

07.07.2025

# **Estimated federal cost savings from the Special Diabetes Program**

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Funding for this research was provided by Breakthrough T1D (formerly JDRF). Avalere Health retained full editorial control.

# 1 Executive summary

Diabetes affects more than 38 million people in the United States and remains the nation's most costly chronic disease, with total costs reaching \$413 billion in 2022. The Special Diabetes Program (SDP), created by Congress in 1997 and administered by the National Institutes of Health (NIH), provides federal funding to support research on the prevention, treatment, and potential cures for type 1 diabetes (T1D). While the program is focused on T1D, many of the innovations it has supported, such as continuous glucose monitors (CGMs) and automated insulin delivery (AID) systems, are now used more broadly, including among people with type 2 diabetes (T2D), and have contributed to improved outcomes across both populations.

To better understand the program's economic impact, Avalere Health conducted an analysis of estimated federal cost savings associated with SDP-supported technologies. The analysis focused on direct medical expenditures and modeled the savings resulting from the use of CGM and AID systems by beneficiaries of public insurance including Medicare, Medicaid, and the Department of Veteran's Affairs (VA).

Findings indicate that CGMs and AID systems alone have generated at least \$50 billion in federal healthcare savings through improved glucose management and reduced diabetes-related complications. Because the analysis does not include indirect cost savings such as improved productivity, reduced disability, or long-term prevention of complications, the actual federal savings and total economic impact of these technologies is likely higher.

Each of the therapies examined in the model has benefited from SDP-supported research. For example, CGMs and AID systems were advanced through clinical trials and technology validation supported by the program. SDP-backed studies also contributed to the development of anti-vascular endothelial growth factor (VEGF) treatments for diabetic eye disease and to disease-modifying therapies such as teplizumab, which has been shown to delay the onset of clinical T1D. The program has also supported early-stage beta-cell replacement research, including the development of donislecel, the first Food and Drug Administration (FDA)-approved allogeneic islet cell therapy.

As policymakers evaluate the future of the SDP, stakeholders may consider how funding decisions will maintain or interrupt momentum in diabetes research and bringing advanced therapies to market. Disruptions in SDP funding may hinder clinical research infrastructure, delay scientific advancement, and slow patient access to therapies that prevent T1D, reduce complications and potentially cure the disease. This study and existing literature confirm that the SDP has demonstrated a strong return on investment both clinically and economically. Ongoing support for diabetes research and treatments will be essential to realizing the full potential of emerging innovations for individuals with diabetes.

## 2 Background

### Economic burden and prevalence of T1D

Among individuals with diabetes, complications and comorbidities such as cardiovascular, vascular, and renal disease are major contributors to morbidity, mortality, and healthcare costs. These issues place a significant financial burden on both patients and the healthcare system. T1D presents a distinct economic profile compared to T2D. Although T1D has historically been associated with childhood onset, recent data indicate that over half of new T1D diagnoses in the United States occurred in adults.<sup>1</sup> T1D requires lifelong insulin therapy, which often includes the use of CGM and AID systems.<sup>2</sup> As a result, patients with T1D often accumulate higher per-patient medical costs over a longer portion of their lives than those with T2D.<sup>3</sup>

One estimate indicates 2.07 million individuals in the United States (1.79 million adults and 280,000 children) have T1D, which translates to a prevalence of 617 per 100,000 people. The average patient age is 47 years.<sup>4</sup> Nearly half of individuals with T1D are covered by commercial insurance (47%), followed by Medicare (29%), Medicaid (15%), and VA (1%); 8% are uninsured.<sup>5</sup>

### Overview of Special Diabetes Program

Established by Congress in 1997, the Special Statutory Funding Program for Type 1 Diabetes Research or Special Diabetes Program was created to support research focused on the prevention, treatment, and potential cure for T1D. The SDP has received broad bipartisan support and has been reauthorized multiple times. Administered by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) within the NIH, the SDP plays a central role in advancing federally supported research on T1D.

The SDP has contributed to several significant research efforts, including the Diabetes Control and Complications Trial (DCCT) and its long-term follow-up, the Epidemiology of Diabetes Interventions and Complications (EDIC) study.<sup>6</sup> The DCCT, launched in the 1980s, found that intensive glucose control reduced the risk of microvascular complications in individuals with T1D.<sup>7</sup> The EDIC, which continues to follow DCCT participants, has demonstrated sustained benefits of early glycemic control, including reductions in cardiovascular events and long-term health risks.<sup>8</sup> These studies helped establish the

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<sup>1</sup> Breakthrough T1D: “[Incidence and prevalence](#).”

<sup>2</sup> Sussman, Matthew, Jennifer Benner, Michael J. Haller, Marian Rewers, and Robert Griffiths. 2020. “Estimated Lifetime Economic Burden of Type 1 Diabetes.” *Diabetes Technology & Therapeutics* 22 (2): 121–30. <https://doi.org/10.1089/dia.2019.0398>

<sup>3</sup> Joish, Vijay N. et al. 2020. Estimation of annual health care costs for adults with type 1 diabetes in the United States. *J. Manag Care Spec. Pharm.* 26(3), 311–318. <https://doi.org/10.18553/jmcp.2020.26.3.311>

<sup>4</sup> Smith RA, Eisenberg S, Turner-Pfifer A, et al. We are on the verge of breakthrough cures for type 1 diabetes, but who are the 2 million Americans who have it? *JHEOR*. 2024;11(2):145–153. doi:10.36469/001c.124604

<sup>5</sup> Smith RA, Eisenberg S, Turner-Pfifer A, et al. We are on the verge of breakthrough cures for type 1 diabetes, but who are the 2 million Americans who have it? *JHEOR*. 2024;11(2):145–153. doi:10.36469/jheor.2024.124455

<sup>6</sup> Judith E. Fradkin, Julie A. Wallace, Beena Akolkar, Griffin P. Rodgers; Type 1 Diabetes—Reaping the Rewards of a Targeted Research Investment. *Diabetes* 1 February 2016; 65 (2): 307–313. <https://doi.org/10.2337/db15-1030>

<sup>7</sup> Diabetes Control and Complications Trial (DCCT): results of feasibility study. The DCCT Research Group. *Diabetes Care*. 1987 Jan-Feb;10(1):1–19. doi: 10.2337/diacare.10.1.1.

<sup>8</sup> Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group. Epidemiology of Diabetes Interventions and Complications (EDIC). Design, implementation, and preliminary results of a long-term follow-up of the Diabetes Control and Complications Trial cohort. *Diabetes Care*. 1999 Jan;22(1):99–111. doi: 10.2337/diacare.22.1.99

clinical framework for T1D management and have informed subsequent research priorities under the SDP.

The program has also supported major research networks that advance understanding of disease onset and progression. Type 1 Diabetes TrialNet, a clinical trials network established under the SDP, identifies individuals at risk for T1D and evaluates immunotherapies to delay or prevent the disease.<sup>9</sup> SDP funding has also supported The Environmental Determinants of Diabetes in the Young (TEDDY) Study, an international, long-term cohort study that investigates how environmental exposures interact with genetic risk to influence the development of T1D in at-risk children.<sup>10</sup> Together, these efforts have expanded knowledge of disease pathways and created the infrastructure needed to support prevention-focused research.

### **SDP funding history and recent developments**

Since its inception, the Special Diabetes Program has received approximately \$3.55 billion in federal funding.<sup>11</sup> Initial Congressional appropriations totaled \$30 million annually from fiscal years (FYs) 1998 to 2000, followed by an increase to \$100 million per year between 2001 and 2003. Beginning in 2004, annual funding rose to \$150 million, a level that has largely remained stable, although occasional reductions occurred due to automatic spending cuts. Despite strong bipartisan support for the program, SDP funding has at times lapsed, requiring short-term extensions to maintain continuity. Most recently, the American Relief Act provided \$39.2 million in funding to support the program from January 1 to March 31, 2025.<sup>12</sup> This was followed by a six-month, \$80 million extension included in the latest continuing resolution passed by Congress.<sup>13</sup>

Over the years, SDP-supported research has contributed to significant therapeutic advancements, including the development and refinement of CGMs, AID systems, anti-VEGFs, and emerging treatments such as beta-cell therapies. In this analysis, we assess the economic benefits of these innovations to illustrate the program's contribution to diabetes treatments and inform future funding decisions.

## **3 Methodology and model output by technology**

Avalere Health modeled the direct medical cost savings generated at the federal level from innovations made possible by the SDP. To model the contribution to diabetes research and treatment advancements, Avalere Health conducted a literature review of peer reviewed research that quantifies the disease burden of diabetes, and the costs and cost savings associated with the innovations SDP has supported.

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<sup>9</sup> TrialNet. "[Type 1 Diabetes TrialNet](#)."

<sup>10</sup> TEDDY. "[The Environmental Determinants of Diabetes in the Young](#)."

<sup>11</sup> NIDDK. "[About the Special Diabetes Program](#)."

<sup>12</sup> Congress 2024. "[H.R.10545 - American Relief Act, 2025](#)."

<sup>13</sup> Congress 2025. "[H.R.1968 - Full-Year Continuing Appropriations and Extensions Act, 2025](#)."

## Modeling methodology

Avalere Health leveraged prior economic analyses to calculate the federal cost savings associated with SDP as well as to provide context to future cost savings based on current clinical trials. To account for inflation in medical costs each year of the time period analyzed (1998–2024), Avalere Health estimated expenditures based on historical Consumer Price Index for Medical Care (CPI-M) factors from US Bureau of Labor Statistics data.<sup>14</sup>

The literature review found that investment and support from SDP contributed to the development of CGMs and AIDs, which are widely used by individuals with diabetes today, as well as anti-VEGFs and beta cell therapies. For CGMs and AIDs, we describe the technology and its role in diabetes management or treatment, the extent of use in T1D and T2D populations, economic benefit, and our modeled findings on the federal return on investment as a result. For anti-VEGFs and beta cell therapies, as newer technologies with smaller populations, we describe the therapies and include directional estimates of cost savings.

## Limitations

The economic model focuses on federal savings from direct medical costs but does not incorporate indirect costs or savings from increased productivity or other intangible benefits (e.g., prevention of blindness or cardiovascular disease). As a result, our findings may understate the true savings resulting from SDP-supported technology. Additionally, the modeling is limited to publicly available data for products and therapies that are widely used. The estimated benefits from newer therapies and those still under development are based on small sample sizes and expected outcomes.

## Continuous Glucose Monitors

CGM systems use a small sensor inserted under the skin to measure glucose levels in real time, providing continuous data and alerts to help individuals proactively manage their blood sugar. SDP-supported studies helped demonstrate that CGM improves glycemic outcomes and is effective across various treatment regimens. For example, CGM use has been associated with a 0.6% to 1.0% reduction in glycated hemoglobin (HbA1c) among individuals using multiple daily insulin injections or insulin pumps, without an increase in hypoglycemia.<sup>15</sup> In addition to clinical improvements, CGM use has been linked to better psychosocial outcomes. CGM users reported increased confidence in managing their diabetes, reduced distress, and improved diabetes-specific quality of life.<sup>16</sup>

Utilization of CGMs among patients with Type 1 and Type 2 diabetes has grown. The improvement in health outcomes due to CGMs has significantly lowered healthcare costs for those living with diabetes resulting from reduced utilization of the emergency room, inpatient hospital, and other healthcare

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<sup>14</sup> US Bureau of Labor Statistics. “Consumer Price Index.”

<sup>15</sup> Beck, Roy W., Riddlesworth, Tonya, Ruedy, Katrina, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA. 2017;317(4):371–378. doi:10.1001/jama.2016.19975

<sup>16</sup> Polonsky, William H., Hessler, Danielle, Ruedy, Katrina J., Beck, Roy W.; for the DIAMOND Study Group, The Impact of Continuous Glucose Monitoring on Markers of Quality of Life in Adults With Type 1 Diabetes: Further Findings From the DIAMOND Randomized Clinical Trial. Diabetes Care 1 June 2017; 40 (6): 736–741. <https://doi.org/10.2337/dc17-0133>

services. Studies have shown CGMs to be cost-effective based on these outcomes.<sup>17,18</sup> One study found a reduction of \$424 (\$458 in 2024 dollars) per-patient-per-month (PPPM) in diabetes-related medical care among a population who utilized CGMs due to reduced HbA1c and hypoglycemia events.<sup>19</sup>

Avalere Health referenced several studies to estimate CGM utilization over the last two decades among people diagnosed with Type 1 and Type 2 diabetes, which showed that 90% of T1D patients utilize CGMs, while around 13% of T2D patients utilize the technology.<sup>20,21</sup> These utilization rates were respectively applied to the entire patient population during the time period to estimate total utilization of CGMs. In 2024, this amounts to 1.53 million T1D users and 3.64 million T2D users. The study of T1D patients found that 51% of CGM users also used an AID. Avalere Health assumed the same percentage of T2D CGM users also use AID. To isolate those that use CGMs without AIDs, Avalere Health removed the populations assumed to be also using AIDs since those products first came to market, resulting in about 750,000 CGM-only T1D users and 1.8 million CGM-only T2D users.<sup>22</sup> Once those using AIDs were removed from the CGM population, Avalere Health applied the \$424 PPPM savings to both the Type 1 and Type 2 populations utilizing CGMs alone to estimate total savings from CGM utilization. Avalere Health assumed similar clinical outcomes for T1D and T2D populations from utilizing CGMs. Historical CPI-M was employed to appropriately calculate savings for each year.

To derive the federal share of the savings, Avalere Health stratified the diabetic population by insurance enrollment and estimated the number enrolled in the Medicare, Medicaid, or VA programs, applying 80%, 57%, and 100% respectively as the federal liability for each.<sup>23</sup> Avalere Health estimates that the federal savings generated from CGM technology reached over \$32 billion by 2024.

### ***Automated insulin delivery system***

Another significant innovation that SDP research efforts have supported is the AID system, also referred to as a closed-loop insulin delivery system or “artificial pancreas” due to its ability to mimic the natural function of a healthy pancreas by regulating insulin levels.<sup>24</sup> These systems integrate a CGM with an insulin pump and computer algorithm that automatically adjusts insulin delivery in real time based on

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<sup>17</sup> Wen Wan, M. Reza Skandari, Alexa Minc, Aviva G. Nathan, Aaron Winn, Parmida Zarei, Michael O’Grady, Elbert S. Huang; Cost-effectiveness of Continuous Glucose Monitoring for Adults With Type 1 Diabetes Compared With Self-Monitoring of Blood Glucose: The DIAMOND Randomized Trial. *Diabetes Care* 1 June 2018; 41 (6): 1227–1234. <https://doi.org/10.2337/dc17-1821>

<sup>18</sup> Hamza Alshannaq, Gregory J. Norman, Peter M. Lynch; 1035-P: Cost-Effectiveness of Real-Time CGM vs. Self-Monitoring of Blood Glucose in People with Insulin-Treated Type 2 Diabetes from a U.S. Payor Perspective. *Diabetes* 14 June 2024; 73 (Supplement\_1): 1035–P. <https://doi.org/10.2337/db24-1035-P>

<sup>19</sup> Norman, Gregory J., Misti L. Paudel, Christopher G. Parkin, Tim Bancroft, and Peter M. Lynch. 2022. “Association between Real-Time Continuous Glucose Monitor Use and Diabetes-Related Medical Costs for Patients with Type 2 Diabetes.” *Diabetes Technology & Therapeutics* 24 (7): 520–24. <https://doi.org/10.1089/dia.2021.0525>.

<sup>20</sup> Lacy ME, Lee KE, Atac O, et al. Patterns and Trends in Continuous Glucose Monitoring Utilization Among Commercially Insured Individuals With Type 1 Diabetes: 2010–2013 to 2016–2019. *Clin Diabetes*. 2024;42(3):388–397. doi:10.2337/cd23-0051

<sup>21</sup> Mayberry LS, Guy C, Hendrickson CD, McCoy AB, Elasy T. Rates and Correlates of Uptake of Continuous Glucose Monitors Among Adults with Type 2 Diabetes in Primary Care and Endocrinology Settings. *J Gen Intern Med*. 2023;38(11):2546–2552. doi:10.1007/s11606-023-08222-3

<sup>22</sup> Jennifer L. Sherr, Lori M. Laffel, Jingwen Liu, Wendy Wolf, Jeoffrey Bispham, Katherine S. Chapman, Daniel Finan, Lina Titievsky, Tina Liu, Kaitlin Hagan, Jason Gaglia, Keval Chandarana, Richard Bergenstal, Jeremy Pettus; Severe Hypoglycemia and Impaired Awareness of Hypoglycemia Persist in People With Type 1 Diabetes Despite Use of Diabetes Technology: Results From a Cross-sectional Survey. *Diabetes Care* 20 May 2024; 47 (6): 941–947. <https://doi.org/10.2337/dc23-1765>

<sup>23</sup> Smith R, Eisenberg S, Turner-Phifer A, et al. We Are on the Verge of Breakthrough Cures for Type 1 Diabetes, but Who Are the 2 Million Americans Who Have It? *JHEOR*. 2024;11(2):145–153. doi:10.36469/001c.124604.

<sup>24</sup> Breakthrough Type 1D: “Automated insulin delivery systems and insulin pumps.”

glucose readings. By continuously responding to changes in glucose levels, AID systems help maintain blood sugar within a target range with minimal manual intervention, reducing the need for frequent fingerstick tests or insulin dose calculations. Research supported by the SDP demonstrated that these systems significantly improve time-in-range (glucose levels between 70–180 mg/dL), a key marker of effective diabetes management. One clinical trial found that AID users spent 11% more time in range per day (equivalent to an average of 2.6 additional hours) compared to those using a standard sensor-augmented insulin pump.<sup>25</sup> These systems also reduced hypoglycemia and nighttime glucose variability—factors critical for long-term health and daily functioning.<sup>26</sup>

With the development of AID technology to ensure longer periods of glycemic control, more patients diagnosed with both T1D and T2D have switched to this newer technology. Literature points to 51% of T1D CGM users employing AID technology and 13% for T2D CGM users in 2024.<sup>27,28</sup> This amounts to over 780,000 T1D and nearly 1.9 million T2D users of AID technology. Avalere Health applied a ramp up to this level of utilization from when AID systems became available through 2024 and applied the utilization to the total number of CGM users by diabetic type to estimate the total population utilizing AID technology each year.

Studies show that with most AID technology, people with diabetes achieve at least 80% of the time within target glucose range. Prior economic analyses found that this time-in-range saves annual direct medical cost close to \$4,300 (\$5,306 in 2024 dollars) from a reduction in HbA1c that avoids complications from diabetes including diabetic ketoacidosis and severe hypoglycemia.<sup>29,30,31</sup> Applying the same approach as calculating economic impact of CGMs, Avalere Health estimates that the total medical cost savings from AID technology has reached nearly \$57 billion. The federal share of this savings is estimated to be over \$18 billion.

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<sup>25</sup> Brown, Sue A., Boris P. Kovatchev, Dan Raghinaru, John W. Lum, Bruce A. Buckingham, Yogish C. Kudva, Lori M. Laffel, et al. 2019. "Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes." *New England Journal of Medicine* 381 (18): 1707–17. <https://doi.org/10.1056/nejmoa1907863>.

<sup>26</sup> Bally L, Thabit H, Kojzar H, Mader JK, Qerimi-Hyseni J, Hartnell S, Tauschmann M, Allen JM, Wilinska ME, Pieber TR, Evans ML, Hovorka R. Day-and-night glycaemic control with closed-loop insulin delivery versus conventional insulin pump therapy in free-living adults with well controlled type 1 diabetes: an open-label, randomised, crossover study. *Lancet Diabetes Endocrinol.* 2017 Apr;5(4):261-270. doi: 10.1016/S2213-8587(17)30001-3.

<sup>27</sup> Lacy ME, Lee KE, Atac O, et al. Patterns and Trends in Continuous Glucose Monitoring Utilization Among Commercially Insured Individuals With Type 1 Diabetes: 2010-2013 to 2016-2019. *Clin Diabetes.* 2024;42(3):388-397. doi:10.2337/cd23-0051

<sup>28</sup> Mayberry LS, Guy C, Hendrickson CD, McCoy AB, Elasy T. Rates and Correlates of Uptake of Continuous Glucose Monitors Among Adults with Type 2 Diabetes in Primary Care and Endocrinology Settings. *J Gen Intern Med.* 2023;38(11):2546-2552. doi:10.1007/s11606-023-08222-3

<sup>29</sup> Grabner, M., S. Abbott, M. Nguyen, Y. Chen, and R. Quimbo. 2013. "Estimated Cost Savings Associated with A1c Reductions in a Large Us Commercial Health Plan." *Value in Health* 16 (3): A160. <https://doi.org/10.1016/j.jval.2013.03.801>.

<sup>30</sup> Wagner, Edward H. 2001. "Effect of Improved Glycemic Control on Health Care Costs and Utilization." *JAMA* 285 (2): 182. <https://doi.org/10.1001/jama.285.2.182>.

<sup>31</sup> Vigersky, Robert A., and Chantal McMahon. 2019. "The Relationship of Hemoglobin A1C to Time-In-Range in Patients with Diabetes." *Diabetes Technology & Therapeutics* 21 (2): 81–85. <https://doi.org/10.1089/dia.2018.0310>.



**Table 1. CGM and AID 2024 Utilization and Savings, Total Federal Savings from Start of SDP**

Technology	Population using technology (2024)	Annual savings per patient (2024)	Federal savings by diabetes type (1998-2024)	Total federal savings (1998-2024)
<b>Continuous Glucose Monitors (CGM without AID)</b>	T1D: 749,700 T2D: 1,783,600	\$5,502	T1D: \$10.9 billion T2D: \$21.2 billion	\$32.1 billion
<b>Automated Insulin Delivery System (AID)</b>	T1D: 780,300 T2D: 1,856,400	\$5,306	T1D: \$5.4 billion T2D: \$12.9 billion	\$18.3 billion

### ***Anti-vascular endothelial growth factors***

In the last two decades, the SDP has helped fund clinical trials of therapies that improve the treatment of diabetic retinopathy and diabetic macular edema, which can lead to vision loss.<sup>32</sup> The latest therapies that have been found to be more effective than laser treatment are known as anti-VEGFs, and include aliberccept (Eylea), brolucizumab (Beovu), faricimab (Vabysmo), and ranibizumab (Lucentis). As biosimilars come to market and additional research is underway, it is likely that anti-VEGFs will have greater uptake and the resulting health benefits will generate overall economic savings to patients and the federal government.<sup>33</sup>

### ***Beta-cell therapies***

Beta cells within the pancreas produce and distribute insulin.<sup>34</sup> Beta cell function is core to treating and preventing the onset and progression of diabetes. The SDP has funded research and clinical trials that delay beta cell destruction, preserve functioning beta cells, and replace non-functioning ones.

The SDP has supported advancements in immunotherapy aimed at preventing or delaying the onset of T1D. A notable example includes the use of anti-CD3 monoclonal antibody therapy to modulate the immune system in high-risk individuals. Clinical trial data show that a single 14-day course of teplizumab (Tzield) delayed progression to clinical T1D by a median of two years in participants with early-stage disease.<sup>35</sup> This product was approved by the FDA in 2022, making it the first disease-modifying therapy available for T1D. Analyses show that medications like teplizumab can achieve annual medical cost savings per patient between \$12,000 and \$23,000 if they reach a 70% response rate and are able to

<sup>32</sup> NIH: "Diabetic Retinopathy."

<sup>33</sup> Li, A., Ferkat, S. "The Current Landscape of Anti-VEGF Biosimilars." 2023. *Retinal Physician*. December 20, 2023.Vol. 20:37-40.

<sup>34</sup> Kulkarni, Rohit N. "The islet  $\beta$ -cell." *The international journal of biochemistry & cell biology* 36, no. 3 (2004): 365-371. <https://doi.org/10.1016/j.biocel.2003.08.010>

<sup>35</sup> Kevan C, Herold, Bundy BN, Long SA, Bluestone JA, DiMeglio LA, Dufort MJ, Gitelman SE, et al. 2020. "An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes." *Yearbook of Pediatric Endocrinology*, October. <https://doi.org/10.1530/ey.17.10.8>.

maintain delayed progression of the disease by at least two years.<sup>36</sup> Due to the cost of the drug and the limitations on those eligible to receive it, there has been little uptake of the drug.<sup>37</sup>

Another important use of immunomodulators is in islet transplantation procedures. Islets are small groups of cells in the pancreas that help control blood sugar by making insulin. In people with T1D, these cells are mistakenly destroyed by the immune system. Islet transplantation is a procedure in which healthy islet cells from a donor are transplanted into a person with diabetes to help them make insulin again.<sup>38</sup> SDP supports clinical trials and a clinical consortium of islet transplantation research in T1D.<sup>39</sup> Clinical trials on islet transplantation have shown promising results, such as improved glycemic control and T cell depletion during immunosuppressive regimen. The first allogenic islet-cell therapy for T1D treatment, donislecel (Lantidra), was approved by the FDA in June 2023.<sup>40</sup> This therapy involves the infusion of dispersed donor islet cells.<sup>41</sup> As the drug was only recently approved, there is little data on uptake, but only a small population is eligible for the medication and it requires the use of immunosuppressive therapies, making it unlikely for wider adoption. For drugs like Lantidra, however, where beta cells are replaced and insulin requirements are reduced by at least 50%, the annual medical cost savings of over \$5,500 per patient.<sup>42</sup> Additional islet transplantation cell therapies are currently in development and expected to come to market in the coming years. The Human Islet Research Network, supported by SDP, provides research into beta cells and is working to develop therapies that can replace non-functioning beta cells through islet transplantation.<sup>43</sup>

There are currently studies underway by Type 1 Diabetes TrialNet, in part funded by the SDP, focused on immunotherapies that preserve beta cell function.<sup>44</sup> Once fully developed and approved, these therapies are estimated to achieve approximately \$3,000 in annual medical cost savings per patient due to reduction in insulin utilization as well as for other medical needs.<sup>45</sup>

## 4 Key findings and SDP return on investment

Federal SDP funding since 1998 has reached \$3.55 billion. As a result of this investment, researchers, scientists, and others in the medical community have made significant advancements in identifying the origins of T1D and developing technology to help those who have the disease. Figure 1 illustrates the

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<sup>36</sup> JDRF. "Modeling the Total Economic Value of Novel Type 1 Diabetes (T1D) Therapeutic Concepts." January 2020.

<sup>37</sup> Fanaropoulou NM, Tsatsani GC, Koufakis T, Kotsa K. Teplizumab: promises and challenges of a recently approved monoclonal antibody for the prevention of type 1 diabetes or preservation of residual beta cell function. *Expert Rev Clin Immunol*. 2024;20(2):185-196. doi:10.1080/1744666X.2023.2281990

<sup>38</sup> NIH. "Islet Transplantation for Treating Difficult-to-Manage Type 1 Diabetes in Adult." 2024.

<sup>39</sup> NIDDK. "Special Diabetes Program: Clinical Trials Recruiting Patients & Families." 2024.

<sup>40</sup> FDA. "FDA Approves First Cellular Therapy to Treat Patients with Type 1 Diabetes" 2023.

<sup>41</sup> Ajmal, Nida, Bogart, Maislin C., Khan, Palwasha, Max-Harry, Ibiagbani M., Healy, Amber M., Nunemaker, Craig S., Identifying Promising Immunomodulators for Type 1 Diabetes (T1D) and Islet Transplantation, *Journal of Diabetes Research*, 2024, 5151171, 15 pages, 2024. <https://doi.org/10.1155/jdr/5151171>

<sup>42</sup> Sussman M, Benner J, Haller MJ, Rewers M, Griffiths R. Estimated Lifetime Economic Burden of Type 1 Diabetes. *Diabetes Technol Ther*. 2020;22(2):121-130. doi:10.1089/dia.2019.0398

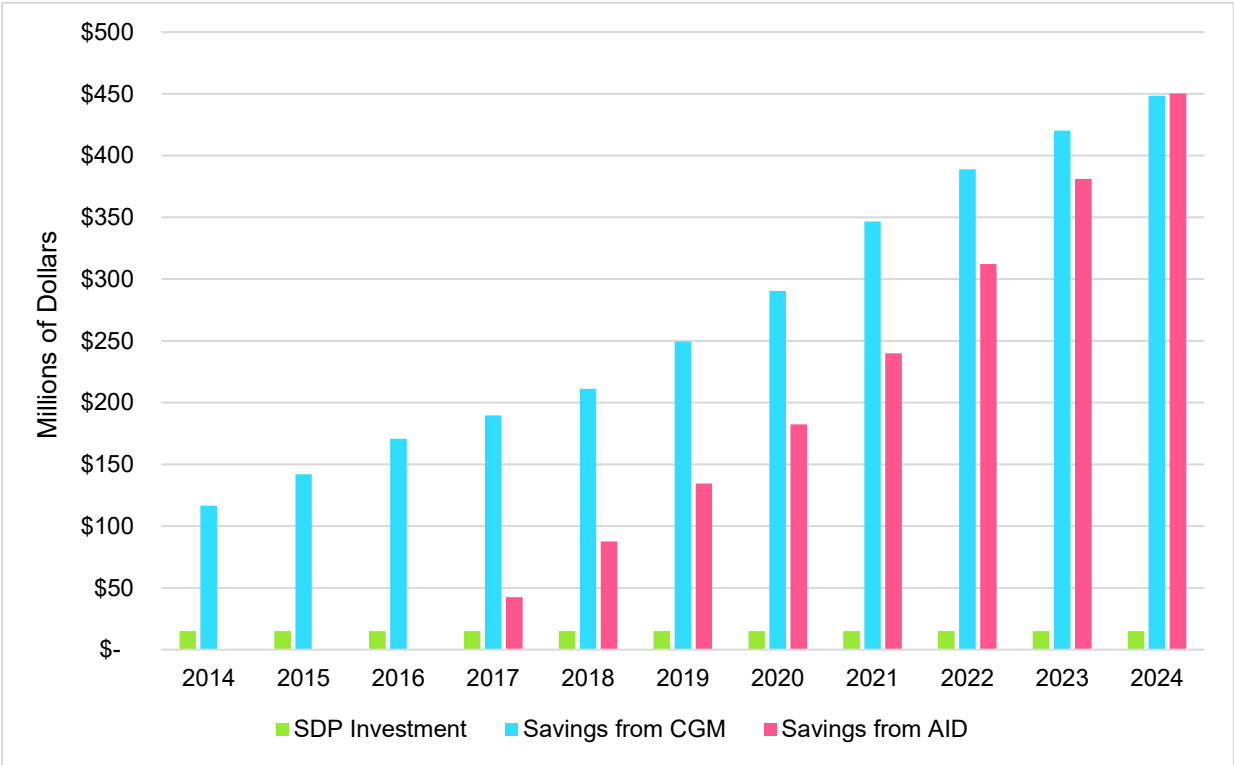
<sup>43</sup> Human Islet Research Network. "Reports."

<sup>44</sup> "Type 1 Diabetes TrialNet. "Our Research."

<sup>45</sup> JDRF. "Modeling the Total Economic Value of Novel Type 1 Diabetes (T1D) Therapeutic Concepts." January 2020.

federal investment in SDP compared to the total federal savings generated by CGM and AID treatments from 2014 through 2024.

Figure 1. Annual SDP investment and federal savings (2014-2024)



The benefits of the resulting research and technologies not only reach those with T1D, but also those with T2D. The development of CGM devices has helped over 1.5 million people with T1D and over 3.5 million with T2D. The resulting decrease in direct medical costs has reached nearly \$34 billion for those with T1D and \$66 billion for those with T2D. The federal portion of those savings amounts to \$32 billion. In addition, AID technology has reached over 780,000 people with T1D and over 1.8 million people with T2D. The direct medical cost savings from this device are estimated to be close to \$17 billion for patients with T1D and \$40 billion for patients with T2D. The federal portion of these savings is over \$18 million.

The cumulative investment from SDP has contributed to total federal government savings of nearly \$50.5 billion over the last 25 years as a result of decreased medical costs from CGM and AID therapies alone. This estimate does not include non-direct medical savings or additional economic output from increased productivity from patients, which could achieve even greater savings for the federal government. As innovation continues and new generations of therapies are developed that could prove more effective than current treatments on the market investments from SDP could generate greater cost savings.

## 5 Policy outlook

Evolving policy dynamics will influence the scope of future research and treatment advancements made possible through the Special Diabetes Program. The SDP is funded by Congress and requires continuous authorization to remain operational. The SDP is funded currently at \$160 million through September 30, 2025. In December 2024, there was a bipartisan agreement to fund the SDP at \$200 million per year for two years; however, like other health extenders, the program ultimately received a short-term extension as part of the year-end continuing resolution.<sup>46</sup> This pattern of short-term reauthorizations underscore a broader challenge: while the SDP has demonstrated long-term impact and value, the lack of multi-year funding commitments creates uncertainty for researchers and institutions planning future clinical trials and technology development.<sup>47</sup>

Over the years, the SDP has garnered bipartisan support in Congress, reflecting broad interest in continuing investment in T1D research. President Trump's FY 2026 Department of Health and Human Services (HHS) budget request includes a proposal to reauthorize the program at \$159 million for the fiscal year.<sup>48</sup> By supporting early-stage research, the program has historically generated foundational data and momentum that enable private sector investment in further development and commercialization of new therapies.

In addition to ongoing uncertainty surrounding continued funding of the SDP program, HHS recently announced its intent to implement large-scale reduction in the HHS workforce and the reorganization of several agencies, including the NIH, which oversees the SDP. Stakeholders have raised concerns about potential delays to funding distribution resulting from the reduced workforce and reorganizations, which may impact not only SDP grants and research but also patient access to new therapies and technologies supported by the program.

Patient access to emerging treatments under the SDP could be at risk as the program funding and reduction in workforce creates uncertainty for the future. AIDs, CGMs and anti-VEGFs have improved life expectancy and reduced the risk of complications related to T1D in recent decades. Still, despite significant progress in research and diabetes technology, T1D is linked to premature death, significant complications, and a substantial daily burden of glucose management for those affected, indicating the need for continued progress and SDP investments that enable such progress.<sup>49</sup>

Advancements in diabetes treatments (CGM and AIDs) have contributed to over \$50 billion in savings to the federal government from reduced healthcare expenditures thanks to these technologies. This estimate is likely conservative, as limitations in available data and modeling approaches may understate the full economic impact of these innovations. Ongoing research supported by the SDP is exploring disease-modifying therapies and beta cell replacement therapies that could prevent the onset of T1D, reduce the need for insulin therapy, or potentially lead to a cure, while supporting improved glycemic

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<sup>46</sup> Congress 2023. "S.1855 - Special Diabetes Program Reauthorization Act of 2023."

<sup>47</sup> Breakthrough T1D. "Special Diabetes Program."

<sup>48</sup> HHS. "Fiscal Year 2026 Budget in Brief." 2025.

<sup>49</sup> Starr, Lynn, Dutta, Sanjoy, Danne, Thomas et al. The Urgent Need for Breakthrough Therapies and a World Without Type 1 Diabetes. *Diabetes Ther* 16, 1063–1076 (2025). <https://doi.org/10.1007/s13300-025-01735-6>

outcomes. Promising therapies in the pipeline include stem cell-derived islet transplants, encapsulation technologies to protect transplanted cells, antigen-specific immunotherapies, and next-generation applications of teplizumab. Emerging therapies in various stages of development and clinical trial testing will require ongoing investment in research and clinical trial support for these therapies to come to market and reach T1D and T2D patients at scale.