TEN KEY FACTS ABOUT THE INSULIN MARKET AND PATIENT AFFORDABILITY

Robust competition in the insulin market has led to declines in net costs for insulins over the past 15 years, but the increasing use of deductibles and coinsurance means that more patients are exposed to the undiscounted list price of medicines at the pharmacy counter. This allows pharmacy benefit managers (PBMs) and health insurers to shift more of the cost of health care onto a small share of patients with diabetes, resulting in affordability and access challenges. The new regulatory pathway for biosimilar insulins is expected to further fuel competition in the market, but commonsense policy solutions are needed in the near term to help address these challenges and ensure patients are able to access the medicines they need. Here are 10 things to keep in mind when considering patient access to insulin:

1. Insurers and middlemen in the biopharmaceutical supply chain known as PBMs—three of which manage more than 77% of all prescriptions filled in the United States—leverage robust competition among a broad range of long and rapid-acting insulins to negotiate deep discounts from manufacturers in exchange for preferable formulary placement.

2. In 2021, the significant rebates, discounts and other payments that manufacturers paid to PBMs, insurers, the government and others, lowered the cost of the most commonly used insulins by 84% on average. Further, the average annual net costs for these insulins have declined by 20% since 2007. In other words, insulins are less expensive today than they were nearly 15 years ago.

3. However, due to misaligned incentives in the system, middlemen—not patients—have been the primary beneficiaries of the deep discounts and rebates that have lowered the cost of insulins. In fact, between 2014 and 2018, the share of total spending on insulins received by PBMs increased 155%. At the same time, the share of total spending on insulins going to manufacturers decreased by 33%.

4. While middlemen in the drug supply chain are receiving more of total spending on insulin each year, patients with diabetes continue to face affordability challenges. That is because health plans and PBMs increasingly use deductibles and coinsurance to shift more costs onto patients. As a result, commercially insured patients taking brand diabetes medicines with deductibles or coinsurance pay 3.6 times more out of pocket, on average, than patients with only fixed copays.

5. This cost shifting has led to a small share of patients with deductibles and coinsurance responsible for the vast majority of total patient out-of-pocket spending on insulin. This is not how insurance should work.

6. To help patients with diabetes afford their insulin, as well as other diabetes medicines, every biopharmaceutical company that produces insulin offers patient assistance and cost-sharing assistance programs.

7. Patient assistance has become a crucial lifeline for many patients. In 2019, average out-of-pocket spending for patients taking brand diabetes medicines would have been more than twice as high without cost-sharing assistance from biopharmaceutical companies. Additionally, in the absence of cost-sharing assistance, patients just beginning treatment with brand medicines are nearly three times more likely to abandon medicines at the pharmacy counter.

8. Even though there are commonly used insulins today that have not had patent protection for many years, the regulatory framework governing insulins has not allowed for generic insulin. There is, however, now a regulatory pathway to bring biosimilar insulins to market. The pathway has been available since March 23, 2020.

9. In advance of the new regulatory pathway, manufacturers have brought “authorized generics” of their own products to market in an effort to offer patients lower list priced insulin. Manufacturers have also launched “follow-on” insulin products, which have contributed greatly to competition and net price declines. For example, following the entrance of a follow-on long-acting insulin, net prices declined by 30% in the class.

10. In July 2021, the U.S. Food and Drug Administration (FDA) approved the first interchangeable biosimilar insulin. Like many generic products today, interchangeable products may be automatically substituted at the pharmacy counter in many states. This product and future approved biosimilar products are expected to further fuel competition in the insulin market in the years ahead.
The System Needs to Work Better for Patients with Diabetes.

Commonsense solutions are needed to address affordability challenges faced by patients. More of the significant discounts, rebates and other payments made by biopharmaceutical companies should be shared with patients at the pharmacy counter. One study found that directly sharing rebates and discounts could save a typical Part D patient with diabetes taking five medicines, including insulin, more than $900 a year in lower out-of-pocket spending. Similarly, another analysis found passing through rebates and discounts at the pharmacy counter could save certain commercially insured patients with diabetes as much as $800 annually while increasing premiums by just about 1%. In fact, some insurers in the commercial market have already taken steps to share rebates and discounts directly with patients at the pharmacy counter, resulting in significant cost savings for patients.

Furthermore, insulin should not be subject to a deductible. Instead, patients managing chronic disease should have at least some of their medicines covered by their insurance from day one. Many insurers have begun to provide first dollar coverage for insulin in high deductible health plans (HDHPs), which has been shown to dramatically improve patient affordability. One study found that if all patients with diabetes in HDHPs had first dollar coverage for insulin, out-of-pocket costs could be 2.4 – 3.7 times lower. In fact, exempting insulin from the deductible could save certain patients more than $1,500 annually in out-of-pocket costs while also allowing them to spread these costs more evenly throughout the year.

In addition to sharing more discounts and rebates with patients at the pharmacy counter and covering more medicines from day one, the following policies can improve insulin affordability in the commercial market:

- Providing flat copays for insulin in commercial health plans and those receiving cost-sharing subsidies in the Exchanges
- Counting cost-sharing assistance toward deductibles and out-of-pocket limits
- Counting out-of-pocket costs paid through third-party discount programs toward deductibles and out-of-pocket limits

In 2020, the Centers for Medicare & Medicaid Services also took steps to address seniors’ out-of-pocket costs through a voluntary demonstration program that would lower cost sharing for certain insulins to a maximum $35 copayment for a 30-day supply. Three manufacturers and over 1,600 Medicare Part D plans participated in the program to offer lower out-of-pocket costs for patients through the demonstration for the 2021 plan year. These efforts represent important steps to improve affordability and predictability for patients who rely on insulin. But more needs to be done to modernize Medicare Part D coverage by establishing an annual cap on out-of-pocket costs, lowering cost-sharing overall and allowing patients to spread costs throughout the year.

Finally, we need to address misaligned incentives in the system which can drive affordability challenges for patients with diabetes. For example, despite the introduction of lower list priced authorized generic insulins in 2019 and 2020, two of the nation’s largest PBMs have repeatedly excluded these insulins from their national formularies. Experts have pointed to this exclusion as evidence that the current system may lead health plans and PBMs to favor medicines with high list prices and large rebates over lower list price alternatives that would cost some patients less. Excluding lower list price alternatives from formularies can drive up out-of-pocket costs for patients with deductibles and coinsurance. To address these perverse incentives, fees for PBMs and other entities in the supply chain should be flat fees based on the services they provide – not calculated as a percent of a medicine’s price – so that patients aren’t left paying more for their medicines.

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xviii https://medicinaccessistance.org/en
xx For example, none of Eli Lilly's commonly used insulins are under patent protection and the patent on its most commonly prescribed insulin product, Humalog U-100, expired in 2014. https://www.lilly.com/resources/diabetes-solution-center/insulin-affordability-conversation