

Statement for the Record
The Diabetes Technology Access Coalition

U.S. House of Representatives Committee on Ways and Means – Subcommittee on Health
Investing in a Healthier America: Chronic Disease Prevention and Treatment
Wednesday, September 18, 2024, 2:00PM

The Diabetes Technology Access Coalition (DTAC) appreciates the opportunity to provide a statement for the record in response to the U.S. House of Representatives Committee on Ways and Means – Subcommittee on Health hearing entitled *Investing in a Healthier America: Chronic Disease Prevention and Treatment*. DTAC is a cross-industry group of diabetes stakeholders. Collectively, the coalition members represent millions of Americans with diabetes, health care professionals who treat them, and major manufacturers that develop diabetes therapies, equipment, and supplies. Thus, our coalition represents those who manufacture and develop diabetes technology, the health care professionals who rely on this technology to best treat their patients, and the patients who benefit from the technologies.

We applaud the Subcommittee for holding this hearing and for recognizing the need for increased investment in chronic disease prevention and treatment. As the Subcommittee noted, diabetes is one of the most common chronic diseases in the United States and the prevalence of both type 1 and type 2 diabetes has been rising over the last 20 years, largely driven by new cases of type 2 diabetes.¹ The prevalence of type 2 diabetes is only expected to grow in the coming years, as an estimated 54.9 million Americans will have diabetes in 2030,² compared to the estimated 38.4 million individuals who currently have diabetes.³ Likewise, the prevalence of type 1 diabetes has increased in the last two decades, which was mostly driven by new cases among our nation's youth.⁴ Both type 1 and type 2 diabetes can have devastating effects on long term health, as they are associated with an increased risk of cancer, hospitalization, heart disease, chronic kidney disease, amputations, blindness, and other severe health consequences.

As Congress examines the impact and burdens of diabetes, it is important to consider access barriers to interventions that have become the standard of care for individuals with diabetes. Of particular importance for people with diabetes are continuous glucose monitors (CGMs), insulin pumps, and other administration devices. CGMs, which are frequently paired with insulin pumps have been proven to achieve optimal glycemic control. Insulin pumps, used with or without a CGM, have been shown to

¹ *National Diabetes Statistics Report*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/diabetes/php/data-research/index.html>. According to the Centers for Disease Control and Prevention (CDC), their reports and estimates of diabetes typically do not differentiate between type 1 and type 2 diabetes, but that type 2 diabetes accounts for 90 to 95 percent of all diabetes cases, see *Methods: National Diabetes Statistics Report*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/diabetes/data/statistics-report/methods.html>.

² William Rowley, et. al., *Diabetes 2030: Insights from Yesterday, Today, and Future Trends*, 20 Population Health Mgmt. 6 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278808/>.

³ *National Diabetes Statistics Report*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/diabetes/php/data-research/index.html>.

⁴ Jasmine Divers, et. al., *Trends in Incidence of Type 1 and Type 2 Diabetes Among Youths — Selected Counties and Indian Reservations, United States, 2002–2015*, 69 Morbidity and Mortality Weekly Report 161 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6906a3.htm?s_cid=mm6906a3_w.

effectively manage an individual's type 1 or type 2 diabetes.⁵ All insulin pumps currently available in the United States pair with a CGM, and through the use of an algorithm can control the flow of insulin provided. This combination of technologies, often called automated insulin delivery (AID) systems, can both improve overall glycemic control and reduce hypoglycemia, which numerous studies have shown to be common occurrences and a significant risk factor for hospitalizations and mortality among individuals with diabetes.⁶ Given this evidence base, both the American Diabetes Association and the American Association of Clinical Endocrinology incorporate CGMs, insulin pumps, and AID systems into their standards of care for individuals with diabetes. Unfortunately, various segments of the population experience disproportionately poor access to diabetes technologies, including those who live in rural areas,⁷ and Medicare beneficiaries. For instance, Medicare beneficiaries experience limited access to CGMs, as a 2022 study using 2018 Medicare data showed that among the more than 1.3 million Medicare beneficiaries using rapid-acting insulin, 38 percent have no record of glucose monitoring – meaning they are administering insulin without glucose measurements – and only three percent obtained a CGM.⁸

DTAC supports efforts to remove unnecessary coverage and access barriers for all individuals with diabetes. To that end, we encourage Congress to consider the following recommendations to ensure that individuals with diabetes can appropriately monitor and manage their chronic condition.

Reforming Medicare Payment Policies

As Representative Adrian Smith recognized during the hearing, the Medicare program can lack treatment flexibility and has outdated payment policies, which lead to increased spending while also making it more difficult for Medicare beneficiaries to access necessary care. DTAC agrees with Representative Smith, especially as it relates to (1) the access barriers newly enrolled Medicare beneficiaries have in accessing their preferred diabetes technology, (2) the outdated and dangerous Medicare coverage policies for Part B insulin pumps, (3) current Medicare payment policies that hinder innovation and patient access to new and groundbreaking diabetes technologies, and (4) inflexible and limited diabetes education interventions that have been proven to improve diabetes management.

Diabetes technologies have been available for decades and manufacturers are continuing to innovate to improve quality of life and overall glucose management. Despite these improvements, Medicare

⁵ See, e.g., Alanna Weisman, et. al., *Effect of artificial pancreas systems on glycaemic control in patients with type 1 diabetes: a systematic review and meta-analysis of outpatient randomised controlled trials*, 5 *The Lancet Diabetes & Endocrinology* P501 (2017), [https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(17\)30167-5/fulltext](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(17)30167-5/fulltext).

⁶ See, e.g., Richard Silbert, et. al., *Hypoglycemia among Patients with Type 2 Diabetes: Epidemiology, Risk Factors, and Prevention Strategies*, 18 *Current Diabetes Reps.* (2018), <https://link.springer.com/article/10.1007/s11892-018-1018-0>; Rozalina McCoy, et. al., *Increased Mortality of Patients With Diabetes Reporting Severe Hypoglycemia*, 35 *Diabetes Care* 1897 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3425008/>;

⁷ See, e.g., Lauren Mitchell and Elbert Huang, *Diffusion and Disparities: Rural Uptake of Continuous Glucose Monitors*, 47 *Diabetes Care* 344 (2024), <https://diabetesjournals.org/care/article/47/3/344/154266/Diffusion-and-Disparities-Rural-Uptake-of>; Arashpreet Gill, et.al., *Glycemic outcomes among rural patients in the type 1 diabetes T1D Exchange registry, January 2016–March 2018: a cross-sectional cohort study*, 10 *BMJ Open Diabetes Research and Care* 1 (2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8768930/>.

⁸ Gary Puckerin, et. al., *Assessment of Glucose Monitoring Adherence in Medicare Beneficiaries with Insulin-Treated Diabetes*, 25 *Diabetes Tech. & Therapeutics* 1 (2022), <https://www.liebertpub.com/doi/abs/10.1089/dia.2022.0377?j> (Of the beneficiaries who did gain access to CGMs, 90 percent were White, less than 8 percent were Black, and less than 2 percent were Hispanic.).

beneficiaries face significant challenges in accessing diabetes technologies, especially for those who newly enroll into Medicare fee-for-service (FFS), who must “re-prove” that they have diabetes to continue using their current diabetes technology when they enter Medicare. This creates an unnecessary, burdensome, and dangerous situation where individuals might face a disruption in care in using diabetes technologies they could have been using for decades, and we urge Congress to remedy this important gap in care.

We recognize recent and important changes to modernize the coverage criteria for CGMs to bring those requirements into alignment with the latest clinical evidence and standard of care. We note that the clinical evidence demonstrating the value of CGM to anyone with diabetes, regardless of whether they use insulin, is continuing to build, and CMS will need to revisit the CGM coverage criteria in the near future to ensure the policy is kept current. DTAC is working with CMS on parallel updates to the National Coverage Determination (NCD) for Part B insulin pumps, which was first released in 2004 and has not been updated since. DTAC submitted a reconsideration request in February 2022, and despite being accepted as a valid request, CMS has taken no action to date. The current NCD relies on outdated evidence and dangerous processes, such as requiring beneficiaries to “fail first” (i.e., experience an adverse diabetes-related health event) before obtaining an insulin pump. As Medicare coverage for CGMs continues to be updated with the latest clinical guidelines, the outdated nature of the Part B insulin pump NCD creates a growing divergence between coverage criteria for CGMs and insulin pumps. This growing disparity creates an unnecessary burden for the beneficiaries who use both technologies, including as an AID system in conjunction with an algorithm. Additionally, CMS must reform its NCD process to ensure that it quickly and efficiently assesses new clinical evidence and incorporate it into new coverage criteria so Medicare beneficiaries can receive access to interventions that reflect the current standards of care.

Relatedly, developers and innovators continue to create new software and algorithms that enable CGMs and insulin pumps to administer an appropriate insulin dosage automatically and to learn from the individual’s behavior and physiological responses to meals, exercise, and insulin. However, Medicare does not separately pay for the software or algorithm that is the “brain” of the AID system despite the fact that the other two parts of an AID system, the insulin pump and CGM, are already covered and paid by Medicare. AID systems are part of the standards of care established by both the American Diabetes Association and the American Association of Clinical Endocrinology. The Food and Drug Administration (FDA) has also established a unique device category for algorithms used in AID systems and recognizes them as a “device.” We believe CMS has an existing pathway to ensure payment of the AID system-enabling algorithm, but this has neither been communicated nor stated clearly by CMS. We share Representative Adrian Smith’s concern that the lack of a clear and long-term reimbursement strategy will limit beneficiary access to innovative technologies that become the standard of care.

As many members of the Subcommittee noted, education is essential to improved health and management of chronic diseases. We agree and believe that holistic and comprehensive care, which includes diabetes technologies, pharmacological interventions, and education programs, such as diabetes self-management training (DSMT), must be available for all individuals with diabetes. DSMT educates individuals on how to use diabetes technologies, administer medications, and incorporate healthy lifestyle changes, ultimately leading to improved diabetes management and overall health. However, Medicare beneficiaries face numerous challenges in accessing this proven intervention including: (1) the benefit is capped at two hours per year after the first year; (2) there is a shortage of qualified DSMT providers; (3) the DSMT referral criteria is overly complicated and restricted to a narrow subset of providers; and (4) beneficiary cost-sharing. We recommend Congress make necessary changes to the DSMT benefit to address these concerns.

We also note that Medicare does not acknowledge or provide separate payment to practitioners who provide insulin pump set-up or training, despite having a payment mechanism for CGM set-up and training. Thus, Medicare beneficiaries must use their limited Medicare DSMT benefit to obtain necessary insulin pump training instead of receiving other necessary education and training. DTAC urges Congress to reform the Medicare DSMT benefit as to make it more accessible to all individuals with diabetes as well as to reform payment policies for insulin pump set-up and training. Separate payment for set-up and training is essential for all diabetes technologies and will be needed for the algorithm component of AID systems.

Removing Barriers Under Managed Care Plans

As the Subcommittee noted, reforms to health care plans like Medicare Advantage (MA) and Medicaid managed care can meaningfully improve access to care. Similarly, DTAC supports equitable access to all forms of diabetes care, including for people with diabetes enrolled in such plans. However, we have learned that some enrollees face onerous barriers in accessing diabetes care, such as through the use of utilization management techniques and participating healthcare providers inappropriately telling enrollees that they are not eligible for certain diabetes technologies. We urge Congress to take steps to ensure that all beneficiaries of MA and Medicaid managed care plans have ready access to the appropriate and medically necessary diabetes care.

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We look forward to working with the Subcommittee to advance our common goal of improving care for individuals with diabetes. Please do not hesitate to reach out to Brian Lee at brian.lee@alston.com with any questions or concerns.