Insight

Federal and State Actions to Address Insulin Costs

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Executive Summary

The rising cost of insulin has received much attention over the past year, and policymakers at the federal and state levels are actively considering policies to reduce costs for patients.

- Most of the policy proposals center on changes to insurance design and coverage of medicines, each of which would likely reduce patients' out-of-pocket (OOP) costs, at least in the short-term.
- Most of the proposals, however, also have potential negative consequences or trade-offs that should be carefully considered: Some policies' trade-offs are likely worth the cost (such as the minimal increase in premiums expected from limiting patients' OOP costs or from requiring rebates to be passed through to the patient at the point of sale), while others are not (such as the increased price that will likely result from tax-funded patient assistance programs).
- The one proposal that is most likely to have positive effects without negative consequences is categorizing insulin as a preventive medicine and thus allowing high-deductible health plans to cover it before the insured individual reaches the deductible. The reach of this policy would be limited, however, as only one-fourth of Americans are enrolled in such a plan.

Introduction

The cost of insulin is a large and growing burden: Roughly one-fourth of the 8.3 million insulin users in the United States reported rationing their insulin because of the cost, despite the fact that rationing could be fatal.[i] As of March 23, 2020, biosimilar insulin products may be developed and sold in the United States, once regulatory approval is granted. Typically, when non-innovator products are introduced to the market, prices fall; but biosimilar insulin won't hit the market for some time.[ii] Meanwhile, state and federal policymakers have introduced numerous proposals to reduce patients' insulin costs, but few of the policy options under consideration are likely to be successful in bringing down prices and reducing overall costs. Most of the proposals currently under consideration involve new rules pertaining to insurance coverage of insulin, and they are most likely to result in cost-shifting rather than cost reduction.

Existing Insurance Coverage

Private Insurance

In 2017, 37 percent of diabetics had private insurance.[iii] Most private insurance plans cover insulin; in fact, 46 states have mandated that insurers must cover diabetes medicine, supplies, and equipment.[iv] Four states—Alabama, Idaho, North Dakota, and Ohio—do not mandate coverage of diabetes treatment, and two states—Mississippi and Missouri—only require that insurers offer one plan with diabetes coverage.[v]

While most plans cover insulin, some products may have preferential treatment while others may not be covered at all. Given that not all insulin products are interchangeable, the limited coverage options of a particular plan may leave certain plan enrollees without a suitable covered option; in this case, the patient would likely have to pay full price for their insulin, unless they qualify for a patient assistance program.

As of July 2019, a high-deductible health plan (HDHP) has the option of treating insulin as a preventive therapeutic. On July 17, 2019, the federal government updated guidelines to expand the ability of patients with HDHPs to receive, before reaching the deductible, coverage for low-cost preventive care such as services and products that help maintain the health of individuals with chronic conditions; this update added insulin and other glucose-lowering agents to the list of medicines considered preventive.

Medicare

With 43 percent of people with diabetes in 2017 aged 65 or older, Medicare enrolls the largest number of diabetics of any health care payer in the United States.[vi] People with Medicare may receive coverage for insulin products through both Medicare Part B and Part D, but most benefits are provided through Part D. Medicare Part B covers insulin infusion pumps and the insulin in the pump, along with blood sugar or glucose testing monitors.[vii] Medicare Part B does not otherwise cover insulin or insulin-administration devices such as pens, syringes, alcohol swabs, or gauze. Under Medicare Part B, diabetic patients pay for 100 percent of insulin costs, unless they use an insulin pump, in which case they pay 20 percent. [viii] Medicare Part D provides broader coverage for diabetic patients, including coverage of the drug itself (for insulin not administered by an insulin pump) and coverage for supplies such as syringes and pens. Medicare Part D drug plans also cover anti-diabetic drugs that regulate blood sugar levels, used by those with type 2 diabetes.[ix] Medicare Part D provides broader coverage for diabetic patients, including coverage of the drug itself (for insulin not administered by an insulin pump) and coverage for supplies such as syringes and pens. In 2018, total Medicare spending for insulin and insulin-administration supplies reached nearly $15 billion. Medicare Part D drug plans also cover anti-diabetic drugs that regulate blood sugar levels, used by those with type 2 diabetes.[x]

Medicaid

Up to 14 percent of adult Medicaid enrollees under age 65 are estimated to have diabetes.[xi][xii] Medicaid coverage varies slightly from state to state, but as of 2016, 46 states and the District of Columbia cover prescribed insulin as well as needles, syringes, and blood glucose strips for qualifying users.[xiii] Four states have exceptions: Arkansas and Georgia Medicaid plans cover insulin, but with restrictions on brand names and dosages; Arkansas does not cover blood glucose test strips; Kentucky does not cover needles or blood glucose test strips; and Mississippi does not cover needles, syringes, or blood glucose test strips. In 2018, insulin costs in Medicaid reached nearly $4 billion.

Policy Proposals to Address Insulin Prices

On March 23, 2020, the regulatory obstacles preventing the introduction of biosimilar insulin in the U.S. market expired. Only time will tell if new manufacturers will take advantage of this new pathway to bring competitor insulin products to market, perhaps at a lower cost. In the meantime, state and federal policymakers as well as private entities are working on various policy changes to address the rising cost of insulin. Most of the policies under consideration revolve around changing insurance coverage rather than directly affecting drug manufacturers or their prices.

With roughly two-thirds of the cost of diabetes in the United States spent on individuals enrolled in a public health-insurance program, federal policymakers have a particular interest in controlling the cost of insulin, for the sake of both patients and taxpayers.[xiv] Congress has recently developed several legislative proposals to reduce drug prices; a few of these bills include provisions specifically targeted at insulin. Diabetes is currently a priority area for 14 states within their state health improvement plans, as well.[xv]

Insurance Coverage of Insulin as a Preventive Medicine

Congressional Action

Included in the Lower Costs, More Cures Act of 2019 (H.R. 19 and S. 3129) is a provision to codify the recent regulatory change allowing high-deductible health plans to treat insulin as a preventive product and provide coverage before the beneficiary reaches the deductible.

The Benefits of Early Insulin Coverage

This is a common-sense policy, as proper insulin use unquestionably prevents numerous medical complications and even death. With nearly half of those with employer-sponsored insurance (roughly 80 million people) now enrolled in HDHPs, and the average deductible for such plans now reaching $5,000, this change alone will likely significantly reduce the out-of-pocket (OOP) costs for many diabetics. Further, the increased affordability that this change offers is likely—and in fact, intended—to increase medication adherence and reduce insulin rationing. The treatment of medical complications that may result from improper insulin use is often more expensive than the cost of the insulin; avoiding these complications will save money for both the individual and insurer. The Congressional Budget Office has previously estimated that the medical savings that result from improved medication adherence would be twice as great as the cost of increased medication utilization.[xvi] Thus, the impact on costs should be positive for both insurers and patients, ultimately driving down premiums: While insurers would be expected to have higher prescription drug expenditures as a result of having to cover insulin costs before a beneficiary reaches the deductible, improved medication adherence should reduce medical costs overall for such patients.

OOP Caps

Congressional Action

H.R. 19 and its Senate companion, S. 3129, require Medicare Part D plans to limit beneficiary OOP costs for insulin to $50 per month.

Administrative Action

The Centers for Medicare and Medicaid Services (CMS) announced a new demonstration on March 11, 2020, that would allow participating enhanced Part D plans to cap OOP costs for insulin users at $35 per 30-day supply, beginning in 2021.[xvii] An estimated 3.3 million Medicare beneficiaries use insulin, and more than half of Part D beneficiaries are enrolled in an enhanced Part D plan and thus may be potentially eligible for this benefit.[xviii] Enhanced plans offer supplemental benefits, such as lower deductibles or cost-sharing requirements, in addition to the basic benefits required of every Part D plan. Under current law, if an enhanced Part D plan offers reduced cost-sharing in the coverage gap, manufacturers' mandatory 70 percent discount is calculated as a share of the lower patient liability, leaving the insurer liable for more costs than they would be

otherwise. The Part D Seniors Savings Model requires manufacturers participating in the program to offer the mandatory 70 percent coverage gap discount as a percentage of the negotiated price, before the deduction of any supplemental benefits, reducing the patient's cost-sharing amount.[xix] This change will reduce plans' current disincentive to offer enhanced benefits in the coverage gap. Because manufacturers will be required to pay a greater discount than otherwise would have been required for enhanced plans, CMS is requiring participating manufacturers to report any increases in list prices for applicable insulin products and will make that information public.

All three of the primary insulin manufacturers will be participating in the program, and the most common insulin products will be subject to the program's requirements.[xx] Plan sponsors wishing to participate must apply by May 1, 2020.[xxi]

State Actions

In December 2018, the Diabetes Patient Advisory Coalition and the National Diabetes Volunteer Leadership Council developed the Access to Lifesaving Medicines Act, which is a state legislative framework to increase drug cost transparency and cap patient cost-sharing for insulin prescriptions and supplies.[xxii] Many states have since taken up measures to impose cost-sharing limits for patients. In May 2019, Colorado became the first state to pass a law limiting co-payments for insulin to $100 for residents.[xxiii] Florida, Illinois, Michigan, New York, Pennsylvania, Rhode Island, Washington, and Wisconsin also introduced similar bills between June and August 2019.[xxiv] In February 2020, New Mexico passed legislation to cap patients' insulin OOP costs at $25 per 30-day prescription or $50 for patients with more than one insulin prescription.[xxv] In March 2020, Virginia passed a law to cap OOP insulin costs at $50 per month.[xxvi] As of April 2020, Minnesota requires manufacturers to establish patient assistance programs for all residents earning up to 400 percent of the federal poverty level (including Medicare Part D enrollees, although providing patient assistance to Part D enrollees may be a violation of the federal Anti-Kickback Statute); patients may not be charged more than $50 for a 90-day supply, and manufacturers must allow an individual to enroll if the patient would financially benefit under this program even if they have insurance and prescription drug coverage.[xxvii]

Insurers and Pharmacy Benefit Managers

Several pharmacy benefit managers have implemented new cost-sharing limits for insulin products. On April 3, 2019, Cigna and ExpressScripts launched the Patient Assurance Program, which allows patients in participating insurance plans to pay no more than $25 for a 30-day supply.[xxviii] CVS Caremark announced on January 29, 2020, that it would offer a new plan allowing all diabetes medications to be available to patients at no OOP cost; the plan will use strategic formulary placement and plan design to do so without increasing premiums or deductibles.[xxix]

Pros and Cons of OOP Caps

Placing a cap on beneficiary OOP costs is one of the most common approaches that Congress, the administration, and states are currently implementing or considering. Such a policy will surely reduce most insulin patients' OOP costs, but it is likely to result in at least some cost-shifting rather than cost reduction. The most likely cost-shifting would be in the form of increased premiums for all insurance plan enrollees, perhaps proportionate to the number of insulin-dependent beneficiaries. This outcome is not necessarily negative, as higher premiums mean the risk and associated costs of the insured population are spread more evenly. Further, to the extent that lower OOP costs increase medication adherence, as discussed previously, the medical cost

savings may offset the need to increase premiums.

There is also a concern that placing an OOP cap on all insulin products will, by eliminating patients' price sensitivity, undermine the effectiveness of common rebate agreements for preferential formulary placement. Such agreements depend upon a guarantee of increased volume in exchange for the discounted price; the increased volume results from a single manufacturer's product having the lowest patient cost in that category; if patient costs are now equal across products, there will no longer be a financial incentive to take one product over another. Such a policy could discourage manufacturers from offering rebates. Insurers, however, may be able to encourage manufacturers to continue offering rebates (or at least a lower net price than their competitors) by implementing utilization management tools to steer patients toward certain products by imposing step therapy or prior authorization for more expensive products.

Rebate Pass-Through at the Point of Sale

Administrative Action

In January 2019, the administration proposed disallowing the use of drug rebates provided to Medicare Part D and Medicaid Managed Care plans unless those rebates were passed along to patients at the point of sale.

Congressional Action

H.R. 19 and S. 3129 would permit Part D plans to offer an additional plan option where beneficiaries would be provided drug rebates at the point of sale.

Pros and Cons of Rebate Pass-Through

Requiring that patients receive manufacturer rebates at the point of sale would allow patients to pay their coinsurance based on the net price of their drug rather than list price, as is the current practice for most products. With rebates for many common insulin products averaging between 30 and 50 percent, this change would significantly reduce OOP costs for most insulin users, assuming manufacturers continue to offer rebates or, alternatively, an equally low net price. Conversely, patients who do not take expensive drugs for which large rebates are offered would likely face higher costs in the form of higher premiums, since currently rebates are typically used to reduce premiums. Numerous analyses of the administration's proposal, however, estimated that the OOP savings would be so substantial that, in the aggregate, any premium increase would be more than offset.

Unfortunately, those same analyses also projected increased government spending based on assumptions that drug manufacturers would no longer offer rebates of the same value and, more important, that the policy change would no longer enable insurers to use those rebates to reduce plan premiums, which the federal government heavily subsidizes in Medicare Part D. As a result, the rule was never finalized.

Because rebates for insulin products are typically much larger than rebates for other products, this policy would likely benefit insulin users more than users of most other classes of drugs. Ultimately, the impact of such a proposal is difficult to predict given the assumptions that must be made, but it would arguably redistribute costs more equitably by making premiums more accurately reflect the true risk of the entire pool and making insurance more valuable to those who need it most.

Price Transparency

Congressional Efforts

Congress has put forth numerous drug pricing transparency proposals, as discussed here and here, though they would apply broadly to any drug meeting certain price thresholds, rather than just insulin products.

Administrative Actions

The administration has also attempted to increase drug price transparency, notably by attempting to require drug manufacturers to include the list price of medicines in direct-to-consumer television advertisements. These efforts have thus far been blocked by court orders.

State Actions

In June 2017, Nevada passed legislation to increase transparency in cost and pricing trends for what the state deemed are essential diabetes drugs (EDDs); both drug manufacturers and pharmacy benefit managers are required to report data pertaining to prices, administration and production costs, rebates provided and retained, and justifications for price increases, among other things, which are then publicly reported.[xxx]

Pros and Cons of Price Transparency

Price transparency, depending on the level of detail, may be helpful in informing policymakers, allowing them to better understand where the underlying costs are hidden, which entities are profiting over others, and make decisions based on that information. Informed decisions help prevent unintended consequences. Transparency may also be useful as a shaming mechanism.

Conversely, there are concerns that price transparency may also have negative consequences by perhaps revealing to manufacturers and insurers how much their competitors are discounting or paying for products and adjusting prices upward to remain competitive while increasing profits.

The effect of Nevada's law is far from conclusive at this point—22 percent of EDDs had significant price increases in either 2017 or 2018 (including nearly 18 percent of insulin products), and 60 percent of those EDDs had significant price increases in both years, with the average two-year price increase nearly 22 percent.[xxxi] Further, Nevada issued $17.4 million in fines for noncompliance to 21 manufacturers of diabetes drugs.[xxxii] The second annual Nevada report, expected to be published in May, might provide greater insight into the effect of transparency requirements.

Bulk Purchasing

Action in Washington State

In addition to imposing a $100 monthly OOP cap, Washington state is working on legislation to create a centralized insulin purchasing program for the state, hoping that the state's bulk purchasing power can be leveraged to obtain lower prices.[xxxiii]

Pros and Cons of Bulk Purchasing

Bulk purchasing is a common business practice used to obtain volume discounts by consolidating negotiating leverage. To be most effective, however, the state may need to establish a preferred insulin product, similar to insurers' use of tiered formularies for preferred drugs. Doing so may result in reduced access to certain products; given the limited ability of some patients to switch insulin products, this preference may create new problems for some individuals.

Free Emergency Supplies

State Action

In May 2019, Oregon enacted a law to allow pharmacists to prescribe and dispense emergency insulin for individuals with a previous prescription; New York lawmakers introduced similar legislation in August 2019.[xxxiv] Included in the legislation passed in Minnesota in April 2020 is a requirement that manufacturers provide for free a 30-day supply of insulin to uninsured individuals or patients with a co-pay requirement of more than $75. Patients will only be eligible to receive the free emergency supply once a year, and may be required by the pharmacy to pay up to $35 to cover the pharmacy's cost.[xxxv]

Pros and Cons of Mandating Free Insulin

Similar to other proposals, requiring manufacturers to provide products for free to people in an emergency will certainly help some individual patients in the short-term, and possibly even save lives. In the long-term, however, history suggests that a policy reducing manufacturers' revenue will lead to increased costs for the majority of patients as manufacturers will seek to offset those costs by increasing prices.

State Assistance Programs

Action in Connecticut

The state of Connecticut is considering the development of a State Assistance Program, which would be funded by imposing taxes on insulin manufacturers.[xxxvi]

Pros and Cons of Tax-Funded Assistance Programs

As with the proposals to require free emergency supplies, such a program will likely help some individuals in the short-term, but, again, it is likely that the cost of such a tax would be added to the price of the product, undermining the intent of the policy.

Recent Manufacturer Responses

For years, each of the three primary insulin manufacturers have offered patient assistance programs to help patients afford their insulin. In the wake of the COVID-19 outbreak that has left millions unemployed, Eli Lilly announced on April 7 that it was implementing the Lilly Insulin Value Program, offering its insulin to patients at a maximum $35 co-payment, whether the patient has insurance or not.[xxxvii] The value of the benefit has an annual cap of $7,500, calculated as the difference between $35 and what the patient would otherwise pay.[xxxviii] Similarly, Novo Nordisk announced on April 15 that it will expand its Diabetes Patient Assistance

Program, offering insulin for free for 90 days for anyone who can prove they lost their employer-sponsored insurance; for anyone denied Medicaid coverage, they will be able to continue receiving free insulin for the remainder of the year.[xxxix] Sanofi has also made free insulin available to some people who have lost their job due to COVID-19 and continues to offer insulin assistance to individuals with and without insurance through its previously existing patient assistance programs.[xl] It is unclear how long these new programs will remain in effect.

Looking Ahead

The prevalence of diabetes is high and is only expected to get worse in the United States. Each year 1.5 million Americans are diagnosed with diabetes.[xli] According to a study by Stanford University, worldwide insulin use is expected to rise an additional 20 percent by the year 2030.[xlii] Further, the rising rate of obesity correlates strongly with the projected increase in diabetic diagnoses.[xliii] About one-third of Americans today are classified as obese, and this statistic is expected to rise to over half of Americans by the year 2030.[xliv] As a major contributing risk factor for type 2 diabetes, the increased prevalence of obesity will result in an increased number of diabetes diagnoses.[xlv] Hence, the importance of the cost of insulin will only continue to rise in the coming years.

Conclusion

The increasing cost of insulin seems primarily to be the result of a lack of competition in the market and convoluted drug pricing and insurance practices. While most policy proposals currently being considered would limit patients' OOP costs, they will likely result in higher costs elsewhere, such as higher premiums. Such a result, however, may be the best solution while patients and policymakers wait for new competitors to come to market, now that biosimilar insulin may be produced.