

Achieving Insulin Access and Innovation

STATEMENT OF PRINCIPLES

All people with type 1 diabetes (T1D) should have affordable access to insulin, which they need to take multiple times a day in order to survive. At the same time, the T1D community needs continued innovation to develop superior insulins that enable people to achieve better health outcomes. JDRF is committed to working with all stakeholders to promote insulin affordability, while fostering an environment that promotes innovation.

As part of this effort, JDRF has established the following principles:

- Access to Insulin: Insulin should be available to people with T1D at a low, predictable out-of-pocket (OOP) cost.
- Choice of Insulin: People with T1D should have access to the insulins that work best for them.
- Research & Development of Next Generation Insulins: Any solution should not impede the development of next-generation insulins, such as faster-acting or glucose-responsive insulins.

Achieving these goals will require commitment and action by many stakeholders.

ACHIEVE ACCESS

JDRF is concerned about the effect that increasing OOP expenses have on individuals' access to insulin and other diabetes tools needed to survive. Although JDRF recognizes the complexity of the healthcare system and the many factors that contribute to the rising cost of insulin, there are solutions that can improve access and affordability.

1. **Manufacturers should ensure discounts and rebates reduce OOP costs for people with T1D.** Although insulin manufacturers offer substantial discounts to pharmacy benefit managers (PBMS) and health insurance plans, these discounts are not always adequately passed along to people with T1D. JDRF urges manufacturers to work to improve the current flow of product and payments, including rebates, in order to reduce OOP costs for people with diabetes, especially those in plans that place significant financial responsibility on the individual.
2. **Health plans, PBMS and employers should set copayments/coinsurance for insulin in a way that reflects its lifesaving role for people with T1D.** Without insulin replacement, people with T1D cannot survive. Additionally, under-dosing insulin can lead to severe and potentially fatal diabetic ketoacidosis and costly, long-term complications. Cost-sharing for insulin should reflect the clinical importance of insulin on the survival of people with T1D. Additionally, people with T1D have no alternative therapy options. In the absence of alternative treatments, people with T1D should not be penalized with high out-of-pocket costs for a treatment that is life sustaining. JDRF urges health plans, PBMs and employers to exempt insulin from deductibles and provide insulin to people with T1D at a low, predictable OOP cost.
3. **Health plans and PBMs should allow individuals with T1D access to the insulin most appropriate for them.** T1D is a very unique disease that affects everyone differently. Evidence suggests that access to insulin analogues is important for people with T1D. Clinical trials often focus on the HbA1c benefit of novel insulins, however the impact on other outcomes (e.g., hypoglycemia risk, compatibility in insulin

pumps) not often tested in these trials are important to people with diabetes. JDRF urges health plans and PBMs to ensure that no type and brand of insulin is exempt from a plan's formulary.

JDRF is working with all stakeholders to try and address the problems. As we work towards a solution, JDRF is developing a toolkit to help individuals with T1D navigate common insurance challenges—including information regarding health plan selection, appeal rights, clinical exceptions and available financial resources to reduce the cost burden of managing T1D.

ACHIEVE INNOVATION

As the leading global organization funding type 1 diabetes research, JDRF is committed to the development of better and faster-acting insulins. Although immense and ongoing challenges remain, innovation in diabetes treatments and technologies allows people with type 1 diabetes to live healthier lives with less fear. However, while today's insulin formulations save lives, it remains difficult to achieve the tight control over blood glucose that occurs naturally in people without diabetes. We believe that managing blood sugar should be much easier and remain significant funders of innovative insulins, such as glucose responsive insulin and faster-acting insulin, as well as other medications that could improve blood-sugar management. The coming advancements in different types of insulin and other medications to help improve glucose control make it vital that any solution that works to ensure access to these lifesaving treatments does not stymie innovation and the development of newer and better insulins.

WHY IT MATTERS

Type 1 diabetes is an autoimmune disorder in which a person's immune system attacks and destroys the insulin-producing cells in the pancreas. Insulin is the hormone that enables people to convert food into energy. Prior to the discovery of insulin, T1D was 100% fatal. Today, due to advancements in insulin, as well as the tools used to administer insulin and monitor one's blood-glucose levels, individuals with T1D who closely manage their disease can expect to live nearly as long as their counterparts without T1D live. However, doing so requires persistent management, which is only possible with affordable access to insulin and other diabetes supplies. Furthermore, diabetes remains the leading cause of end-stage renal disease, blindness and lower-limb amputations. JDRF recognizes that the current U.S. healthcare system is very complex and changing rapidly and that to improve access changes must be made throughout the system.

However, individuals must be able to access these breakthroughs in order to benefit from them, and achieve better outcomes. It is well known that as cost-sharing requirements increase, medication adherence goes down, leading to poorer health outcomes. A RAND study from 2004 found that doubling copays for medicines reduced adherence by 25 to 45 percent. Another study looking at the association of medication adherence for individuals with diabetes found that each 10 percent increase in adherence was associated with an 8.6 to 28.9 percent decrease in total annual healthcare costs.¹

Type 1 diabetes must be continuously managed and requires individualized modifications in order for an individual to maintain glycemic control. Insulin is the most important factor in this daily management and the advent of injectable insulin is the reason individuals with diabetes can expect to live long after being diagnosed. However, insulin must be affordable to provide its far-reaching impact.

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¹ Iuga AO, McGuire MJ. Adherence and health care costs. *Risk Management and Healthcare Policy*. 2014;7:35-44. doi:10.2147/RMHP.S19801.