

INCREASING INSULIN AFFORDABILITY

INTRODUCTION

Insulin is a lifesaving medication for people with diabetes. However, its cost has nearly tripled in the past fifteen years making it difficult for many patients to afford this medication and effectively manage their disease.¹ This has put patient safety in jeopardy as patients opt to ration their insulin or forgo other medical care. Research indicates that a lack of transparency in the drug supply chain has made it challenging to identify the root cause of price increases. This position statement will identify barriers to accessing affordable insulin and potential policy solutions that could address this growing problem.

BACKGROUND

More than 30 million Americans have diabetes with another 84 million at risk for developing the disease.² Having diabetes increases one's risk for serious health problems including heart attack, stroke, blindness, kidney failure, amputations, and death.³ Diabetes is also the most expensive chronic condition in the United States.⁴ Average medical expenses are 2.3 times higher for people with diabetes.⁵ In 2017, the cost of diagnosed diabetes was estimated to be \$327 billion annually, with \$237 billion in direct medical costs.⁶ This equates to one-in-four health care dollars being spent on people with diagnosed diabetes.⁷ And since one-in-four are unaware they have the disease⁸, costs to the healthcare system are even higher than estimated.

Given the complex nature of diabetes, it is essential that patients adhere to their medication regimen to avoid unnecessary complications and hospitalizations. However, adherence can be difficult as people with diabetes often have co-morbidities that require them to take multiple, costly medications or they may be unable to make sustained lifestyle

changes that could improve outcomes. One study indicates that improved adherence among people with diabetes could prevent nearly 700,000 emergency department visits, 341,000 hospitalizations and save \$4.7 billion annually.⁹ Recent increases in drug costs and changes to insurance design are some of the most common reasons for poor medication adherence, particularly for patients on insulin.^{10,11}

Rising Insulin Costs

The true cost of insulin can be difficult to pinpoint because of a lack of transparency in financial agreements between stakeholders in the supply chain, geographical differences in cost, and insurance coverage.¹² From 2001-2016, the list price of Novolog, a commonly used insulin, increased by 353% per vial.¹³ Humulin U500 increased from \$170 to more than \$1,400 since 1987.¹⁴ From 2001-2015, the price of Humalog increased 585% for a vial of insulin.¹⁵ GoodRx.com, a website that aggregates claims data to estimate the average list price of medications (the price of insulin without the negotiated discounts or rebates), published cost information per vial (1000 units) for commonly prescribed insulins in August 2018. The following prices are averaged from Walgreens and CVS pharmacies:

- Lantus: \$302
- Humalog: \$322
- Novolog: \$336
- Humulin N: \$180
- Novolin N: \$155
- Basaglar: \$261*
- Levemir: \$394
- Toujeo: \$338*
- Humulin R: \$180
- Novolin R: \$155
- Humulin 70/30: \$177
- Novolin 70/30: \$156
- Novolog 70/30: \$338
- Humalog 75/25: \$351
- Tresiba: \$388*
- Apidra: \$368
- Admelog: \$254

*cost based on conversion to 1000 units

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¹Hua X, Carvalho N, Tew M, Huang ES, Herman WH, Clarke P. Expenditures and prices of antihyperglycemic medications in the United States: 2002-2013. *JAMA* 2016;315:1400-1402.

²Centers for Disease Control and Prevention. National Diabetes Statistics Report. <https://www.cdc.gov/diabetes/data/statistics/statistics-report.html>

³National Diabetes Prevention Program. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/prevention/prediabetes-type2/index.html>. Accessed September 1, 2018.

⁴Petersen, M. Economic Costs of Diabetes in the U.S. in 2017, Diabetes Care. American Diabetes Association. <http://care.diabetesjournals.org/content/41/5/917>. Accessed September 1, 2018.

⁵National Diabetes Prevention Program. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/prevention/prediabetes-type2/index.html>. Accessed September 1, 2018.

⁶Petersen, M. Economic Costs of Diabetes in the U.S. in 2017, Diabetes Care. American Diabetes Association. <http://care.diabetesjournals.org/content/41/5/917>. Accessed September 1, 2018.

⁷The Cost of Diabetes, American Diabetes Association. <http://www.diabetes.org/advocacy/news-events/cost-of-diabetes.html>. Accessed September 1, 2018

⁸More than 29 million Americans have diabetes; 1 in 4 doesn't know. Centers for Disease Control and Prevention. <https://www.cdc.gov/media/releases/2014/p0610-diabetes-report.html>. Accessed September 1, 2018.

⁹Jha, A.K., Aubert, R. E., Yao, J., Teagarden, J.R., & Epstein, R.S. (2012) Greater adherence to diabetes drugs is linked to less hospital use and could save nearly \$5 billion annually. *Health Affairs*, 31 (8), 1836.

¹⁰IHS Markit. Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare. May 14, 2018.

¹¹Ibid.

¹²Health Care Cost Institute. http://www.healthcostinstitute.org/healthy_bytes/price-insulin-prescription-doubled-2012-2016/. Accessed September 1, 2018.

¹³Cefalu, W. T., Dawes, D. E., Gavlak, G., Goldman, D., Herman, W. H., Nuys, K. V., Yatvin, A. L. (2018). Erratum. Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care* 2018;41:1299-1311. *Diabetes Care*, 41(8), 1831-1831. American Diabetes Association doi:10.2337/dc18-er08

¹⁴Good RX. Humulin R. https://www.goodrx.com/humulin-r/?=&form=vial&dosage=20ml-of-500-units/ml&quantity=1&days_supply=&label_override=Humulin%20R. Accessed September 1, 2018.



POSITION STATEMENT

Currently, 7.4 million Americans use insulin to treat their diabetes.¹⁶ At minimum, these patients use one vial of insulin each month. However, some patients require multiple vials of insulin or use multiple types of insulins (which necessitates multiple vials) each month. According to a survey conducted by the American Diabetes Association, 27% of respondents stated that insulin costs have affected their past year purchase or use of insulin. Thirty-four percent of families with children on insulin were impacted.¹⁷ Those affected by rising costs were more likely to experience adverse health effects than those for whom cost did not impact their purchase or use of insulin and twice as likely to experience negative emotions like stress and anxiety. Many of these patients were also forced to forgo other needs such as transportation (32%), utilities (30%), housing (27%), doctor's visits (32%), or other medications (36%)¹⁸, and were more likely to ration their insulin.

Patient Cost-Sharing

Insurance plan design directly impacts out-of-pocket costs. Patients who are uninsured pay the list price of insulin. These individuals may be eligible for a manufacturer-sponsored patient assistance program (PAP), however, these programs are restrictive, difficult to navigate, and it is unclear how many patients are able to utilize them.

Patients on some forms of commercial plans may need to pay full price, depending on the plan design, for their insulin until they meet an annual deductible and then pay a fixed co-pay. They may also be required to pay co-insurance, a percentage of the cost based on the list price of insulin that does not include rebates or discounts negotiated by the pharmacy benefit manager (PBM).

For patients with high-deductible plans (plans with a deductible greater than \$1,350 for an individual or \$2,700 for a family), out-of-pocket insulin costs are significant. Individuals must pay for the full list price of insulin until they meet their annual deductible. In 2016,

approximately 40% of Americans had a high-deductible health plan with an average annual deductible of \$4,358 for individual health plans and \$7,983 for family plans.¹⁹ In the same year, 44% reported selecting plans with annual deductibles of \$6,000 or greater in 2016.²⁰

Medicare beneficiaries with Part D coverage without a supplemental plan must also pay full price for insulin until they meet their deductible, after which point they will pay co-insurance until meeting their plan's initial coverage limit for prescription drugs (\$3,750 in 2018).²¹ At this point, they experience the Part D "donut hole", a coverage gap between the plan's initial coverage limit and when catastrophic coverage kicks in. While Medicare beneficiaries are in the donut hole, they will pay 35% of the plan's cost for covered brand-name prescription drugs until reaching their annual out-of-pocket limit of \$5,000 in true out-of-pocket spending. Catastrophic coverage will then begin, and the Medicare beneficiary will pay a small co-insurance or copayment for covered prescription drugs.²²

In some cases, purchasing medications outside of their pharmacy benefit allows patients to pay lower costs. So-called "gag rules" have prevented pharmacists from counseling patients about options to take advantage of this cost-savings and should be eliminated.

There are many stakeholders across the drug supply chain who influence rising costs, including wholesalers, PBMs, pharmacies, health plans, and employers. While manufacturers establish the list price, each of these players impact the out-of-pocket cost to a patient on insulin through a complex series of negotiations and rebates not transparent to the public. The lack of transparency makes it difficult, if not impossible, to understand how much each stakeholder gains when costs to the patient increase. Research indicates that while list prices have skyrocketed, the net price increase that manufacturers earn has risen at a far slower rate (3-36% net increases).²³ Increasing transparency is critical to understand this divergence and other contributors to rising insulin costs.

¹⁶Good RX. Insulins. <https://www.goodrx.com/insulins>. Accessed September 1, 2018.

¹⁷Cefalu, W. et al. Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care* 2018 May; doi:180019

¹⁸American Diabetes Association. Insulin Affordability Survey 2018. American Diabetes Association. <http://www.diabetes.org/assets/pdfs/advocacy/insulin-affordability-survey.pdf>. Accessed September 1, 2018.

¹⁹Ibid.

²⁰Health Insurance Price Index Report: 2016 Open Enrollment Period. eHealth. https://news.ehealthinsurance.com/_ir/68/20169/eHealth%20Health%20Insurance%20Price%20Index%20Report%20for%20the%202016%20Open%20Enrollment%20Period%20-%20October%202016.pdf. Accessed September 1, 2018.

²¹Ibid.

²²Burke, V. The Medicare Part D Coverage Gap ("Donut Hole") Made Simple. Medicare.com. <https://medicare.com/medicare-part-d/coverage-gap-donut-hole-made-simple/>. Accessed September 1, 2018.

²³Medicare Part D.org. The Part D donut hole. <https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-costs/the-part-d-donut-hole>. Accessed October 24, 2018.

²⁴Cefalu, W. T., Dawes, D. E., Gaviak, G., Goldman, D., Herman, W. H., Nuys, K. V., Yatvin, A. L. (2018). Erratum. Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care* 2018;41:1299–1311. *Diabetes Care*, 41(8), 1831-1831. American Diabetes Association doi:10.2337/dc18-er08



POSITION STATEMENT

CONSIDERATIONS

Complexity of the Supply Chain

The complexity of the supply chain makes it difficult to pinpoint the drivers behind increasing insulin prices. Manufacturers set the list price for the medication and typically sell their medications to wholesalers or PBMs. The process to get the medication from the manufacturer to the patient is rather straightforward, but the flow of money and the methodology to establish the price that the patient ultimately pays is much more complex. The net price manufacturers receive is based on the list price minus any fees paid to the wholesaler, discounts paid to the pharmacy, and rebates paid to the PBMs or health plans. Financial agreements between the stakeholders are confidential. For example, manufacturers are not privy to the PBM's negotiations with the health plans.

Despite significant financial incentives negotiated between the stakeholders in the supply chain, most of these savings are never shared with the consumer. As such, an individual's cost is largely based on the list price. As list prices grow at double-digit rates, people with high-deductible plans, co-insurance, or no insurance suffer the effects.

Net Price

The process to establish the net price involves the exchange of rebates, discounts and other payments to encourage the purchase of a drug. For example, a manufacturer may offer distributor volume discounts to purchase their drug or provide financial incentives to a PBM for placement on the preferred tier of their drug formulary. Manufacturers cite these financial incentives as a major driver of high list prices; the more incentives provided to the players across the supply chain, the higher the list price must be for the manufacturer to realize any profit. In theory, the rebates offered to a PBM to place the drug on their preferred formulary tier should reduce costs for the patient. However, these rebates may be used by the employer or the health plan to reduce insurance premiums, not the cost of the drug at point-of-sale. However, due a lack of transparency, it is unclear the extent to which premiums are actually affected.

Patient Assistance Programs and Discount Cards

To address high out-of-pocket costs, manufacturers offer patient assistance programs (PAPs) that provide insulin at low or no cost to low-income patients who qualify. These requirements vary by company and patients must apply annually which can be problematic as PAPs can be difficult to navigate. Manufacturers also offer co-pay cards but these are typically used to incentivizing the use of higher cost medications and have been shown to result in overall higher medication prices.

Lower-cost Alternatives

Competition in the marketplace for both brand name and generics typically drives down prices. This has not been the case with insulin. The price of modern insulins has continued to increase despite the availability of multiple competing insulins on the market. In a true free-market economy, this should promote greater competition and drive down costs. Human insulins (i.e, NPH and regular insulins) have been available for decades, would be an effective therapy for some patients with Type 2 Diabetes, and can still be purchased at a significantly lower cost. However, most health care providers are no longer trained on how to use these.

Value-based Purchasing

Some experts believe that value-based purchasing (VBP) agreements have the potential to reduce drug costs. These agreements between manufacturers and health plans base payment on how effective a medication is at treating a disease and can be structured in different ways; if a drug does not improve outcomes or leads to poorer health among the health plan's patient population, the manufacturer will provide discounts, rebates, or refunds to the health plan. However, further research is needed to understand whether value-based purchasing agreements will reduce patient costs. Furthermore, regulatory barriers have limited the number of existing VBP contracts, thereby making it difficult to assess the real benefit of value-based purchasing on reducing drug costs.

POSITIONS

Rising costs have made access to affordable insulin far more difficult for people with diabetes, especially low-income individuals, those on high deductible health plans, Medicare beneficiaries in the Part D donut hole, or those who are uninsured. Addressing insulin affordability is critical in ensuring that patients can effectively manage their diabetes and avoid unnecessary complications and hospitalizations. For many patients with diabetes, insulin is a life-saving medication. Policymakers should address drivers of rising insulin prices and implement solutions that would reduce high out-of-pocket expenditures for patients.



POSITION STATEMENT

The Endocrine Society believes the following policy and practice changes could help expand access to lower cost insulin.

- Greater transparency is needed across the supply chain to understand rising insulin costs.
- Future list price increases should be limited and reasonable financial incentives should be pursued by all stakeholders.
- To reduce out-of-pocket expenditures, cost-sharing should be limited to a co-pay. In addition, NPH and regular insulin should be available at no cost to the patient.
- Rebates should be passed along to consumers without increasing premiums or deductibles.
- Patient Assistance Programs should be less restrictive and expanded to include more accessible and easier to complete applications that can be used for multiple programs (e.g. a common application).
- Health care providers should be trained to use lower-cost human insulins (e.g., NPH and regular), so they can prescribe as appropriate.
- When clinically equivalent options are available, physicians should consider prescribing the lowest cost insulin.
- The Federal government should address regulatory barriers to create a more favorable environment for the testing of incentive programs that reduce cost and improve care (e.g. value-based purchasing agreements).
- Electronic medical records should include up-to-date formulary and price information
- Co-pay savings cards should be eliminated as they have been shown to incentivize the use of higher cost medications and raise the overall cost of drugs.
- Patients should be educated about low-income assistance programs (e.g. the Extra Help program under Medicare) and to ask their physicians about alternatives if they cannot afford their insulin.
- Gag rules, which prevent pharmacists from helping patients find less expensive ways to pay for their medications, should be eliminated.