MILLIMAN WHITE PAPER

Analysis of Insulin Competition and Costs in the United States

A Study of the Evolution of Insulin Products and Pricing from 2007 to 2021

Commissioned by PhRMA

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Executive Summary

This report discusses the increasing gross-to-net cost differential for insulin products from 2007 to 2021. This differential has been driven by growing manufacturer rebates, discounts, and other payments that lower the final amount received by the manufacturer[i].

In recent years, rising prescription drug prices have been a focal point of legislative and media debate[1,2] in the United States. Insulin products are frequently mentioned as prime examples in this debate because of the rising out-of-pocket costs for some patients and the number of Americans who rely on insulin to survive.[3]

While insulin manufacturers offer significant rebates that reduce costs to payers, patients with deductibles or coinsurance generally do not realize reduced out-of-pocket costs from these discounts. This dynamic exists because their cost sharing is tied to the list price of the drug at the point-of-sale, rather than the net amount the plan pays after price concessions from manufacturers. The issue of whether or not rebates and discounts should be reflected in patients' out-of-pocket costs is frequently debated, especially in the Medicare Part D space, and lawmakers on both sides of the aisle have called for passing rebates through to patients at the point-of-sale.[ii]

While there is concern over rising gross prescription drug prices, some suggest it is important for the *net price* (i.e., list price less manufacturer rebates, discounts, and other price concessions) to be part of the conversation. Despite public reports of rising insulin list prices, several major manufacturers have reported decreased *net* prices over the same period.[3,4]

Key findings:

- The difference between the total gross and net expenditure for insulin products in the U.S. increased from **17% in Q1 2007 to 84% in Q1 2021**. This increased differential is primarily due to a significant increase in manufacturer rebates, discounts, and other price concessions over the analysis period.
- While the average list price of insulin products has risen significantly, the average annual *net* cost per treatment decreased by 20% over the study period, from **$1,319 per year in Q1 2007 to $1,055 per year in Q1 2021**. Plan sponsors pay less for insulin today than they did in 2007.

[i] *Other payments that lower the final amount received by the manufacturer are defined as pharmacy discounts, patient assistance, and manufacturer-funded price concessions, such as rebates, coverage gap discounts in Medicare, federal and supplemental rebates in Medicaid, and 340B drug discounts.*

[ii] *HHS finalized a rule requiring most rebates and price concessions to be reflected at the point of sale in 2020, but Congress delayed enforcement of this provision until 2026 as part of H.R. 3684, the Infrastructure Investment and Jobs Act of 2021, which was signed into law on November 15, 2021. Congress is further considering an indefinite delay of implementation as part of the Build Back Better Act, which is still in the middle of the legislative process as of this writing.*

Background

OVERVIEW OF DIABETES AND INSULIN PRODUCTS

Diabetes is a chronic disease where the body is unable to manage elevated blood glucose. Diabetes has a tremendous impact on the health of Americans. The Centers for Disease Control and Prevention (CDC) estimates that 34.2 million Americans (10.5% of the U.S. population) were living with diabetes in 2018.[iii] There are two main types of diabetes, which are described in Table 1.

TABLE 1: COMPARING TYPE 1 AND TYPE 2 DIABETES

	Type 1 Diabetes	Type 2 Diabetes
Population (2018)[5]	1.6 M	32.6 M
Age at Diagnosis	Most often diagnosed in children or young adults, but can occur at any age	Most often diagnosed in adulthood, but can occur at any age
Insulin Production	Insulin dependent (patient is unable to produce insulin)	Insulin resistant (patient develops resistance to insulin)
Common Pharmacological Treatments	Insulin	Oral antidiabetics (alpha-glucosidase inhibitors, biguanides, DPP4 inhibitors, meglitinides, SGLT-2 inhibitors, sulfonylureas, thiazolidinediones) Injectable antidiabetics (amylin analogs, Incretin mimetics or GLP-1s, insulin)

DPP4: dipeptidyl peptidase-4; SGLT2: sodium-glucose cotransporter 2; GLP-1: glucagon-like peptide-1
Source: American Diabetes Association, Centers for Disease Control and Prevention

Every year, 1.5 million Americans are newly diagnosed with diabetes.[9] Because the disease may be asymptomatic in early stages, approximately one in five people with diabetes are undiagnosed.[12] If the disease is left untreated, or treated but poorly controlled, prolonged blood glucose elevation can lead to serious comorbidities, such as cardiovascular diseases, chronic kidney disease, neuropathy, and vision loss. Approximately 50% of patients treated for diabetes do not have the disease successfully controlled.[6] Diabetes is the leading cause of end-stage kidney disease and blindness, as well as the seventh leading cause of death in the United States.[7]

Diabetes is associated with significant economic burden. In the United States, the estimated direct medical cost was $237 billion in 2017, including both medical and prescription drug costs.[8] Given the high prevalence of uncontrolled disease and significant economic burden, treatments offering to ease and improve the management of diabetes are important to improving both patient adherence and clinical outcomes.

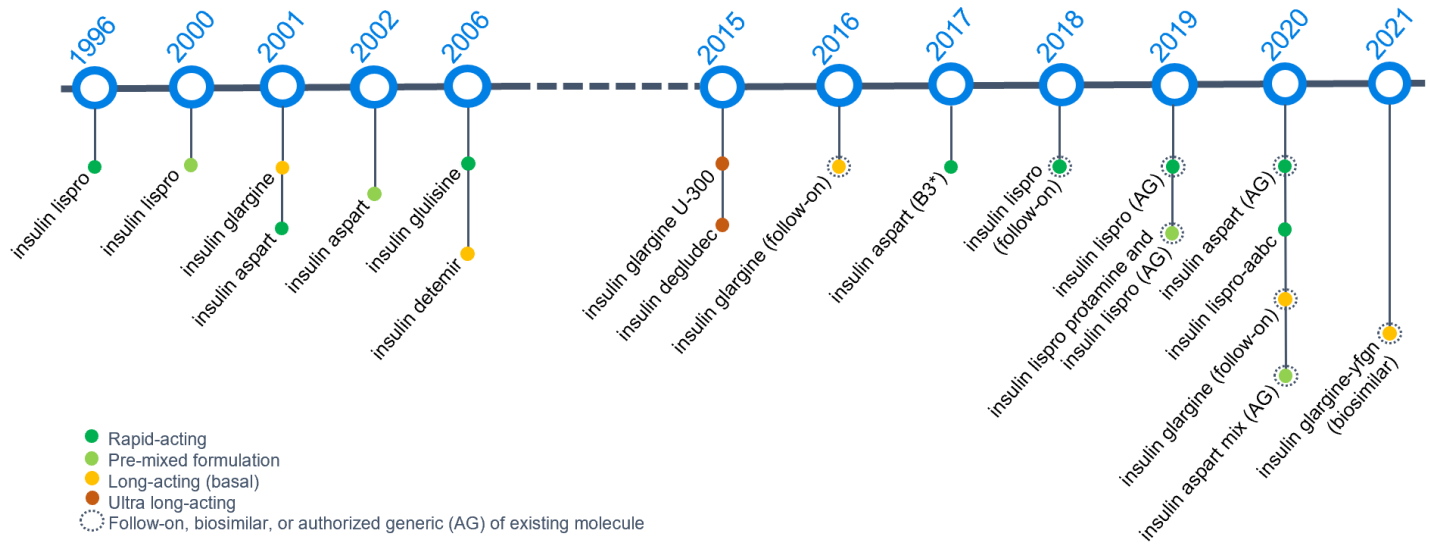
Although many diabetes treatments are available (e.g., oral and other injectable medications), this analysis is focused exclusively on insulin. The use of insulin therapy differs for type 1 vs. type 2 diabetes. Current treatment guidelines indicate that insulin is the gold standard pharmacological option for type 1 diabetes, with the preferred treatment plan comprising both rapid-acting insulins, which are used to manage blood glucose spikes occurring after meals, and long-acting (basal) insulins, which provide a base-level of insulin throughout the day.[9] Although insulins are not considered the first-line option for patients with type 2 diabetes, many patients may ultimately require insulin to meet their treatment goals as their condition progresses.[iv]

Today, insulin analogs are the most widely used insulin products in the U.S. and are available in rapid-acting, long-acting, and ultra-long acting classes.[10] Analogs more closely resemble insulin production naturally occurring in the body compared to earlier insulins (e.g., synthetic human insulins, animal-derived insulins). As a result, analog insulins are associated with improved management of blood glucose levels and reduced side effects associated with insulin therapy (e.g., weight gain and hypoglycemia). Following the introduction of the first rapid-acting insulin analog in 1996, the number of rapid-acting and long-acting insulin analogs has grown, leading to an expanded offering of treatment options and approaches. More recently, another class of basal insulins, known as ultra-long-acting insulins, also became available, offering a longer duration of action.

In this analysis, we focus only on insulin analogs and pre-mixed formulations that contain insulin analogs as they are the most commonly used insulin products in the U.S. and are subject to unique market dynamics. Though synthetic human insulins remain an important treatment option for some patients today, these products are not included in this analysis. Figure 1 displays a timeline of U.S. launch dates for insulin analogs beginning in 1996 categorized by class, including rapid-acting insulins, long-acting and ultra-long acting basal insulins, as well as pre-mixed formulations[v]

[iii] *Of the 34.2 million adults with diabetes, 26.8 million were diagnosed, and 7.3 million were undiagnosed.*
[iv] *In type 2 diabetes, insulin is recommended for patients experiencing weight loss, hyperglycemia, very high A1C or blood glucose levels, patients who are unable to tolerate first-line therapies, or those who need to intensify existing therapeutic regimen.*
[v] *The timeline in Figure 1 only references launches of initial insulins (i.e., the molecule). This figure does not include various pens and other delivery devices that have become available in subsequent years after the initial launch.*

FIGURE 1: INSULIN ANALOG PRODUCTS TIMELINE OF U.S. LAUNCH



**Insulin aspart plus vitamin B3*
Figure 1 depicts years of U.S. product. launches. Products launched after 2018 are not included in the data supporting Figures 2 and 3 due to data limitations, but we include these products in Figure 1 for completion. Following the transition date, discussed in detail below, authorized generics are regarded as unbranded biologics.

REGULATORY HISTORY INFLUENCING COMPETITION IN THE INSULIN MARKET

Though many of the most commonly used insulin analogs are no longer under patent protection, there are no generic insulin products[vi] on the market today.[11] This is because insulins are biologic products, meaning they are large, complex molecules derived from living cells or tissue. There is no regulatory pathway for "generic" biologic products, including insulins.[12] Biologic medicines cannot be easily reproduced or copied like generic small molecule medicines. In recognition of this challenge, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) as part of the 2010 Patient Protection and Affordable Care Act, which made it possible to bring biosimilars of marketed biologics to market. Biosimilar medicines are "highly similar" to and have no "clinically meaningfully differences" from the original medicine in terms of safety, purity, and potency.

Although insulins are biologics, they are unusual because historically they were regulated by the U.S. Food and Drug Administration (FDA) as small-molecule drugs, not biologics, when they were first developed. Considering the unique nature and complex manufacturing process of biologic medications, this discrepancy posed scientific and data challenges to generic insulin development.[13] To address this challenge, BPCIA included a 10-year timeline to transition biologic products approved and regulated as small-molecule drugs, like insulins, and designated a transition date to begin regulating these products as biologic medicines.[13] After the transition date, which was March 23, 2020, a new FDA regulatory pathway opened up for companies to pursue biosimilar and "interchangeable" biosimilar approvals for these "transition products," including insulin.[13]

Interchangeable biosimilars are biosimilar products that are, among other things, expected to produce the same clinical result in any given patient. The first interchangeable biosimilar insulin was approved by the FDA in July 2021.[14] Like many generics today, interchangeable biosimilars may be substituted at the pharmacy counter without the need for prescriber intervention in most states. The impact of interchangeable biosimilar insulins is expected to be substantial in terms of driving savings and downward pressure on prices.

Prior to the transition date and the first interchangeable biosimilar insulin approval, manufacturers brought "follow-on" insulin products to market.[vii] Although they are not generic or biosimilar insulins, and cannot be automatically substituted at the pharmacy counter, follow-on insulins compete directly against comparable brand insulin products on the market (See Figure 1). Insulin manufacturers also brought "authorized generics" of their own products to market in advance of the transition date, at lower list prices than the original versions.[viii]

COVERAGE AND REIMBURSEMENT INFLUENCING COMPETITION IN THE INSULIN MARKET

Health plans and pharmacy benefit managers (PBMs) often opt to include a "preferred" brand medicine on formulary that either produces superior clinical outcomes and/or is lower cost to the health plan than competing brand medicines. These preferred treatments benefit from lower patient cost sharing and/or fewer access restrictions, which increases utilization and market share for the preferred product.

[vi] *Generic products have been approved using an Abbreviated New Drug Application (ANDA), which is commonly used for small molecule medicines.*
[vii] *Follow-on products exist when a manufacturer creates its own version of another company's drug. Follow-on biologics do not have therapeutic interchangeability with the originator product.*
[viii] *An authorized generic (AG) refers to a brand drug that is marketed without the brand name on the label.*

Though various insulin products may differ in terms of rapid action profile or duration of action within each insulin class (e.g., rapid-acting, long-acting, etc.), products within a class are generally viewed by insurers and providers as producing comparable patient outcomes with limited clinical differentiation for the purposes of diabetes management.[ix] As a result, insulin manufacturers compete primarily on price within classes to win preferred formulary placement.

The PBM market is consolidated into three major entities, each of which has significant leverage in negotiating rebates.[15] Typically, the PBM includes or prefers only one insulin within each class on a formulary.[16] This can create an intense, competitive pricing dynamic among different insulin manufacturers to capture as much of the market as possible.

Lower net prices are achieved through manufacturer price concessions, often in the form of retrospective rebates and discounts, which are provided to PBMs. Some or all of these savings are then passed onto PBMs' health plan clients, lowering the net cost of the medicines to plans.

PBMs are often financially evaluated by potential customers based on the size of negotiated rebates and rely on generating large rebate guarantees to attract and retain customers. Therefore, PBMs have been found to favor products with high list prices and large rebates over lower-list price equivalents, even though the net price to a plan may be the same. For example, evidence suggests there has been limited uptake of lower-list priced insulin authorized generics (AGs), as PBMs have chosen to favor products offering high gross-to-net differentials.[17] This can have unintended consequences for patients with coinsurance and deductibles, whose cost sharing is based on the list price of a medicine.

DEFINING THE COST OF INSULIN PRODUCTS

This report exclusively focuses on the cost of insulin products from Q1 2007 to Q1 2021. Other direct costs, such as non-insulin health care costs, or indirect costs, like productivity, were not included in our analysis. Product-specific manufacturer price concessions are considered proprietary information and are not publicly reported. We rely on independent, third-party data from SSR Health to estimate gross and net insulin costs and the difference between the two:

- Gross cost, defined as the list price or wholesale acquisition cost (WAC), represents the price at which the manufacturer sells to a wholesaler and excludes any price concessions, for example, pharmacy discounts, rebates, or fees
- Net cost is defined as the WAC less all price concessions and other payments that lower the final amount received by the manufacturer, including pharmacy discounts, patient assistance, rebates, coverage gap discounts in Medicare, statutory and supplemental rebates in Medicaid, and 340B drug discounts

Changes in both gross and net costs translates to different revenue and costs for various stakeholders – including manufacturers, PBMs, health plans, state / federal budgets, and patients themselves.

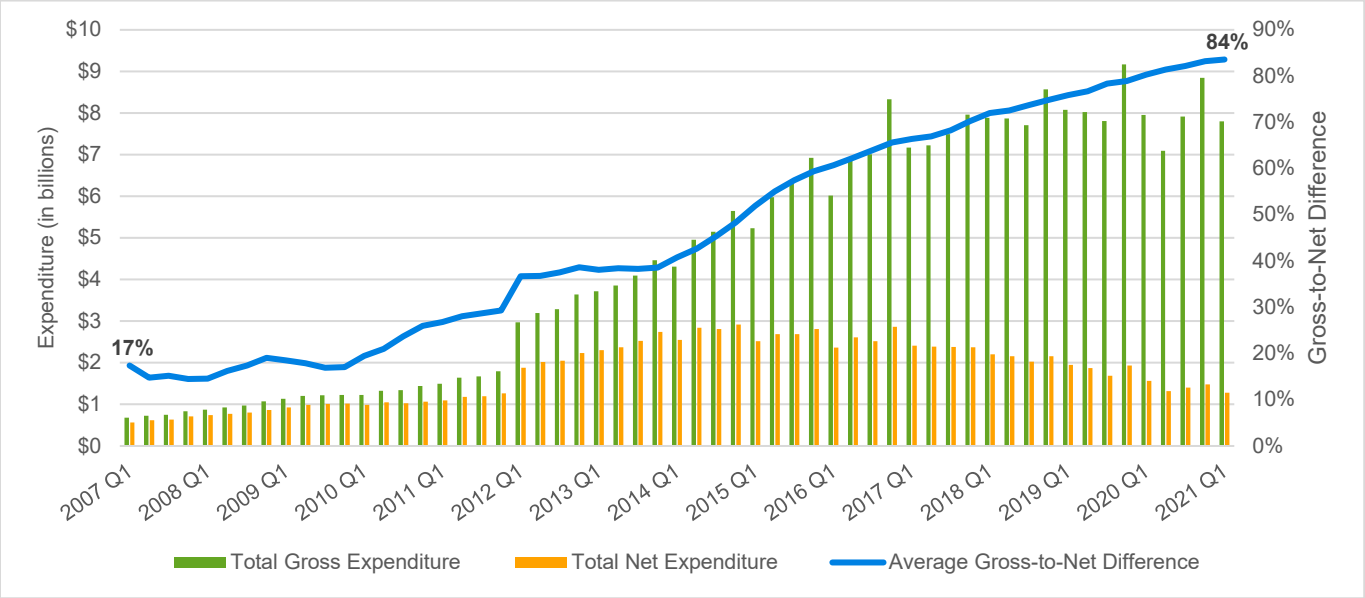
[ix] *Though insulin products compete in the market within each class of insulin, there can be some meaningful differences among products within classes as well as differences in outcomes among patients. Switching insulin products may require further consultation with a healthcare professional.*

Results

CHANGES IN THE GROSS AND NET COST OF INSULIN THERAPIES

Figure 2 illustrates the total U.S. gross and net spending for insulin analogs across all markets since Q1 2007.[x] As shown below, while gross spending has risen from $68 million in Q1 2007 to $7.8 billion in Q1 2021, the gross-to-net difference has increased from approximately 17% to 84% over the same period. As a result, net spending on insulins in the U.S. has increased far more slowly than gross spending.

FIGURE 2: INSULIN ANALOGS: TOTAL GROSS EXPENDITURES AND NET MANUFACTURER REVENUE BY QUARTER 2007-2021



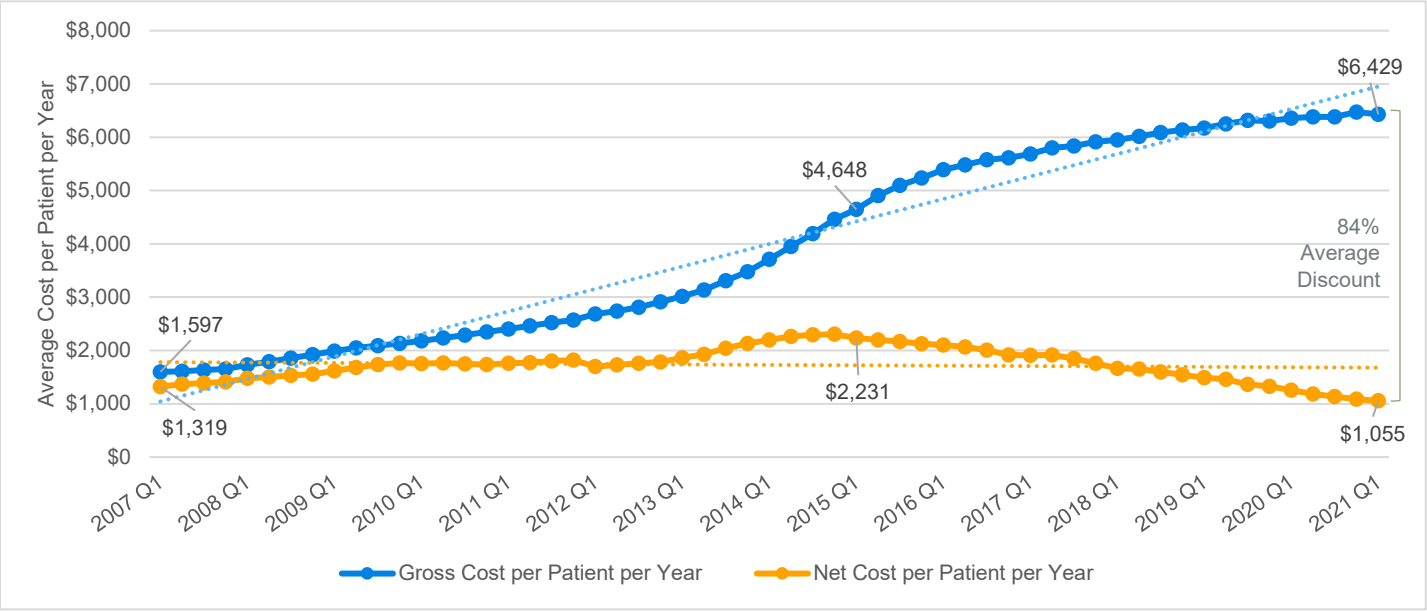
Source: SSR Health data, total expenditure for products listed in Figure 1 launched prior to 2019.

The combination of increases in both insulin product utilization and gross unit prices drove the rising aggregate gross spending on insulin products in the U.S. from 2007 to 2021. Total net costs increased moderately from 2007 to the peak around 2014 Q4 and have decreased since. In 2020, total net spending was approximately $5.8B, which is just $3.2B more than total spending in 2007, despite significantly higher levels of insulin utilization due to an increasing prevalence of diabetes over that period in the U.S.[18]

Figure 3 displays the average annual gross and net cost of treatment per patient per year using insulin products from Q1 2007 to Q1 2021. Consistent with Figure 2, we observe a significant increase in the gap between gross and net costs of insulin products over the analysis period. On average, the gross cost of treatment per patient per year increased significantly, while the average annual net treatment cost per patient in 2021 Q1 is approximately $264 *lower* than in Q1 2007.

[x] *Note that costs vary by market. Notably, rebates in the Medicaid market are statutorily defined and includes an inflationary component that generally creates a larger gross-to-net difference than other markets, such as commercial or Medicare.*

FIGURE 3: INSULIN ANALOGS: AVERAGE GROSS COST AND NET MANUFACTURER REVENUE PER PATIENT PER YEAR, BY QUARTER 2007-2021



Source: SSR Health data, utilization-weighted average annual gross and net costs of treatment for products listed in Figure 1 launched prior to 2019.

DISCUSSION

As demonstrated in Figure 1, prior to 2006, multiple rapid-acting and long-acting insulins were launched, driving competition in the market. Between 2006 and 2015, the insulin market was static with no new drug launches. After 2015, novel rapid-acting and ultra-long-acting insulin molecules launched and several follow-on rapid-acting and long-acting insulins and AGs were introduced to the market to compete directly with earlier-introduced and commonly used insulin products. All of this competition preceded the March 23, 2020 transition date, which opened up a new regulatory pathway for insulin manufacturers to bring biosimilar insulins to the market.

Generally, competition leads to greater price concessions and lower net costs, which is consistent with our data analysis. In Figure 3, we observe a growing net cost per year up until Q4 2014, after which costs began to steadily decrease. The change in net costs per year aligns closely with the timing of new product launches in 2015 and 2016, suggesting increased brand-to-brand competition drove significant price concessions and lowered the net price of insulin.

Despite net prices falling, rising gross costs have created pressure on patient affordability for insulin, leading to public concerns about insulin prices.[19,20] There have been efforts among federal and state governments to address patient affordability challenges for insulin, including:

- Beginning January 1, 2021, the Centers for Medicare and Medicaid Services (CMS) launched a demonstration known as the Senior Savings Model (SSM) to help limit insulin out-of-pocket costs for Part D beneficiaries. Part D payers can opt to participate in this model, which limits patient cost sharing on selected insulin products to a maximum $35 copay per 30-day supply for beneficiaries who are not eligible for Part D Low Income subsidies. Patients in participating plans continue to pay this limited copay amount on insulin products until reaching their true-out-of-pocket (TrOOP) and entering the catastrophic phase.[21] In 2021, approximately 29% of Part D plans[xi] participated in the SSM, including plans sponsored by United Health Care and Humana.[22]

- Twenty-one states have laws to cap insulin copays at a certain amount for patients with commercial insurance – typically between $25 and $100 for a 30-day supply. Connecticut's legislation also caps copays for insulin-related diabetic supplies, such as test strips and glucose meters..[23,24]

Price concessions can be significant in reducing the cost of insulin. However, the way pharmaceutical reimbursement works in the U.S., the gap between the gross and net prices for insulins does not result in direct savings for patients at the pharmacy counter.

[xi] *Based on February 2021 CMS enrollment files. Inclusive of individual MA-PD and PDP plans.*

Data, Methodology, and Limitations

DATA SOURCES

Product-specific manufacturer price concessions are considered proprietary information and are not publicly reported. We relied on estimates of average gross and net costs developed by SSR Health LLC, which uses its own methodology to derive information and estimate net prices on a quarterly basis. We used data from the period of Q1 2007 to Q1 2021.

METHODOLOGY

We used SSR Health data to summarize gross and net expenditure in aggregate for all insulin products included in our analysis (insulin lispro, insulin glargine, insulin aspart, insulin glulisine, insulin detemir, insulin degludec, and pre-mixed formulations and follow-on products of insulin glargine and insulin lispro) and the utilization-weighted average gross and net annual cost of treatment of the aforementioned products.

LIMITATIONS

Our analysis and methodology are limited to information available within the data sets. Our analysis is not able to account for the following:

- Due to a lack of U.S. reporting, pricing and sales data were unavailable in the SSR Health data for insulin glulisine from U.S. launch (2006) until 2008 and additionally for insulin detemir and insulin aspart from the time of U.S. launch (2006 and 2001, respectively) until 2012. Exclusion of these products during these years may influence results and may overestimate net spending and net prices in the first five years of our analysis period in Figures 2 and 3.
- Different components of net price reduction – i.e., we were unable to separate manufacturer rebates from other discounts and price concessions (e.g., 340B).
- Impacts of price changes on beneficiary cost sharing, state or federal government expenditures, or plan-specific impacts, all of which vary by payer type.

This report was prepared for PhRMA. Our findings are based on an analysis of U.S. cost across all markets. Contracting terms vary widely among markets and regions. Results from this analysis may not be applicable to other therapeutic areas or markets.

The results presented herein are estimates based on the best information available as of the date of publication. Differences between our results and other analyses may arise due to variations in definitions, methodology, or data updates.

This report represents the opinion of the authors and is not representative of the views of Milliman. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Susan Silseth and Madeleine Cline are actuaries for Milliman. They are members of the American Academy of Actuaries and meet the qualification standards to render the actuarial opinion contained herein.

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