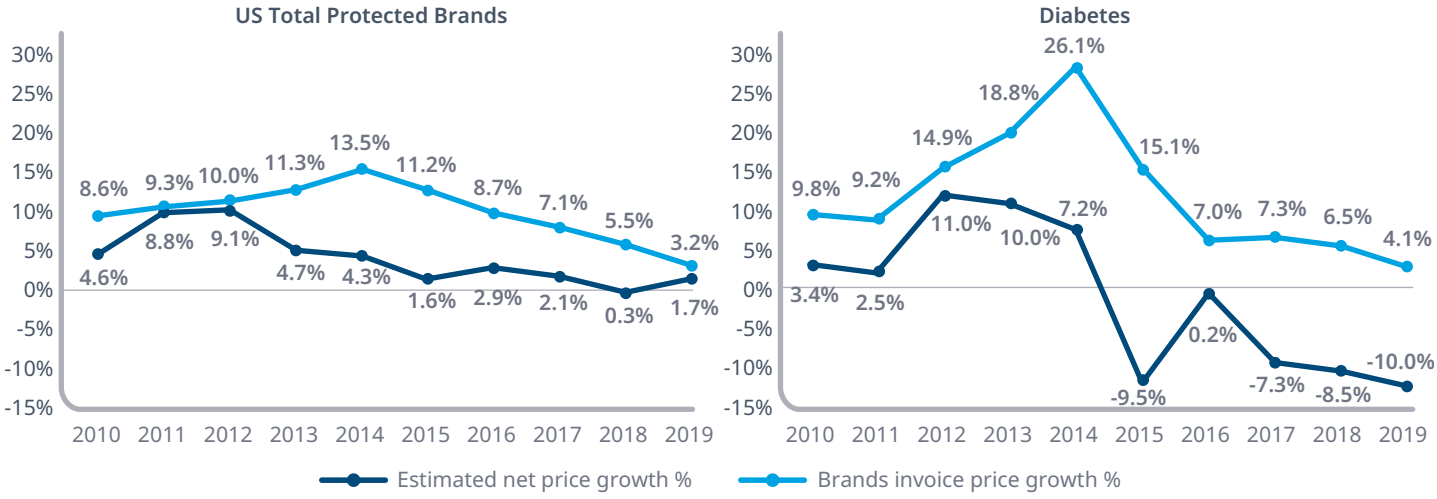
+ The distribution of patients with very high out-of-pocket prescription costs varies by drug type and insurance type and even among patients with the same insurance. Disease co-morbidities and use of specific medicines can mean some patients reach deductibles sooner than others and face differing costs for their diabetes medicines.

+ Patient out-of-pocket costs are determined through a combination of factors including list prices, benefit designs and patient spending throughout the year and the list price is rarely the same as the price that patient ultimately pays out-of-pocket.

+ A number of recent policies and environmental factors may impact patient costs for diabetes and other medicines in the near term.

Invoice prices for diabetes medicines have been growing above inflation while net prices have been declining to flat for five years

Exhibit 1: Invoice and Estimated Net Price Growth, 2010–2019



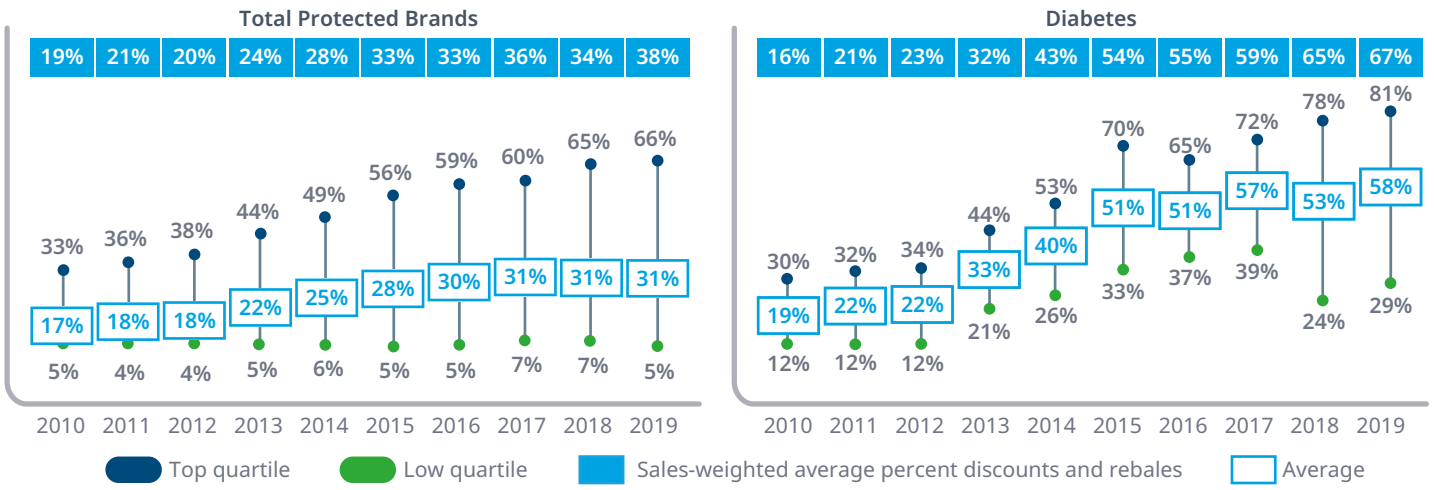
Source: IQVIA Institute, National Sales Perspectives, Dec 2019

- Invoice price growth in diabetes rose sharply from 2012 to 2015, but in other periods trends have mirrored the market overall, albeit at much lower rates.
- In 2016, invoice prices grew only 7% compared to 15% in the prior year, while net price declines paused for a year, restarting a trend of declines for the subsequent three years.
- The statutory and negotiated discounts in the system, which vary by insurance type and insurer in aggregate, make net trends much lower than invoice.
- Broadly, the use of price-protection contracts and the presence of statutory rebates in Medicaid are among the most impactful drivers of lower net prices.
- Pharmacy benefit managers (PBMs) are most often contractually required to share a large percentage of rebates they receive with their plan sponsors (either health plans or employers), who then determine how much of these discounts are available to consumers through formulary and benefit designs.
- It is notable that as net prices have declined, patient out-of-pocket costs have been flat to rising slightly (see Exhibit 3).

Exhibit notes: "Invoice" values are IQVIA reported values from wholesaler transactions measured at trade/invoice prices and exclude off-invoice discounts and rebates that reduce net revenue received by manufacturers. "Net" values denote company recognized revenue after discounts, rebates and other price concessions. These discounts could include patient copay coupons, wholesaler distribution fees, 340B discounts, coverage gap subsidies in Medicare Part D as well as other statutory and customary discounts and rebates. Results are based on a comparative analysis of company reported net sales and IQVIA reported sales and prices at product level for branded products representing 75—93% of brand spending in the period displayed. All growth numbers calculated over same cohort of products in the prior year. Protected brands are those medicines with active patent or other market protections and are not facing direct competition from a generic or biosimilar, and for the purposes of pricing analyses also exclude products launched within the past two years.

The various discounts and rebates that lower manufacturer net revenues are not uniform even for products in the same class

Exhibit 2: Percent Difference Between Invoice Prices And Manufacturer Net Revenues



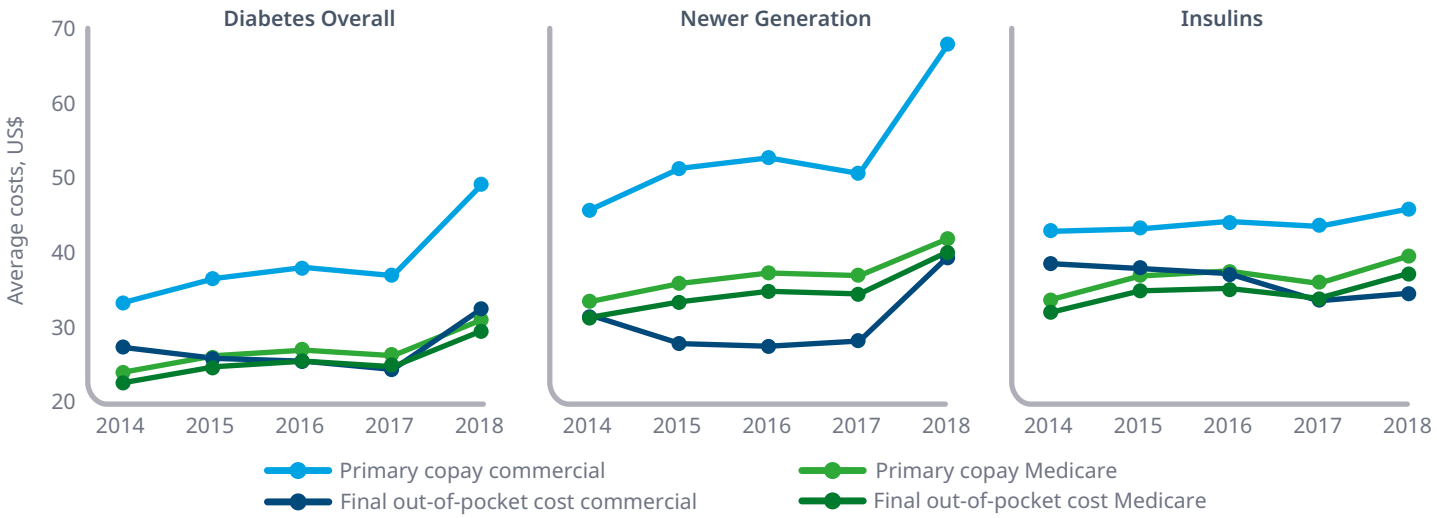
Source: IQVIA Institute, Apr 2020

- Over the past ten years, off-invoice discounts and rebates have doubled, on average, from 19% to 38% while those in diabetes have risen more than four-fold from 16% to 67%.
- A variety of mechanisms are embedded in these discounts and rebates including statutory rules governing Medicaid, the veterans administration, the 340b program, Medicare coverage gap discounts for patients, and the use of 'price protection' contracts in Medicare Part D and commercial plans which has been predominant at least since 2012, and the use of patient copay coupons.
- Competition in some therapy areas additionally drive greater levels of discounting and rebating.
- With all of these dynamics in effect, discounts and rebates are not uniform in the market and even within a therapy area.
- The upward trajectory of rebates overall reflects the mix of these pricing dynamics and suggests that much of the revenues manufacturers would have earned, in former times, through price increases are now paid back in various statutory rebates or in negotiated concessions to payers or in coupons to patients.
- With diabetes patients more often in Medicaid or Medicare with low-income subsidies (LIS), rebates are generally much higher than in other therapy areas.
- Manufacturer coverage gap discounts, which provide a 70% subsidy for patients in the Medicare Part D coverage gap, contribute to lower patient costs and a significant reduction in net revenues, and 31% of all coverage gap discounts across all diseases are paid by companies for diabetes products.*

Exhibit notes: *Medicare coverage gap discounts in 2017 were 31% diabetes. Data available from: http://www.medpac.gov/docs/default-source/reports/jun19_ch2_medpac_reporttocongress_sec.pdf

Initial copays are substantially higher for Commercial patients, though final out-of-pocket costs are similar to Medicare patients'

Exhibit 3: Average Primary Copay and Final Out-of-Pocket Costs for Diabetes and Selected Drug Classes by Payer Type, 2014–2018



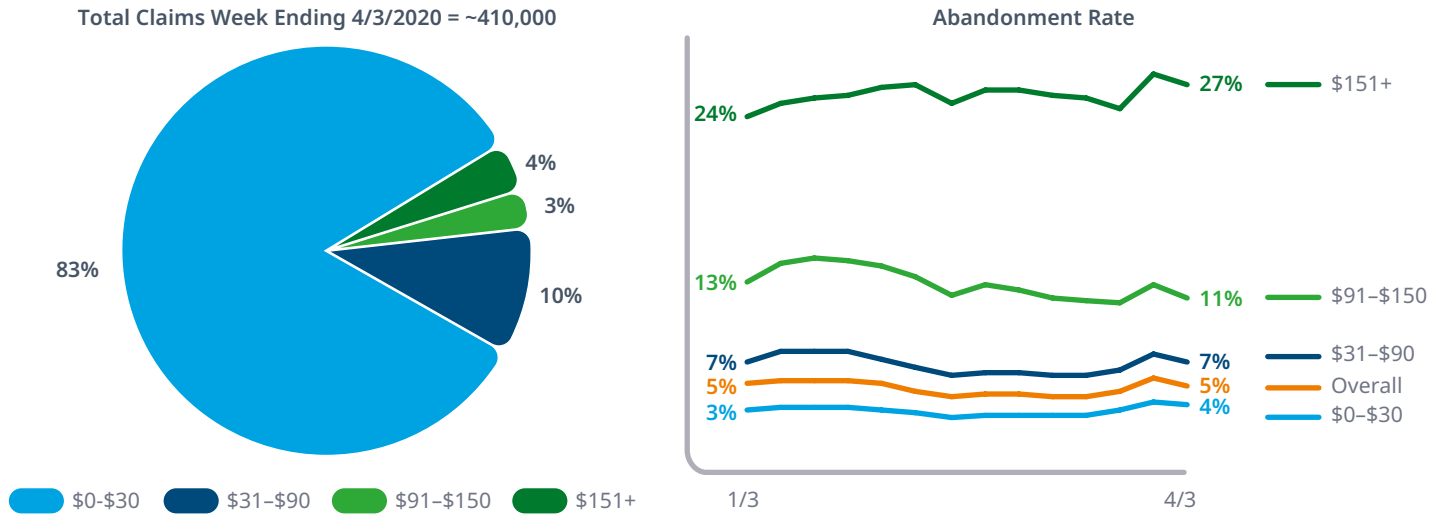
Source: IQVIA LAAD, Jan 2019

- Many patients are exposed to list prices through their benefit designs, which include cost exposure during a deductible period and lower exposure during a coinsurance phase.
- From 2014 to 2018, in Commercial the average final out-of-pocket costs for insulins have declined from $37 to $32, but have risen nearly $5 from $30 to $35 for Medicare patients.
- For most commercially-insured patients, fixed copays still apply in traditional insurance plans, while a rising proportion have high-deductible health plans (HDHP).
- Primary copay, the amount patients are initially asked to pay at a pharmacy before they use coupons in commercial plans or apply supplementary insurance under Medicare, has been rising steadily for insulins.
- Overall, the average primary copay is lower than the list price of insulins due to the mix of patients with standard insurance versus HDHP plans.
- There are opportunities for some plans to change this copay design with the IRS rule change in 2019 or the new senior savings model moving ahead in 2021 (see Exhibit 7).
- As benefit designs and product preferences within certain commercial plans have changed, newer generation drugs have been less preferred, leading to higher copays, though much of this higher cost exposure has been offset in final out-of-pocket costs predominantly through coupons.
- HDHP patients are more exposed to the full list price of a drug in what is called their primary copay.

Exhibit notes: Diabetes Overall treatment includes all drug classes, such as insulins, sulfonylureas, biguanides, DPP-4s,GLP-1s, and SGLT-2s. Newer Generation diabetes medicines are defined as DPP-4s, GLP-1s, and SGLT-2s.

Patient sensitivity to cost has been largely unchanged during COVID-19

Exhibit 4: Patient Out-of-Pocket Costs and Abandonment



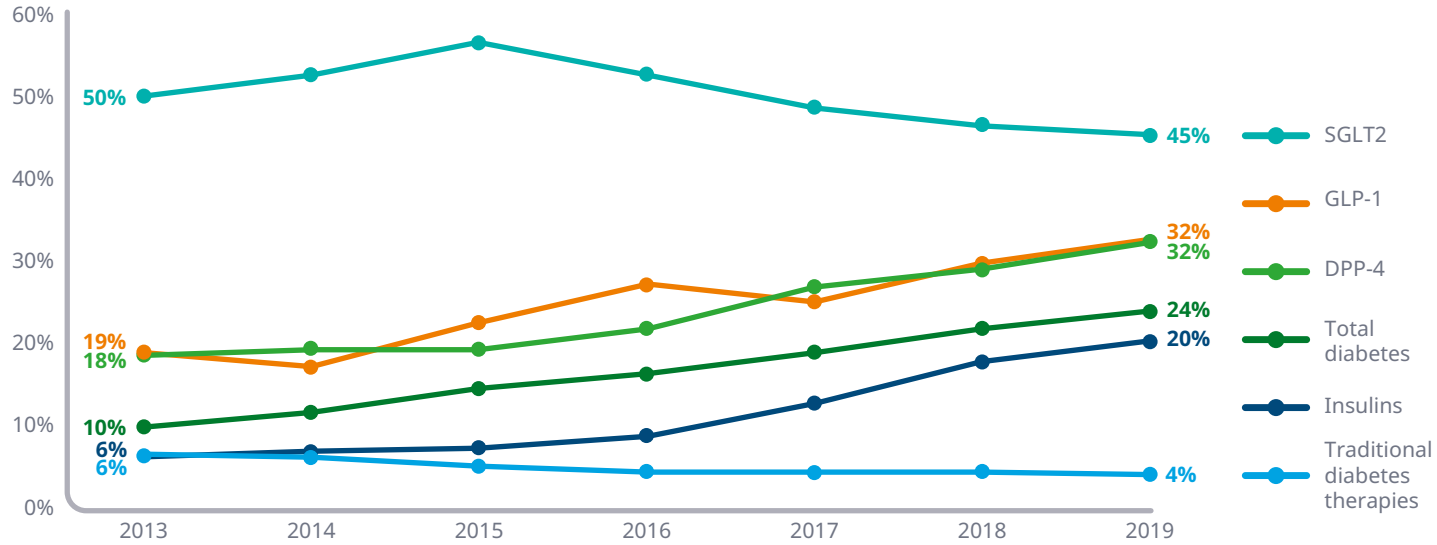
Source IQVIA Formulary Impact Analyzer (FIA), Longitudinal Access & Adjudication Data (LAAD), Apr 17, 2020

- Abandonment is a term reflecting the preparation of a prescription for an individual patient which is ultimately not taken home, often due to cost.
- The vast majority of prescriptions are low-cost — with less than $30 patient out-of-pocket cost — and only 4% of patients abandon those prescriptions at the pharmacy.
- The slight increase in abandonment of these low-cost prescriptions is expected to be more related to social-distancing than price sensitivity to date.
- There are much higher levels of abandonment as patient cost responsibility rises, with seven times more abandonment at costs over $150 than under $30.
- At intermediate copays there have been a decrease in patient abandonment rates as patients are showing increased willingness to obtain the 'mid-priced' medication.
- Price sensitivity is potentially a leading indicator here but as many patients have yet to lose insurance coverage, the effects may still take place later in May or June 2020, and further study will be required.

Exhibit notes: Data updated through April 17th has been analyzed but abandonment has been assessed only through April 3rd to allow for abandoned prescription coding to be reflected. Total LAAD claims represent a subset of total prescriptions. Total claims estimated based on 5% abandonment overall and total prescriptions in week ending April 3rd (81.1mn).

A significant proportion of patients are using coupons to lower their costs in Commercial plans

Exhibit 5: Coupon Penetration for Brand Products in Commercial Insurance



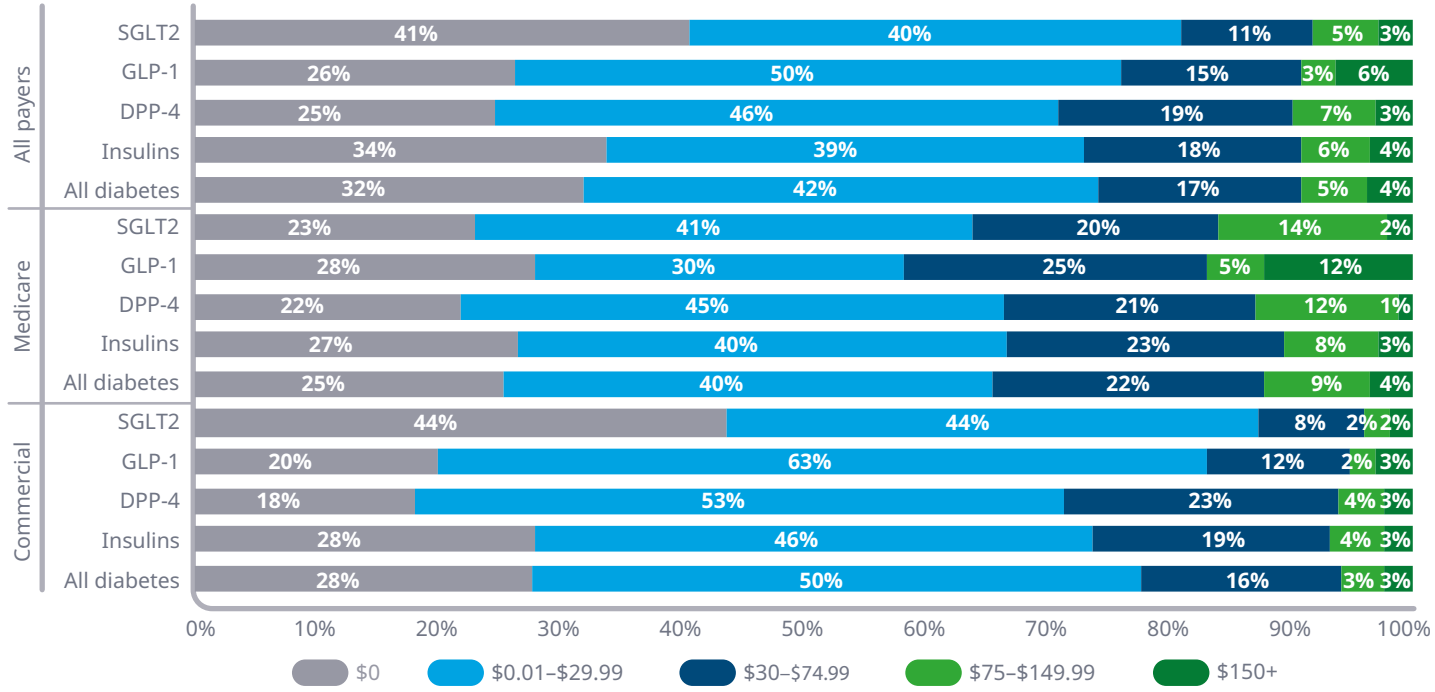
Source: IQVIA Formulary Impact Analyzer; IQVIA Analysis, Dec 2019

- Final out-of-pocket cost is generally lower than initial cost exposure due to coupons and is typically below $35 per prescription.
- An average of 24% of diabetes prescriptions used a coupon in 2019, up from 10% in 2013 and ranging from 4% among traditional therapies to 45% in the newer class of SGLT-2 inhibitors.
- Drugs with more novel mechanisms, like SGLT-2, GLP-1 and DPP-4, all have more patients using coupons to lower their out-of-pocket costs.
- Increasingly, coupon users are in high deductible plans (HDHP) where the patients' costs would be linked to the list price, despite other rebates manufacturers paid to PBMs.
- While most patient's per prescription costs are often low after applying a coupon, the chronic nature of diabetes means patients can still accumulate high annual costs.
- Additionally, drug costs are only one of the many cost burdens diabetes patients face. Other cost burdens include more frequent healthcare utilization, testing equipment and comorbid conditions.
- The inability for patients to use coupons as they move from Commercial insurance to Medicare may create 'sticker shock' or 'copay surprise' as they are now potentially asked to pay more than they would have previously.
- The new senior savings model could potentially change the number of Medicare beneficiaries exposed to higher costs, to the extent these are adopted in plan designs in the coming years.

Exhibit notes: Includes Brands in commercial insurance, coupon penetration includes eCoupons, coupons used as a primary payer and coupons used as a secondary payer. Drug manufacturers are generally providing coupons which are used as a secondary payer.

The distribution of patients with very high annual out-of-pocket costs varies by drug type and insurance type

Exhibit 6: Final Out-of-Pocket Cost per Patient per Prescription by Payer Type and Diabetes Medicine, 2019



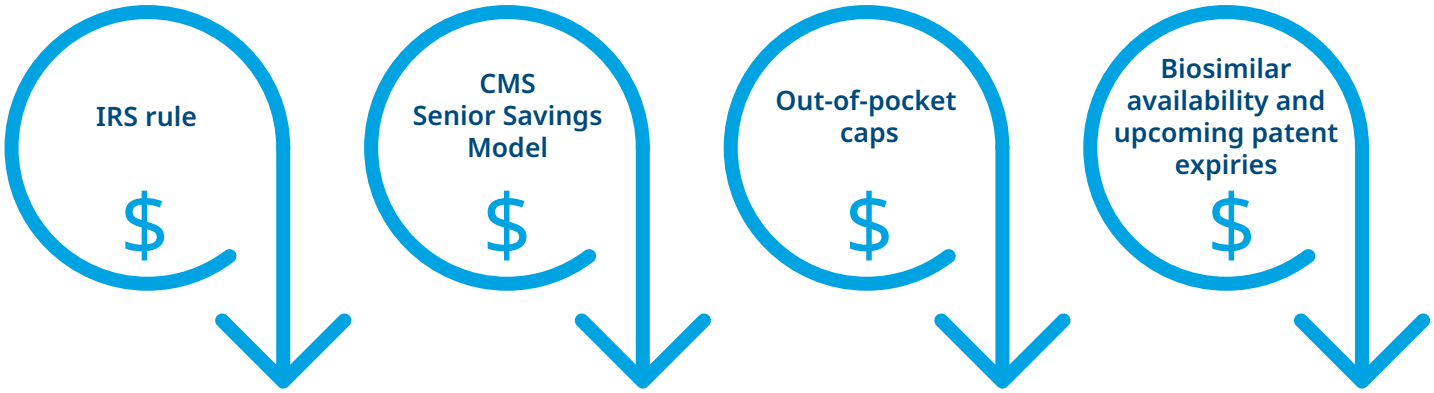
Source: IQVIA LAAD, Dec 2019

- Final out-of-pocket cost is tied to a combination of a patient's benefit design, their disease burden (i.e. medicines for comorbidities) and the specific diabetes medicines prescribed.
- Patients paid out-of-pocket costs of less than $30 for 74% of all diabetes prescriptions, and 91% are less than $75.
- These costs vary by insurance type, the specific medicines dispensed and by time of year as patient cost burden shifts based on spending-to-date relative to deductibles or Medicare cost-sharing.
- About 4% of prescriptions cost more than $150, but those were more likely to be in Medicare, and are often for GLP-1 therapies, where some members of this class are not preferred on some Part D plans.
- The impact of the ability of patients with commercial insurance to use coupons, compared to Medicare patients who are barred by law from doing so, is clear, with Commercial having a lower share of prescriptions with costs in the range above $30.
- A higher proportion of Medicare patients have prescriptions that cost more than $75–13% compared to 6% in commercial plans.

Exhibit notes: All payers includes commercial, Medicare Part D, and Medicaid.

A number of recent policies and environmental factors may impact patient costs for diabetes and other medicines

Exhibit 7: Policies Expected to Impact Diabetes Drug Prices in 2020 and Beyond



Source: IQVIA Institute, Apr 2020

- In mid-2019, the IRS extended the group of therapies that are considered preventive in high-deductible plans with health savings accounts (HDHP/HSA) and can be covered by pre-deductible plan cost-sharing. As this was a mid-year change, the impact will likely be felt in 2020 and beyond if plans offer these benefit designs and employers adopt them.
- As the policy affects several classes where common disease comorbidities mean diabetics could benefit from savings for several of their drugs or medical supplies including hypertension, heart disease, cholesterol among others.
- The new CMS Senior Savings Model for diabetes announced in March 2020 would enable some plans to offer lower patient costs for diabetes and as with all Part D plan choices, if patients choose these plans they could begin to see these cost savings in 2021 plan year.
- Some states have adopted caps for diabetes out-of-pocket spending which will benefit patients in those states but may illustrate how few patients reach maximum costs, and may result in costs shifting to other patients.
- Non-original versions of insulin glargine and lispro, while not approved through the biosimilar pathway, continue to contribute to lower costs for some patients and will likely see wider uptake. Additionally, small molecule patent expiries in the next five years for notable products including Januvia, Byetta and Victoza will likely bring cost savings.

Exhibit notes: IRS rule https://www.irs.gov/newsroom/irs-expands-list-of-preventive-care-for-hsa-participants-to-include-certain-care-for-chronic-conditions July 17 2019; CMS senior savings model announced Mar 11 2020 https://www.cms.gov/newsroom/fact-sheets/part-d-senior-savings-model

Notes on sources

THIS REPORT IS BASED ON THE IQVIA SERVICES DETAILED BELOW

NATIONAL SALES PERSPECTIVES (NSP)™ measures revenue within the U.S. pharmaceutical market by pharmacies, clinics, hospitals and other healthcare providers. NSP reports 100% coverage of the retail and non-retail channels for national pharmaceutical sales at actual transaction prices. The prices do not reflect off-invoice price concessions that reduce the net amount received by manufacturers.

NATIONAL PRESCRIPTION AUDIT (NPA)™ is a suite of services that provides the industry standard source of national prescription activity for all products and markets across the retail, mail, and long term care channels.

REAL WORLD EVIDENCE is a suite of services that provides clinical evidence regarding the usage and potential benefits or risks of medical products or procedures derived from analysis of IQVIA Real World Data (RWD). IQVIA's RWD are a variety of information assets that represent the healthcare experiences of the patient. IQVIA's RWD provides near census-level coverage of dispensed prescription information at a prescriber and insurance plan level and tracks deidentified anonymous patient records over time to analyze distinct use patterns. Additionally, IQVIA's RWD captures information about the patient's medical, hospital, EMR, consumer, and laboratory experiences, among other details.

LONGITUDINAL ACCESS AND ADJUDICATION DATA (LAAD) is an all-inclusive patient-centric dataset, which integrates IQVIA's pharmacy, lifecycle and medical claims information. LAAD provides a simplified path to understanding the total patient experience by offering one source of the truth for all longitudinal analytics. LAAD extracts longitudinal prescription, diagnosis and procedure data, applies business logic and provides analytical synergies across claims. IQVIA collects prescription and lifecycle data from retail, mail, LTC facilities, a-typical pharmacies, switch clearinghouses, as well as collecting medical claims, remit data other medical procedures that are administered to patients.

Definitions

Cost exposure is the price a patient faces when presenting a prescription to be filled, prior to the application of benefit design or coupons which can contribute to lower final out-of-pocket costs.

Final out-of-pocket costs are the observed patient costs for their prescriptions after applying benefit design rules at the point of sale, and applying coupons presented by the patient.

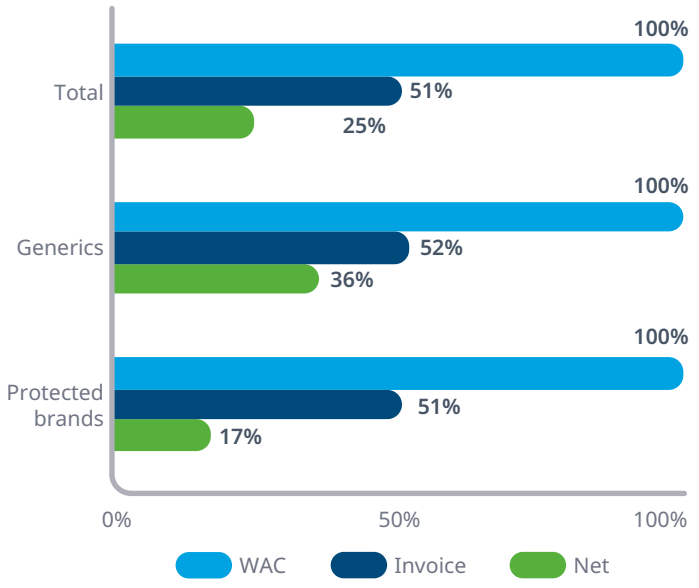
Diabetes subclasses defined as:
Older treatments including sulphonylureas, biguanides are included if relevant in overall diabetes analyses. Insulins includes human insulins and insulin analogues Newer classes of diabetes medicines often have combination versions combined with older treatments such as a biguanide like metformin, and the combinations are grouped for analysis with the more novel agents. SGLT2 Sodium/glucose cotransporter 2, DPP4 Dipeptidyl peptidase-4, GLP-1 Glucagon-like peptide-1.

ESTIMATES OF NET MANUFACTURER REVENUE AND PRICES

IQVIA audits reflect invoice-based pricing derived from proprietary information gathered from wholesalers and company direct sales. While IQVIA invoice prices reflect supply-chain price concessions, they do not reflect the off-invoice discounts and rebates separately paid to insurers, or other price concessions paid to patients or other health system participants. Estimated net prices and revenue are projected from a sample of large and mid-sized companies analyzed from 2011–2019. Branded products are included in the sample if their net sales amount is disclosed in financial filings with the Securities and Exchange Commission (SEC) and if the volume of sales captured in IQVIA audits is consistent with information provided directly by manufacturers in support of IQVIA proprietary datasets. Net prices are calculated by dividing publicly reported net sales values by volumes for the same products reported to IQVIA. Estimated brand net price growth for the total market is projected from the analysis sample to the total market. Net prices represent an estimate of the average manufacturer realized price, reflecting any reductions in net revenues due to off-invoice discounts, rebates, co-pay assistance or other price concessions, and do not necessarily reflect the net costs paid by insurers, the federal government or patients, which all vary significantly and independently. For generic companies, a sample of five large generic companies' generic portfolios were analyzed in aggregate consistent with their SEC filings, as specific generic product analyses are not possible. See Medicine Use and Spending in the United States, April 2018 for more details.

The IQVIA "net sales adjustment" analysis is based on ex-manufacturer invoice sale prices which are lower than wholesaler acquisition cost (WAC). In Diabetes, Invoice is 48-49% below WAC, and net manufacturer revenues in diabetes are 67% lower for protected brands, 30% for generics and 51% overall.

Exhibit 8: WAC, Invoice and Net Prices in Diabetes 2019



About the authors

MICHAEL KLEINROCK
Research Director, IQVIA Institute for Human Data Science

Michael Kleinrock serves as research director for the IQVIA Institute for Human Data Science, setting the research agenda for the Institute, leading the development of reports and projects focused on the current and future role of human data science in healthcare in the United States and globally. Kleinrock leads the research development included in Institute reports published throughout the year. The research is focused on advancing the understanding of healthcare and the complex systems and markets around the world that deliver it. Throughout his tenure at IMS Health, which began in 1999, he has held roles in customer service, marketing, product management, and in 2006 joined the Market Insights team, which is now the IQVIA Institute for Human Data Science. He holds a BA degree in History and Political Science from the University of Essex, Colchester, UK, and a MA in Journalism and Radio Production from Goldsmiths College, University of London, UK.

LUKE GREENWALT
Vice President and Lead, IQVIA Market Access Center of Excellence

Luke Greenwalt is the Vice President of the Market Access Center of Excellence for IQVIA and leads a team of over 400 market access specialists across a number of functional areas. He has been in the industry for 20 years and has held a variety of roles ranging from sales to marketing to market access. Luke has firsthand experience launching brands, managing product portfolios, and addressing real world challenges manufacturers face as they go to market. He has worked across dozens of clients and is a recognized thought leader in market access with focuses on macroeconomic industry trends, pricing and value, launch excellence, understanding the impact of payer controls on brand performance, patient affordability and copay programs, and gross-to-net strategies. Luke is an originator and collaborator on over a dozen white papers and frequent speaker on contemporary topics in the life science industry. He holds an undergraduate degree from the University of Iowa and a MBA from St. Ambrose University where he graduated summa cum laude.

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Kyle Crowell is a Senior Principal and co-leads the Market Access Strategy Consulting (MASC) practice at IQVIA. He has over 10 years of experience in strategy consulting in the healthcare industry. MASC serves its clients through custom projects focused on gross-to-net optimization, local market tactical planning, stakeholder economic evaluations, payer contracting strategy, copay program design, medical reimbursement, and salesforce targeting.

Mr. Crowell has extensive experience in advanced analytics, including longitudinal patient data assessments for medical and pharmacy reimbursed therapies. Prior to joining the Amundsen Group (later acquired by IQVIA), Mr. Crowell worked as an analyst for Decision Resources, where he provided market research, consulting and advisory services to the pharmaceutical and biotech industries. He holds a B.S. in biochemistry from Boston College.

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry and payers.

Research Agenda

The research agenda for the Institute centers on 5 areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding Principles

The Institute operates from a set of Guiding Principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.

The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.

The artwork on the cover of this report was generated using data assessing average initial cost exposure and final out-of-pocket costs that patients face depending on product and payer type in the United States from 2015-2019.

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