

Diabetes Management is Not "One-Size-Fits-All":

Importance of Patient Choice in Use of Diabetes Technologies



EXECUTIVE SUMMARY

On April 29, 2025, the Diabetes Leadership Council convened a panel of experienced clinicians and representatives from diabetes patient advocacy organizations to discuss the importance of patient choice and access to diabetes technologies, with a focus on continuous glucose monitoring (CGM) and automated insulin delivery (AID) technologies. Panelists discussed the transformative impact of these technologies on patient outcomes and identified the significant barriers patients and clinicians face in obtaining and utilizing them. This report summarizes the key obstacles to ensuring patient choice in obtaining their devices and presents recommendations for overcoming these obstacles.

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BACKGROUND

Landmark studies have shown that persistent hyperglycemia leads to a constellation of microvascular and macrovascular complications. However, less than half of Americans with diabetes are achieving the established glycosylated hemoglobin (HbAIc) goal of <7%. Innovations in glucose monitoring and insulin delivery technologies have led to the development of new tools, specifically, continuous glucose monitoring (CGM) and automated insulin delivery (AID) systems.

Unlike traditional fingerstick blood glucose monitoring (BGM) systems, which provide only a point-in-time "snapshot" of a person's glucose level, CGM sensors transmit a continuous stream of real-time glucose data to a person's smartphone or handheld reader every five minutes. The data from CGM sensors are displayed in numerical and graphical formats, indicating the current glucose level and historical readings. Trend arrows show the direction and velocity of changing glucose levels. Importantly, current CGM devices feature programmable alerts that warn peoplewith diabetes (PwD) of immediate and impending hypoglycemia and hyperglycemia. Additionally, current devices are sufficiently accurate for the Center for Devices and Radiological Health to have approved them for insulin dosing.

AID systems utilize sophisticated controller algorithms that continuously adjust insulin infusion in response to CGM sensor levels, allowing the pump to respond to other factors such as carbohydrate intake and physical activity.⁴ The more advanced AID systems have the added capability to deliver automated correction boluses.⁴

Numerous randomized trials and observational studies have shown that both technologies are efficacious in lowering HbAIc, increasing time in the target glucose range, reducing the frequency and severity of hypoglycemia events, improving quality of life, and reducing all-cause and diabetes-related hospitalizations.^{5,6} However, despite their demonstrated benefits, these technologies are underutilized within the vast majority of the diabetes population due to several barriers that impede patient choice.

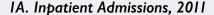
On April 29, 2025, the Diabetes Leadership Council convened a panel of clinicians experienced in diabetes management and representatives from diabetes patient advocacy organizations to discuss the importance of patient choice in all tools people with diabetes (PwD) use to manage their condition, with a focus on continuous glucose monitoring (CGM) and automated insulin delivery (AID) technologies. This article summarizes the key points raised by the panel and presents recommendations for addressing this issue.

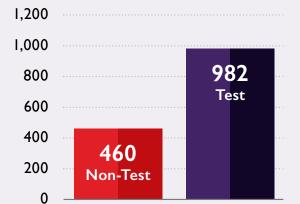
LESSONS NOT LEARNED

In January 2011, the Centers for Medicare & Medicaid Services (CMS) initiated its Competitive Bidding Program (CBP) in nine test markets. The goal of the program was to reduce beneficiary out-of-pocket expenses and Medicare costs while ensuring beneficiary access to quality items and services. As a result, the single payment rate for BGM test strips was reduced from \$34 to \$14 per

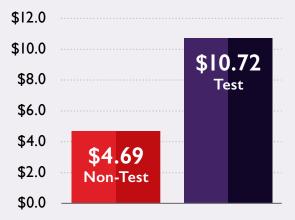
vial. However, only BGM supplies obtained through mail-order channels were initially impacted. CMS subsequently reported that no disruption of access to diabetes testing supplies occurred and that no adverse healthcare consequences resulted in beneficiaries from the program.⁷ However, in March 2016, Puckrein et al. published findings from a retrospective, longitudinal study assessing the impact of the 2011 CBP rollout on insulin-treated beneficiaries. The study compared beneficiary outcomes in the nine test markets with those in the remaining Medicare markets.⁸ Contrary to the agency's report of no disruption and no adverse health outcomes, the investigators reported that, among beneficiaries with full acquisition of prescribed insulin, migration from full acquisition of BGM supplies to partial or no acquisition was associated with increased mortality, along with higher inpatient admissions (*Figure IA*), and higher healthcare costs (*Figure IB*). A notable disruption in beneficiaries' acquisition of BGM supplies from the mail-order to retail pharmacy channels was also observed in test market beneficiaries, but not in the non-test market beneficiaries.

Figure 1. Impact of Migration from Full BGM Acquisition to Partial/ No BGM Acquisition in 2011 on Hospital Admissions and Inpatient Costs





IB. Inpatient Costs, 2011 (in millions)



The increased migration to Partial/No BGM in the TEST markets was associated with more than twice as many inpatient admissions (A) and a >2-fold increase in inpatient costs (B) compared with NON-TEST beneficiaries who migrated from Full to Partial/No SMBG acquisition.

These outcomes resulted from both the disruption of access to supplies and restrictions on the specific BGM systems that mail-order companies provided. A survey conducted by the Association of Diabetes Care & Education Specialists (ADCES) reported that beneficiaries who chose to obtain their diabetes testing supplies through mail-order suppliers were "effectively being made to either switch to different testing systems or purchase supplies through non-mail-order settings."

The lesson was clear: disruption of access to each person's chosen diabetes technology leads to suboptimal diabetes management and adverse clinical outcomes. However, the lesson was not learned. Despite the findings reported by Puckrein et al., CMS launched the CBP nationally with similar results. Although CMS continued to defend the program, pressure from Congress, which was influenced by Puckrein et al., caused the agency to pause the program. The overarching lesson: Access is essential; Choice matters.

WHY CHOICE MATTERS

Giving patients a choice in selecting the diabetes technologies that meet their specific clinical needs is an essential component of providing person-centered care to PwD. Person-centered care is an approach to diabetes management that enables patients to achieve optimal health and live meaningful lives. 10 For healthcare providers (HCPs), ensuring patient choice requires shared decision-making, treating patients as equal partners in developing their diabetes management plans, and recognizing and respecting each patient's unique clinical needs, perspectives, preferences, and life situations. Shared decision-making supports a sense of autonomy for PwD, which in turn enhances their participation and perceived competence in selfmanagement, leading to greater engagement and improved diabetes outcomes. 11, 12 Fostering autonomy requires HCPs to provide their patients with sufficient



information about the various treatment options. This is particularly important when discussing the features, advantages, and disadvantages of current diabetes technologies. Armed with this information, patients and their HCPs will be able to make informed, shared decisions in selecting the device or technology that meets each person's unique needs. *Table 1* presents a listing of the major benefits of allowing patients to choose the specific technology that works best for them.

Table I. Benefits of Patient Choice

Greater Empowerment, Engagement, Autonomy and Adherence

- Allowing PwD to choose their diabetes technologies fosters empowerment and engagement with their self-management.
- Patient choice engenders a sense of autonomy and confidence, enabling PwD to take control of their diabetes management.
- PwD are more likely to follow their treatment plans and actively manage their diabetes when using devices that work best for them.
- Allowing choice ensures tools align with each individual's lifestyle, job, physical activity, and health conditions, which supports continued adherence.

Improved Clinical Outcomes

- Limited access to a patient's chosen devices leads to poor glycemic control, increasing the risk of acute and chronic complications.
- PwD who have a choice in their diabetes devices achieve better glycemic control, fewer hypoglycemic events, and reduced risk of complications.

Higher Quality of Life

- The ability to use their chosen technology enhances patients' daily lives, eases the psychological burden of diabetes, and helps patients thrive rather than merely survive.
- Access to their chosen technologies reduces stress and burnout, alleviating the psychological burden of diabetes.
- The use of chosen devices helps minimize the stigma associated with visible diabetes management tools.

Flexibility Across Life Stages

Patient choice allows flexibility as their needs evolve during life stages, such as pregnancy, aging, or burnout.

True Individualized Care

Patient choice ensures that tools align with individual lifestyles, jobs, physical activity levels, and other health conditions.

Current clinical guidelines from the American Diabetes Association clearly state that the choice of a diabetes technology, including CGM and AID devices, should be made based on each person's circumstances, preferences, and needs.¹³ Sadly, many PwD who would benefit from these technologies are denied access. In contrast, those who are fortunate enough to obtain these technologies often are not afforded a choice in the specific device they can use due to a number of barriers.

BARRIERS TO CHOICE

Restrictive Insurance Coverage Policies

In response to growing public pressure, CMS changed its eligibility criteria in 2023 by expanding access to CGM technology for all Medicare beneficiaries with diabetes who are treated with insulin (intensive and nonintensive) or have experienced problematic hypoglycemia, regardless of their therapy. If Importantly, CMS has also dropped the requirement for documentation of ≥4 blood glucose tests per day. However, there is growing concern that CMS will reimplement the disastrous CBP, which as discussed earlier, not only interrupted access to diabetes testing supplies but increased hospitalizations, mortality, and costs. Applying competitive bidding to diabetes technologies would not only disrupt acquisition of these devices, but would likely interfere with the interoperability of the devices, which would limit patient choice. While not specifically identifying diabetes technologies as a target, the Department of Health and Human Services devotes an extensive section of its latest report, "Justification of Estimates for Appropriations Committees," for fiscal year 2026 (page 21). IS

Despite changes in Medicare and the ADA's Standards of Care recommendations for CGM usage, many state Medicaid programs have not expanded access, only cover specific types of diabetes, or do not publish their coverage criteria for CGM.¹⁶ Among the Medicaid programs that provide coverage, eligibility criteria vary greatly from state to state.¹⁷ Additionally, PwD will be locked into using their insulin pump for several years due to insurance policies or agreements with medical device companies. For Medicare, beneficiaries must wait five years, which extends well beyond the typical warranty period of most manufacturers. For example, the warranty for the Dexcom G7 is one year.¹⁸ Moreover, these requirements limit the person's ability to switch to a different brand or technology that may better meet their needs. This lack of flexibility will be problematic if the person's needs change.

In a review of CGM eligibility criteria from eight major commercial health insurance providers, Aleppo et al. identified notable disparities in who is covered. For example, one commercial plan still requires ≥3 blood glucose tests per day, and four commercial plans require people with type I diabetes (TID), type 2 diabetes (T2D), or gestational diabetes (GDM) to provide documented frequency of multiple (≥3) daily insulin doses. ¹⁹⁻²² These requirements are impugned by the growing number of studies demonstrating the clinical benefits of CGM use in patients treated with nonintensive insulin and non-insulin therapies. ⁵ It is also concerning that coverage is denied to PwD who are not treated with insulin and/or have no problematic hypoglycemia. ^{20, 22-24} In essence, PwD are forced to forego CGM use until they initiate insulin therapy, develop problematic hypoglycemia, or struggle to maintain their glycemic goals. ^{20, 22-24} Although many plans are modifying their eligibility criteria, differences in plans will potentially lead to discontinuation of device use if a patient changes plans.

Unlike Medicare's criteria for CGM eligibility, the agency's criteria for insulin pump and AID coverage are much more restrictive in that they essentially exclude PwD with T2D due to their C-peptide testing requirement.²⁵ (See Appendix A) The pancreas releases C-peptide when it makes insulin. A C-peptide test measures the amount of C-peptide in the blood or urine and was previously used to determine if the pancreas was making insulin, meaning if there was C-peptide in a person's urine their pancreas was making insulin. This requirement was drafted almost two decades ago, and scientific understanding of the relevance of C-peptide assessment has evolved to the point where this requirement is no longer evidence-based. These tests are costly, add no value to clinical decision-making, and impose additional burdens on patients and their healthcare providers. Moreover, the accuracy of this measurement is influenced by several factors.²⁶ Alarmingly, even in PwD with TID, studies published after the implementation of the Medicare requirement have shown the persistence of C-peptide levels in patients with TID.²⁷⁻³⁰ However, the limitations of C-peptide testing in T2D diabetes are even more profound. A recent study reported that a higher C-peptide level is a strong marker for insulin resistance³¹ and is consistently associated with cardiovascular and all-cause mortality in people without diabetes. 32-34 Therefore, one would expect to see higher C-peptide levels in patients with T2D, given the high prevalence of insulin resistance and obesity in these PwD.³⁵ While most commercial plans do not require C-peptide testing, other coverage eligibility policies are equally restrictive, limiting coverage for AID systems to patients with TID.^{36, 37} Medicaid coverage for insulin pumps is often limited and varies from state to state.

Even when coverage is provided, some insurance plans exclude coverage for certain CGM devices, AID systems, or specific meters—or they may limit the number of supplies covered. With other insurance plans, excessive co-pays and out-of-pockets can make use of diabetes technologies cost prohibitive. Here, again, personalized care—along with patient choice—is challenged.

Onerous Prior Authorization Requirements

Due to complex pre-approval processes, patients with diabetes and their providers face delays and administrative burdens. In a survey of 1,000 clinicians, 54% of respondents reported that the required preauthorization documentation for medications and medical devices always or often resulted in care delays, and 92% reported that these delays had a significant or somewhat negative impact on clinical outcomes.³⁸ These delays will significantly impact the health and safety of pregnant patients with pre-existing diabetes or GDM.

Despite the urgency of managing blood glucose levels during pregnancy, many women face delays in accessing CGM devices due to insurance eligibility issues and preauthorization requirements. These delays will result in adverse maternal and neonatal outcomes, including diabetic ketoacidosis (DKA), pre-eclampsia, longer delivery times, Caesarean delivery, increased mortality, congenital malformations, macrosomia, increased mortality risk, impaired nervous system development, long-term impact on psychomotor and cognitive development, and increased neonatal intensive care unit (NICU) admissions.^{39, 40}

The preauthorization issue is slowly being addressed, as many public and private health insurers are now covering CGM as a pharmacy benefit, which requires less onerous documentation requirements. However, the burden remains for clinicians who prescribe through durable medical equipment (DME) suppliers, which requires significantly more documentation to obtain authorization than prescribing through the pharmacy. Many physician offices are unable to provide team-based care due to time constraints, inadequate staffing, and a lack of experience using CGM and other diabetes technologies, which often leads to therapeutic inertia and poor outcomes.⁴¹ In a recent study, Allaire et al. observed that treatment adherence was significantly higher, and healthcare costs were lower, for patients who obtained their CGM devices and supplies through a DME supplier than for those who received them through a pharmacy.⁴²

Institutional Policies

Hospitals, nursing homes, and prisons often prohibit or restrict the use of personal diabetes devices, forcing patients to revert to less effective methods. For example, patients are often required to remove their CGMs or insulin pumps upon admission, even when these devices are critical for managing their condition. This policy stems from a lack of understanding or training among healthcare staff regarding diabetes technology. As a result, patients may experience poor glycemic control, leading to complications such as DKA, hyperosmolarity, or severe hypoglycemia. Such policies not only undermine patient autonomy but also increase healthcare costs due to preventable emergencies.

Similarly, prisons often enforce policies that strip inmates of their diabetes technologies, reverting them to outdated methods like Neutral Protamine Hagedorn (NPH) insulin and BGM. This will lead to dangerous health outcomes. These policies reflect systemic discrimination and a lack of prioritization for diabetes management, further exacerbating health disparities.

Social Determinants

The use of diabetes technologies is notably low among patients from racial/ethnic minority groups and low socioeconomic backgrounds. ^{40, 41} In a recent study of 300 young adults with type I diabetes, Agarwal et al. found that only 28% of Black patients used continuous glucose monitors, compared to 71% of White patients. Despite their regression analyses of socioeconomic status, healthcare factors, and diabetes self-management behaviors, researchers were unable to fully explain these disparities, suggesting the possibility of implicit bias. Similar findings were reported in a review of 227 adults with TID at an urban safety-net endocrinology clinic, where only 37% of patients used any diabetes technology. ⁴¹ CGM and/or insulin pump usage was significantly lower among Black (4%) and Hispanic (9%) patients compared to White patients (35%). Although all these PwD were eligible for CGM under most commercial and government coverage policies, the results from these studies suggest that use of diabetes technologies among patients with T2D in lower socioeconomic and racial/ethnic communities is virtually nonexistent.

Disparities in the use of diabetes technologies are also related to socioeconomic status and geographic location. PwD living in rural areas or underserved regions face limited access to diabetes specialists with expertise in diabetes technologies.⁴³ Access to primary care providers will also be limited. Nguyen et al. recently reported that PwD living in low-income urban and rural areas are more likely to have fewer primary care providers (0.5% and 7.4%, respectively) than those living in higher socioeconomic communities.⁴⁴

Clinician Challenges

Integrating CGM and AID systems into routine patient care requires clinical practices to establish a multidisciplinary team of diabetes specialists who will provide comprehensive diabetes education, training in device use, and expertise in interpreting the data and making appropriate treatment adjustments.^{45, 46} Moreover, while there are specific billing codes for CGM training, initiation, and data interpretation, there are no codes for insulin pump or AID training.

In addition to the barriers to choice discussed earlier, many clinicians are reluctant to prescribe these technologies due to their unfamiliarity with current diabetes devices, lack of support staff who can provide training and ongoing patient monitoring, and the excessive burden of securing preauthorizations for their patients.

A survey of 41 rural clinic HCPs revealed that only 47.4% reported that they prescribe any diabetes devices due to a lack of a medical team with the expertise to utilize diabetes technologies with their patients effectively.⁴⁷ In a more recent survey of 102 primary care physicians and 100 endocrinologists, Grunberger et al. queried participants about their current practices, comfort level, and perspectives on the use of diabetes technologies. According to investigators, the major barriers to adoption were the complexity of the devices, the extra resources and office time required to train and monitor patients, and patient acceptance.⁴⁸

Although Certified Diabetes Care and Education Specialists (CDCESs) will provide the necessary training and education for their patients, many practices have limited access to these people or are unaware of these specialists. As such, both integration of CDCESs into primary care practices and external referrals for diabetes care and education remain suboptimal, as does coverage for sufficient hours of diabetes care and education for those who have access to the benefit in their insurance plan.

Patient Challenges

Many PwD are unaware of the availability or benefits of CGM and AID systems. If their HCPs are unfamiliar with these technologies, patients remain uninformed and may not ask for these tools or learn how they can improve their diabetes management.

Another major challenge is cost. Because insurance coverage for CGM and AID is often more restrictive than standards of care, patients who do not meet the eligibility criteria imposed by their insurance plan have to pay out of pocket, which will be cost-prohibitive. This is especially true for



PwD who Medicaid insures, which is inconsistent and impose exclusionary policies that limit access to CGM and AID for certain populations, such as those not on insulin or those who frequently miss in-office visits. Women with GDM are also particularly disadvantaged, as their condition is generally diagnosed late in pregnancy (24–28 weeks), which leaves little time to obtain and utilize CGM effectively, complicated by coverage barriers which inhibit access.

Moreover, because Medicaid and many commercial insurance providers limit coverage to their list of "preferred" products and devices, patients may also be discouraged from using any diabetes technology if their chosen CGM or AID system is not covered by insurance or if they are forced to use a device that does not meet their needs and preferences. Whereas an adolescent may prioritize a discreet device, an older adult may prioritize ease of use over discretion. Patients may also become victimized by "non-medical switching," which is a common practice among many commercial insurers who "switch out" the specific devices included in their formulary for financial advantage. If an insurance plan only covers one device or switches the device they cover, and technology continues to develop and choices expand, the devices might not be compatible, and the patient can no longer use the AID system. Finally, patients may experience interruptions in receiving disposable supplies, such as sensors and infusion sets, which will lead to gaps in their diabetes management. This is particularly problematic for those on Medicare, where strict rules like the requirement for visits with their treating practitioner every six months for continued coverage of supplies will delay access to necessary supplies.

Because educational resources are often not available in multiple languages, PwD from diverse backgrounds may be challenged by language barriers and cultural differences. These will impede collaboration with their HCPs and contribute to implicit clinician bias. HCPs are less likely to prescribe diabetes technologies to patients they believe do not have the willingness and/or ability to use these tools effectively. As a result, patients may internalize stigma or bias from their HCPs or insurers, believing they are not a candidate or do not "deserve" access to advanced diabetes technology, which will discourage them from pursuing CGM or AID systems.

It is also important to recognize that daily diabetes self-management is already a significant mental and emotional burden. Adding the complexity of learning and using new technology can overwhelm some PwD, especially if they do not receive adequate support or training. Although peer support networks provide valuable information about CGM and AID systems, many patients are unaware of or lack access to these groups.

RECOMMENDATIONS FOR ENSURING PATIENT CHOICE

The panel developed a list of recommendations that could provide a roadmap for medical organizations and patient advocacy groups to address the barriers to patient choice and increase patient access to diabetes technologies that have been demonstrated to improve metabolic control, enrich quality of life, and reduce hospitalizations and associated costs.

Table 2. Roadmap for Addressing Barriers to Patient Choice and Access to Diabetes Technologies

Foster Collaboration Among Stakeholders

- Bring together patient advocacy groups, healthcare providers, device manufacturers, and policymakers to work collaboratively on improving access to diabetes technology.
- Organize roundtables and forums to discuss barriers to access and potential solutions.
- Develop joint campaigns to raise awareness about the importance of diabetes technology.
- Share resources and best practices among organizations to amplify advocacy efforts.

Advocate for Expanded Access and Choice

- Advocate for policy changes at the federal and state levels to expand coverage for diabetes technologies that align with the current Standards of Care in Diabetes.
- Eliminate restrictive criteria, such as requiring insulin use or frequent fingerstick testing, for CGM coverage.
- Advocate for universal coverage of diabetes technology under Medicare, Medicaid, and private insurance plans.
- Collaborate with manufacturers to promote interoperability of diabetes technologies.
- Advocate for CGM coverage for PwD diagnosed with gestational diabetes, regardless of treatment type.
- Develop protocols for early CGM initiation in pre-existing diabetes early in pregnancy to improve glycemic control and reduce complications.
- Educate OB-GYNs and other providers on the benefits of CGMs in managing gestational diabetes and pre-existing T2D.
- Advocate for legislation that prevents insurance companies from specifying one brand or device for coverage (e.g., Medicaid, commercial insurance).
- Advocate to prevent insurance company efforts to reduce cost from narrowing choice for patients.

Promote Early Adoption of Technology

- Advocate for offering CGM initiation at the time of diagnosis for all PwD.
- Develop educational programs to help newly diagnosed patients understand the benefits of diabetes technology.
- Work with payers to ensure coverage for early adoption of CGMs and other devices.

Reduce Administrative Barriers

- Advocate for the elimination of prior authorization requirements for diabetes technology.
- Advocate for coverage under both pharmacy and DME benefits so that patients can obtain the devices they need through the channel that is most accessible to them.
- Simplify the prescription process for CGMs and insulin pumps, ensuring timely access for patients.
- Work with payers to reduce bureaucratic obstacles, such as redundant paperwork and frequent reauthorization requirements.

Address Disparities in Access

- Advocate for Medicaid programs in all states to cover CGMs, insulin pumps, AID systems, and other diabetes technologies and patient training on how to use these devices.
- Develop outreach programs to educate underserved communities about diabetes technology.
- Partner with community organizations to provide resources and support for patients facing barriers to access.

Address Stigma and Bias

- Educate healthcare providers on the psychological and emotional burden of diabetes and the importance of compassionate care.
- Develop campaigns to raise awareness about the stigma associated with diabetes and its impact on patient outcomes.
- Advocate for policies that ensure equitable access to diabetes technology for all PwD, regardless of perceived compliance or control.
- Develop educational/training programs to help providers recognize and mitigate implicit bias.

Address Provider Education and Training

- Collaborate with medical schools and clinician organizations to develop and implement training programs for medical students, residents, and practicing healthcare providers on diabetes technology.
- Collaborate with device manufacturers to create educational materials focused on the benefits, features, and proper use of CGM devices, insulin pumps, and AID systems.

Improve Education for Patients

- Develop person-friendly, multi-language educational materials that explain the features and benefits of diabetes technology.
- Create peer support programs to connect patients with others who have experience using diabetes technology.
- Offer workshops and webinars to teach patients how to navigate insurance appeals and advocate for their needs.

Leverage Peer Support Networks

- Expand peer support programs to connect patients with experienced users of diabetes technology.
- Develop online platforms and forums for patients to share their experiences and learn from others.
- Partner with patient advocacy organizations to promote peer support as a valuable resource.

Advocate for Coverage of Diabetes Self-Management Education and Support (DSMES)

- Advocate for policies that mandate coverage of DSMES under Medicare, Medicaid, and private insurance. This would include person-to-person and telehealth delivery of education/training material.
- Expand access to diabetes care and education specialists, particularly in rural and under resourced areas, including coverage of telemedicine.
- Promote the integration of diabetes education into routine care for all PwD.

Promote Continuation of Diabetes Technology Use in Institutions

- Advocate for institutional policy changes to ensure that hospitals, nursing homes, prisons, and other institutions allow patients to use their diabetes technology during their stay.
- Provide training for institutional staff on how to manage patients using diabetes technology.

Support Research and Data Collection

- Fund research that compares clinical and cost outcomes for patients using CGM versus traditional BGM.
- Collect data on the long-term benefits of diabetes technology in reducing complications and healthcare costs.
- Share research findings with policymakers, payers, and healthcare providers to support advocacy efforts.



SUMMARY

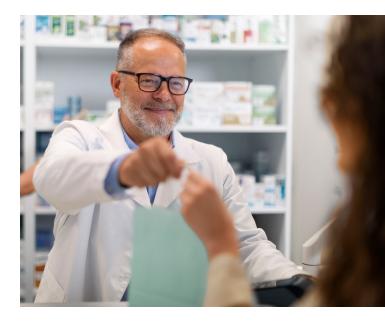
Persistent hyperglycemia in diabetes leads to severe complications, yet less than half of Americans with diabetes are meeting their HbAIc goals.³ Continuous glucose monitoring (CGM) and automated insulin delivery (AID) systems have proven effective in improving glycemic management, reducing complications, and enhancing quality of life.^{5,6} However, patient choice and access to these technologies remain limited due to barriers such as restrictive insurance policies, administrative hurdles, institutional restrictions, socioeconomic disparities, and clinician challenges.

Restrictive insurance policies—government and commercial—often deny coverage for CGM and AID systems based on outdated criteria, such as requiring insulin or frequent finger-stick testing to obtain coverage for CGM access. Ensuring the interoperability between the various products also remains a concern. Administrative burdens such as prior authorization requirements further hinder access, especially for pregnant women with gestational diabetes. Additionally, institutional policies in hospitals, nursing homes, and prisons often prohibit the use of personal diabetes devices, leading to difficulty maintaining glycemic targets and avoiding preventable complications. Other barriers, such as socioeconomic and racial disparities and implicit bias from providers, also limit access, leading to minority and low-income patients being significantly underrepresented in using diabetes technologies. Clinicians' unfamiliarity with these devices and lack of support staff further exacerbate the problem.

However, restricted access to diabetes technologies is only part of the problem. Patients must be given a choice. This will require insurers to eliminate their lists of "preferred" products and allow patients the ability to choose the specific devices that meet their specific needs. Patients who are forced to use a device that does not meet their needs, preferences, or lifestyle are more likely to discontinue its use. Additionally, HCPs must spend time learning about the various devices available

and then communicate that information to their patients. Patients have the right to be informed about all available options.

Giving patients a choice must start with HCPs recognizing and addressing their own implicit biases toward patients. Neither race/ethnicity nor socioeconomic status inherently limits a patient's intelligence, ability, or motivation to manage their diabetes effectively. PwD must be informed about all of the tools available to them and then given the opportunity to choose the tools that are right for them. This goes hand-in-hand with recognizing the stigma of having diabetes and how this can adversely impact a person's willingness to engage with their daily self-management. One of the best ways to



advocate for reducing stigma is for HCPs to make sure they are doing their part by reflecting on how they talk with patients about having diabetes, how they manage it, and the challenges that are associated with it.

Fostering collaboration among patient advocates, healthcare providers, manufacturers, and policymakers is an effective way to expand access and promote patient choice. Advocacy efforts should focus on eliminating restrictive criteria, reducing administrative burdens, and ensuring equitable access across all populations. Patient and provider education, including training programs, multilingual resources, and peer support networks, is also critical. Moreover, institutions need to revise their policies to allow for the use of diabetes technology and provide appropriate staff training in these settings. Finally, to facilitate meaningful policy changes, there is a need for additional research studies that demonstrate the benefits of diabetes technologies and the ability of PwD to choose devices that best fit their needs.

Limiting patient choice and restricting access to innovative diabetes technologies will lead to poor clinical outcomes and low quality of life. HCPs and diabetes patient advocacy groups have the influence, wherewithal, and opportunity to bring about the changes needed to empower PwD to make informed choices and access diabetes technology that best meets their needs. Diabetes is not a "one-size-fits-all" condition.

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Diabetes Leadership Council policies restrict funders from controlling program content.

APPENDIX A

Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD). External Infusion Pumps²⁵

Administration of continuous subcutaneous insulin for the treatment of diabetes mellitus (Refer to the ICD-IO code list in the LCD-related Policy Article for applicable diagnoses) if criterion A or B is met, and if criterion C or D is met:

A. C-peptide testing requirement—must meet criterion I or 2 and criterion 3:

- I. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method
- 2. For beneficiaries with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 percent of the lower limit of normal of the laboratory's measurement method.
- 3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.

B. Beta cell autoantibody test is positive.

C. The beneficiary has:

- 1. Completed a comprehensive diabetes education program
- 2. Been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump
- 3. Has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump,
- 4. Meets one or more of the following criteria (I-5) while on the multiple injection regimen:
 - a. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
 - b. History of recurring hypoglycemia
 - c. Wide fluctuations in blood glucose before mealtime
 - d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
 - e. History of severe glycemic excursions

D. The beneficiary has:

- 1. Been on an external insulin infusion pump prior to enrollment in Medicare
- 2. Has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.



If criterion A or B is not met,

the pump and related accessories, supplies, and insulin will be denied as not reasonable and necessary.



If criterion C or D is not met,

the pump and related accessories, supplies, and insulin will be denied as not reasonable and necessary.

Continued coverage of an external insulin pump and supplies requires that the beneficiary be seen and evaluated by the treating practitioner at least every 3 months.

In addition, the external insulin infusion pump must be ordered and follow-up care rendered by a practitioner who manages multiple beneficiaries on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators, and registered dietitians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.

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