

# Improving Insulin Access and Affordability

## Summary of Recommendations

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### INTRODUCTION

Insulin costs have been steadily increasing, forcing many people with diabetes to choose between purchasing this life-sustaining medication or paying for other necessities. In May of 2018, the American Diabetes Association's (ADA) Insulin Access and Affordability Working Group released findings from their research and stakeholder discussions. Utilizing the conclusions and recommendations from the Working Group, the ADA has released a Public Policy Statement: Improving Insulin Access and Affordability, with a series of policy recommendations to increase transparency and lower insulin costs. The Public Policy Statement provides an array of short-term and long-term recommendations to help shed additional light on the issue, to combat increasing insulin costs, and to improve affordable access to medications. Following is a summary of the policy recommendations:

### KEY TAKEAWAYS

- Insulin costs have been steadily increasing, forcing many people with diabetes to choose between purchasing this life-sustaining medication or paying for other necessities.
- This Public Policy Statement provides an array of short-term and long-term recommendations to help shed additional light on the issue, to combat increasing insulin costs, and to improve affordable access to medications, including:
  - Streamlining the biosimilar approval process;
  - Increasing pricing transparency throughout the insulin supply chain;
  - Lowering or removing patient cost-sharing for insulin;
  - Increasing access to health care coverage for all people with diabetes.

## **SUPPLY CHAIN TRANSPARENCY**

The ADA recommends increased transparency throughout the full insulin supply chain. To meet this recommendation, we have outlined pieces of information that entities could provide to help determine what factors are contributing to high insulin prices. In the Public Policy Statement, we recommend information from entities in the supply chain be released to a third-party evaluator such as Congress or a government agency. To understand the full scope of this problem, every entity in the insulin supply chain would need to provide this information.

## **COMPETITION AND BIOSIMILARS**

Insulin is a biologic medication made from living cells. The regulatory process to introduce “generic” versions (called biosimilars or follow-on biologics) is different from traditional generics. Currently, there are only two follow-on biologic insulins for sale in the United States. The list prices for these insulins were 15% lower than their original versions. Increasing the number of insulin options available could lead to lower costs for patients. The ADA recommends the U.S. Food and Drug Administration continue its efforts to encourage competition within the insulin landscape, including fostering biosimilar competition.

## **HEALTH PLAN DESIGN AND PATIENT-COST SHARING**

The Public Policy Statement offers a spectrum of health plan benefit design changes that can help decrease patient costs for insulin.

## **Eliminate Cost-Sharing**

The ADA’s primary recommendation is for health plans and government programs to cover insulin without cost-sharing. Providing diabetes medications with low or no cost-sharing has been shown to increase medication adherence and results in better long-term health outcomes.

## **No Deductibles or Co-Insurance**

At minimum, we recommend insulins not be subject to a deductible nor co-insurance. Deductibles and co-insurance for insulin expose people with diabetes to high list prices, often creating financial barriers to accessing the medicine. If cost-sharing is imposed for insulins, it should be a flat dollar amount, which can be more manageable and consistent for consumers.

## **Patients Should Pay Lowest Price Available**

To ensure people with diabetes pay the lowest price available, the ADA recommends that all discounts negotiated amongst the various supply chain entities (manufacturers, pharmacies, pharmacy benefit managers (PBMs), etc.) be incorporated into the calculation of patient costs.

## **HSA-eligible HDHPs**

Under current federal rules, contributions to health savings accounts (HSAs) linked with high-deductible health plans (HDHPs) are not subject to income tax, so long as the plan meets certain requirements. Under those requirements, HSA-eligible HDHPs can cover primary preventive benefits before the deductible is paid. To encourage employers to limit out-of-pocket expenses for insulin costs, the ADA recommends the Department of Treasury provide additional guidance to clarify that HSA-eligible HDHPs can exempt insulin from the deductible without impacting the tax status of such plans.

## **INCREASED ACCESS TO AND AFFORDABILITY OF MEDICATIONS**

### **Limits to Out-of-Pocket Costs**

Currently, most health plans must limit the amount enrollees spend out-of-pocket for their health care each year. However, this maximum is generally applied to all health care spending combined. The ADA recommends health plans and government programs be required to limit out-of-pocket spending for medications.

### **Medicare Drug Pricing Negotiations**

The ADA supports allowing the U.S. Department of Health and Human Services to negotiate prices for the Medicare Part D program. Currently, the Secretary of HHS is prohibited from interfering with the negotiations between drug manufacturers and Part D plan issuers.

### **Continuity of Care**

Health plans and government health care programs should be prohibited from removing medications from formularies or moving medications to a higher tier during the plan year, except when the FDA calls into question the clinical safety of the drug. Already prohibited in Medicare Part D, the ADA recommends the prohibition apply to all health plans and government health care programs.

## **Formulary Development Process**

The ADA recommends that health plans, government health care programs and the PBMs they work with be required to follow rigorous standards when developing prescription drug formularies. This includes:

- Requiring formularies to be developed in accordance with evidence-based standards of care and provide coverage for a wide range of options within each therapeutic area;
- Requiring all utilization management protocols to be developed based on evidence-based standards of care;
- Utilizing a transparent process for the development of formularies;
- Requiring a minimum number of Pharmacy and Therapeutics Committee members without a conflict of interest and prohibiting members with a conflict of interest from voting on matters for which the conflict exists.

## **Value-Based Insurance Design**

The ADA supports many public policies consistent with the concept of value-based insurance design. When value-based insurance design is implemented, the ADA recommends regulators, health plans and government programs ensure the design is evidence-based and that it includes consumer cost-sharing protections, such as low or no co-pays and accessible exceptions processes.

# IMPROVING ACCESS TO ADEQUATE, AFFORDABLE HEALTH CARE

## Medicaid Expansion

The Affordable Care Act made tremendous positive changes to the availability and affordability of health insurance for people with pre-existing conditions, like diabetes. However, just over 12% of adults in the U.S. were uninsured at the end of 2017, which is due in part to the so-called Medicaid gap. This gap exists in states that have chosen not to expand Medicaid coverage to non-disabled adults earning less than 138% of the federal poverty level (FPL). The ADA recommends all states expand Medicaid eligibility to those earning less than 138% FPL. In addition, states should take steps to maintain or improve upon existing consumer protections that ensure people with diabetes have meaningful access to adequate, affordable health insurance coverage.

## Health Insurance Transparency for Consumers

While the ADA does not expect insulin supply chain transparency itself to directly lead to lower costs for patients, providing consumers additional transparency in their expected costs could. All health insurance plans and government programs should be required to provide consumer-friendly tools to help individuals search for the medications they need and provide specific cost-sharing amounts.

## Language Access

Latinos, African Americans, American Indians, Alaska Natives, Asian Americans, Native Hawaiians, and Pacific Islanders have a higher incidence of diabetes and are often less able to obtain the care they need to manage their disease than their Caucasian counterparts. The ADA recommends all health plans, government programs, health insurance agents and brokers be required to provide on websites and documents taglines in non-English languages indicating the availability of language services. These taglines greatly help reduce barriers to obtaining and understanding health insurance.

### ABOUT THE AUTHORS

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