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Increase Access, Reduce Disparities: Recommendations for Modifying Medicaid CGM Coverage Eligibility Criteria

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Abstract

Numerous studies have demonstrated the clinical value of continuous glucose monitoring (CGM) in type 1 diabetes (T1D) and type 2 diabetes (T2D) populations. However, the eligibility criteria for CGM coverage required by the Centers for Medicare & Medicaid Services (CMS) ignore the conclusive evidence that supports CGM use in various diabetes populations that are currently deemed ineligible. In an earlier article, we discussed the limitations and inconsistencies of the agency's CGM eligibility criteria relative to current scientific evidence and proposed practice solutions to address this issue and improve the safety and care of Medicare beneficiaries with diabetes. Although Medicaid is administered through CMS, there is no consistent Medicaid policy for CGM coverage in the United States. This article presents a rationale for modifying and standardizing Medicaid CGM coverage eligibility across the United States.

Keywords

type 1 diabetes, type 2 diabetes, Medicaid, continuous glucose monitoring, insulin

Introduction

The prevalence of diabetes among all adults in the United States was 13.0% in 2018.[1] However, prevalence is disproportionally higher in Native American (14.5%), Hispanic (11.8%), and black populations (12.1%) compared with white individuals (7.4%), particularly in those with low socioeconomic status.[1,2] Individuals with less than a high school education (16.6%)[1] and/or low socioeconomic status are also at significantly greater risk of diabetes complications regardless of race or ethnicity.[2,3]

According to the Centers for Medicare & Medicaid Services (CMS), 87 384 715 individuals are enrolled in Medicaid and Children's Health Insurance Programs (CHIP)[4]; more than half are under 21 years of age.[5] Black (32.0%) and Hispanic (30.0%) beneficiaries comprise the largest percentage of the Medicaid population.[6]

Despite advances in medications and diabetes technologies, the median percentage of Medicaid/CHIP beneficiaries with HbA1c levels $>$ 9.0% within the 31 states that report this measure is estimated to be 39.0%.[7] Only 12% of Medicaid beneficiaries have achieved the recommended HbA1c target of $<$ 7.0%[8] compared with those covered by commercial health plans (20%) or Medicare (26%).[9] Higher rates of disability, depression, and comorbidities among Medicaid beneficiaries compared with individuals covered by Medicare or commercial health plans have also been reported,[10] all of which can impact treatment adherence and clinical outcomes.

Frequent glucose monitoring is recommended by all major diabetes organizations[11-14]; it is considered essential to glycemic management in individuals with type 1 diabetes (T1D) and insulin-treated type 2 diabetes (T2D). Although fingerstick blood glucose monitoring (BGM) is the most common method for testing, a growing number of patients have adopted continuous glucose monitoring (CGM). Large, randomized trials and real-world studies have shown CGM

to be safe and effective in improving HbA1c, lowering hypoglycemia risk, and reducing diabetes-related hospitalizations in patients treated with insulin.[15-21] The current optimal care for persons with T1D and insulin-requiring T2D is with an insulin pump with automated insulin delivery (AID). These systems require CGM connectivity and input for determination of pump-delivered insulin doses. A recent study showed equal benefit among publically insured users compared with those with private insurance.[22]

Many Medicaid beneficiaries do not have access to CGM, due, primarily, to overly restrictive eligibility criteria. For example, two states (Georgia and Alabama) only provide CGM coverage for pediatric patients.[23] Because lower socioeconomic status and race/ethnicity are strong predictors for the development of diabetes-related complications and mortality,[24,25] it is important that Medicaid reconsider their eligibility criteria for CGM coverage.

In an earlier article, we discussed the limitations and inconsistencies of CMS's CGM eligibility criteria relative to current scientific evidence and proposed practical solutions to address this issue and improve the safety and care of Medicare beneficiaries with diabetes.[26] Table 1 presents a summary of our recommendations for modifying the eligibility requirements. These recommendations closely align with the agency's proposed changes to CGM eligibility[27] (Table 2). The purpose of this article is to present a rationale for applying and standardizing these recommendations across all state Medicaid programs.

Rationale for Modification and Standardization of Medicare Coverage

Current Medicaid Eligibility Criteria for CGM Coverage Is Inconsistent

Although Medicaid is administered through CMS, there is no consistent Medicaid policy for CGM coverage in the United States. According to the latest industry data (Abbott Diabetes Care, data on file), seven states have published no CGM coverage criteria except through medical necessity. Among states that provide coverage there are significant variations in eligibility criteria. Whereas some states cover CGM for individuals with T1D and T2D, 22 others cover T1D beneficiaries only. In addition to differences in the type of diabetes covered for CGM, state Medicaid programs also differ in other ways, including age, prior fingerstick testing frequency, type of insulin therapy, prescriber requirements, and how beneficiaries receive their supplies. Table 3 illustrates how state Medicaid programs can vary in their eligibility requirements; states were selected to demonstrate the wide variability. A state-by-state listing of the most current requirements is presented in Supplementary Table 1.

Strong Evidence Supports CGM Use in Various Diabetes Populations

Unlike BGM, which only provides a single, point-in-time value, CGM continuously measures glucose levels and automatically transmits the data the user's smartphone or dedicated reader in numerical and graphical formats. This immediate access to glucose data enables users to more accurately determine insulin dosages and take immediate action to mitigate current or impending glycemic events (eg, severe hypoglycemia and hyperglycemia). Some CGM systems also feature a predictive low glucose alert that notifies the user when severe hypoglycemia is predicted to occur within the next 20 minutes. Moreover, current CGM systems can be programmed to transmit users' data to their clinicians for in-depth analysis and treatment recommendations.

The clinical efficacy of CGM has been demonstrated in numerous studies of individuals with T1D and those with T2D who are treated with intensive insulin therapy regardless of insulin delivery method.[15,17,19,20,28-30,32,36,37,40,43-45,47,48,50,73-75]

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Table 1. Recommendations for Modifying Medicare CGM Eligibility Requirements.[26]

Criterion	Supporting evidence
1. Diagnosed with T1D.	*CGM use confers*: • Significant reductions in HbA1c.[15,17,28-36] • Significant reductions in severe hypoglycemia events.[18,32,33,37] • Significant increases in %TIR.[17,20,30,36,38] • Significant decreases in %TBR.[17,30,36] • Significant reductions in diabetes-related hospitalizations.[18,32,33,39]
2. Diagnosed with T2D and treated with any insulin therapy.	*CGM use confers*: • Significant reductions in HbA1c.[29,31,40-47] • Significant increases in %TIR.[29,40,47] • Significant decreases in %TBR.[19,48] • Significant decreases in %TAR.[47] • Significant reductions in severe hypoglycemia events.[37] • Significant reductions in diabetes-related hospitalizations.[39,49]
3. Diagnosed with T2D and documented problematic hypoglycemia regardless of diabetes therapy. This would include a history of at least one of the following conditions: • Level 2 (moderate) hypoglycemia—characterized by glucose levels ≤ 54 mg/dL. • Level 3 (severe) hypoglycemia—characterized by physical/mental dysfunction requiring third-party assistance. Nocturnal hypoglycemia.	*Older diabetes patients are at increased hypoglycemia risk*: • T2D patients treated with antihyperglycemic medications (eg, insulin and sulfonylureas) are at higher risk for hypoglycemia than those treated with non-hypoglycemia medications (eg, metformin).[50] • T2D patients ≥65 years treated with basal insulin (typically one injection per day) are at increased risk for severe hypoglycemia.[51] • A key driver of hypoglycemia risk is impaired hypoglycemia awareness.[52,53] *CGM use confers*: • Significant reductions in diabetes-related hospitalizations, including severe hypoglycemia events.[39,49] • Significant reductions in severe hypoglycemia events.[37] • Significant reductions in hypoglycemia fear and increases in patient confidence in avoiding/treating hypoglycemia,[28,54] thereby supporting treatment adherence.[55,56]
4. Chronic kidney disease (CKD).	*CGM use facilitates*: • More frequent treatment changes and improved glycemic control without increased risk of hypoglycemia.[57] • Effective monitoring and managing glycemic levels in patients without diabetes with ESRD undergoing dialysis.[58]
5. In-person or telemedicine consultation with the prescribing healthcare provider prior to CGM initiation and every 6 months thereafter while continuing CGM therapy.	*Use of telemedicine consults*: • Significantly reduces HbA1c.[59-64] • Reduces the incidence of severe hypoglycemic events.[63] • Significantly reduces diabetes-related distress.[65] • Significantly improves medication adherence.[66] • Effectively addresses the obstacles caused by the COVID-19 pandemic.[67-71] • Are more effective for patients who are residents of cities and using the websites as their intervention method.[61] *Use of downloaded CGM data into standardized reports*: • Supports patient education.[72] • Enhances patient engagement in their self-management.[72]

Abbreviations: CGM, continuous glucose monitoring; %TIR, percentage time in range; %TBR, percentage time below range; HbA1c, glycated hemoglobin; %TAR, percentage time above range; ESRD, end-stage renal disease.

Table 2. CMS Proposed LCD for Glucose Monitors.[27]

To be eligible for coverage of a CGM and related supplies, the beneficiary must meet all of the following initial coverage criteria 1-5:

1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,
2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and,
3. The CGM is prescribed in accordance with its FDA indications for use; and,
4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:
   (A) The beneficiary is insulin-treated with at least one daily administration of insulin; or,
   (B) The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following:
   - Recurrent level 2 hypoglycemic events (glucose < 54 mg/dL (3.0 mmol/L) that persist despite multiple (two or more) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or A history of one level 3 hypoglycemic event (glucose < 54 mg/dL (3.0 mmol/L) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia
5. Within 6 months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria 1-4 above are met.

Abbreviations: CMS, Centers for Medicare & Medicaid Services; LCD, Local Coverage Determination; CGM, continuous glucose monitoring; ICD, International Classification of Diseases.

Table 3. CGM Eligibility Criteria for Selected States.

Criteria	T1D	T2D	GDM	≥3 daily injections or insulin pump[a]	BGM ≥ 4 times daily	HbA1c ≥7%[b]	Frequent severe hypo (<50mg/dL)	Hypoglycemia unawareness	History of hyperglycemia[c]	Nocturnal hypoglycemia	DKA	Preprandial-postprandial hyperglycemia	Dawn phenomenon	Benefit
Arkansas	Yes	Yes		Yes			Yes	Yes						DME
Georgia[d,e]	Yes	Yes		Yes	Yes		Yes	Yes			Yes			DME
Idaho	Yes	Yes		Yes	Yes	Yes		Yes	Yes	Yes		Yes	Yes	DME
Kentucky[a]	Yes	Yes												Rx
Michigan	Yes			Yes	Yes			Yes			Yes			DME
Missouri	Yes	Yes[f]	Yes[f]	Yes[a]										Rx
Nevada	Yes			Yes	Yes		Yes	Yes				Yes	Yes	Rx
New Hampshire	Yes					Yes	Yes	Yes			Yes	Yes		Rx
New York[e]	Yes	Yes	Yes	Yes	Yes									Rx
Oklahoma	Yes	Yes		Yes	Yes	Yes	Yes	Yes			Yes	Yes		Rx
Rhode Island	Yes			Yes	Yes		Yes	Yes						DME

Abbreviations: CGM, continuous glucose monitoring; GDM, gestational diabetes; BGM, blood glucose monitoring; HbA1c, glycated hemoglobin; DKA, diabetic ketoacidosis; DME, Durable Medical Equipment; Rx, pharmacy benefit.

[a]≥3 times daily or insulin pump which may require frequent adjustments.

[b]Or not achieving target HbA1c.

[c]Including unexplained hyperglycemia.

[d]Pediatric coverage only.

[e]Prescription by an endocrinologist.

[f]Use of rapid-acting insulin is required.

Benefits of CGM use in this population include reductions in HbA1c,[15,17,28-35,36,37,76] fewer severe hypoglycemia events,[18,32,33,37] less hypoglycemia fear,[18,77] reductions in diabetic ketoacidosis (DKA),[37] increased time within target glucose range (TIR),[17,20,30,38,78] and reductions in time below range.[17,30,78] Large observational registry and database studies have also shown an association between CGM use and significant reductions in hospitalizations for severe hypoglycemia and DKA.[18,32,33,39] The clinical benefits of CGM are not limited to individuals treated with intensive insulin regimens. Several recent studies have demonstrated improvements in glycemic control, reduction in hypoglycemia, and lower rates of hospitalizations in and health resource utilization.[47,79,80] The use of CGM in children and young adults has become the standard of care treatment as stated in the diabetes treatment guidelines given the overwhelming evidence indicating favorable outcomes with CGM use.[81]

The value of CGM use within the Medicaid/Chip population is underscored by recent data from Addala et al[82] who assessed the impact of continued and interrupted CGM use on HbA1c within a cohort of young adolescents (age 12.9 ± 4.2 years) who were enrolled in public insurance plans. Investigators reported improvements in HbA1c among those patients who were provided uninterrupted access to CGM; whereas HbA1c levels increased in patients whose access was interrupted due to insurance-related issues. Use of CGM in persons with T1D and T2D is critical for diabetes management with AID systems. Individuals covered by Medicare or Medicaid showed equal benefit from use of at least one AID pump/CGM system.[22]

An additional advantage of CGM technology is the ability to automatically share and discuss glucose data with healthcare professionals in real time. Use of virtual telehealth visits in conjuction with remote monitoring of CGM data has been shown to improve glycemic control,[59-64] reduce diabetes-related distress,[65] and enhance treatment adherence,[66] with increased cost and time efficiences compared with in-clinic diabetes visits.[59,83-85] Use of these technologies proved extremely valuable and effective in overcoming many of the obstacles encountered throughout the COVID-19 pandemic.[67-69,71,86]

Racial/Socioeconomic Disparities Impact Access and Treatment

Medicaid beneficiaries have greater difficulty accessing specialists, such as endocrinologists, than those with private insurance.[87] This is significant because many primary care providers are challenged to provide adequate diabetes care to individuals treated with intensive insulin therapy and often delay intensifying insulin therapy due to the complexity of these regimens.[88]

Importantly, as recently reported by the American Diabetes Association, Medicaid beneficiaries who are treated with insulin are 2-5 times less likely to use a CGM than those covered by commercial insurance; however, this gap in coverage is less pronounced when considering only white beneficiaries.[89]

Pihoker et al[90] found that younger T1D patients who are covered by Medicaid are more likely to be treated with less-intensive insulin therapy and receive fewer changes to their current insulin regimens than those with private insurance, a disparity that is particularly pervasive among black and Hispanic patients.

In a cross-sectional, multicenter analysis of patient- and chart-reported variables, Agarwal et al[91] investigated racial/ethnic disparities within a cohort of 300 young adults (20 years) with T1D: 33% white, 32% black, and 34% Hispanic. Investigators reported that significantly fewer black (28%) and Hispanic (37%) patients had ever used a CGM device compared with white patients (71%), $P < 0.001$. Additionally, they found that young black and Hispanic participants had lower annual household incomes, less education, and higher neighborhood poverty. Lai et al[92] reported similar findings of racial disparities in CGM initiation and continued use.

Similar disparities in CGM use were reported in a retrospective review of 227 adult T1D patients.[93] Among the 68 (30%) patients who used CGM, differences in the proportions of users were notable: 47% white, 22% Hispanic, and 14% black.[93] Patients covered by government health insurance had lower odds of using technology (odds ratio [OR], 0.43) compared with patients with private health insurance.

As reported by Pihoker et al, younger T1D patients covered by Medicaid are more likely to be treated with less-intensive insulin therapy and receive fewer changes to their current insulin regimens than those with private insurance. This disparity is particularly striking among black and Hispanic patients.[90] Numerous studies have shown that children/adolescents with T1D who are of lower socioeconomic status and covered by public health plans have higher HbA1c values, greater incidence of DKA, and diminished quality of life.[94-97]

Use of CGM Can Reduce Healthcare Resource Utilization and Associated Costs

Early data have shown higher hospitalization rates for DKA over time for Medicaid beneficiaries compared with individuals covered by commercial health plans.[98] Analyses of 2012 Medicaid claims data[99] and the MarketScan multistate Medicaid database[100] also revealed significantly higher costs for adults and children/adolescents with diabetes (with and without a disability) compared with individuals without diabetes. As reported by Ng et al,[99] diabetes-related costs were significantly higher among adults with diabetes ($9530) and no disability compared with no diabetes or disability ($4545). Shrestha et al[100] reported similar findings, with even greater

Table 4. Change in Glycemic and Patient-Reported Outcomes Among CGM Users by Baseline BGM Frequency in the REPLACE Study: ≥4 vs <4 Tests/Day.[102]

	BGM change from baseline		Adjusted mean change from baseline			
	BGM frequency/day		BGM frequency/day		Difference in adjusted means	*P* value
	≥4 (n = 90)	<4 (n = 59)	≥4 (n = 90)	<4 (n = 59)		
HbA1c (%)	−0.21	−0.37	−0.29	−0.24	−0.05	.6891
%Time < 70 mg/dL (%)	−3.44	−2.23	−3.01	−2.90	−0.11	.8497
%Time < 55 mg/dL (%)	−1.77	−1.53	−1.63	−1.73	0.10	.7012
Number of hypos < 70 mg/dL	−0.32	−0.19	−0.27	−0.26	−0.01	.9050
Number of hypos < 55 mg/dL	−0.20	−0.18	−0.18	−0.22	0.04	.3222
Treatment satisfaction	13.54	13.65	13.42	13.48	−0.06	.9444

Abbreviations: CGM, continuous glucose monitoring; BGM, blood glucose monitoring; HbA1c, glycated hemoglobin.

cost disparities between children/adolescents with diabetes ($24 093) and those with no diabetes ($14 149).

Disparities in healthcare resource utilization and costs are likely related to differences in access to care between individuals living in low-income vs high-income communities.[87] As reported by Nguyen et al,[101] individuals living in low-income urban and rural areas are more likely to have fewer primary care providers in their communities (0.5% and 7.4%, respectively) than those living in higher socioeconomic communities.

Given the demonstrated impacts of CGM use in improving overall glycemic control[15,17,20,28-35,38,76,78] and reducing incidence of DKA and severe hypoglycemia events,[18,32,33,39] increasing beneficiary access to this vital technology has the potential to improve their health and well-being while reducing the long-term costs of diabetes.

Because diabetes-related costs differ from state to state, it is difficult to assess the total diabetes-related costs among Medicaid beneficiaries. However, program administrators can calculate the potential savings associated with CGM use in their state based on findings from a recent large, multicenter prospective observational cohort study of T1D adults (n = 515).[18] The study showed that use of CGM during an observation period was associated with significant reductions in the number of patients with severe hypoglycemia and/or DKA hospitalizations, which decreased by 73% (from 11% to 3%) and 80% (from 5% to 1%), respectively, after 1 year.

Current Eligibility Criteria Are Overly Restrictive in Most States

Coverage requires history of frequent fingerstick testing. Although the medical community traditionally relies on high-quality scientific evidence when developing clinical guidelines for managing diabetes and other conditions, state Medicaid programs tend to ignore the evidence when establishing coverage eligibility criteria for CGM. For example, in many states, beneficiaries must document a history of prior fingerstick testing. (Supplemental Table 1) This requirement is both unduly restrictive and medically unfounded.[26]

As reported in the DIAMOND study, only 48% of the rtCGM users (T1D and T2D) were preforming fingerstick testing ≥4 times per day at baseline; however, there was no association between Hb1c reductions at study end and baseline fingerstick frequency.[29] A similar absence of association between previous BGM frequency and positive clinical outcomes with rtCGM use has been observed in other large, randomized trials.

In a study of adult T2D patients, the mean self-reported fingerstick frequency at baseline for the BGM and rtCGM and BGM groups was 3.2 and 3.3, respectively.[40] The mean change in HbA1c at 6 months, was significantly greater in the rtCGM group (−1.0) compared with BGM users (−0.6%), P = 0.005. Again, there was no association between baseline BGM frequency and rtCGM outcomes. Similar findings that showed no association between fingerstick testing frequency and glycemic outcomes were observed in a post hoc analysis of the REPLACE study (Table 4).[19] Results from a recent retrospective claims data analysis also showed no association between prior fingerstick frequency and reductions in acute diabetes events (ADE).[39]

Findings from a recent retrospective claims data analysis have also shown no association between prior BGM frequency and reductions in ADE associated with CGM use. A cohort of 12 521 individuals with T1D and T2D experienced reductions in ADE from 0.245 to 0.132 events/patient-year (P < 0.001), with similar reductions observed in patients testing <4 and ≥4 times per day.[39]

Coverage is limited to intensive insulin therapy. Given that the vast majority of individuals with T1D are currently treated with either multiple daily insulin injections (MDI) or insulin pump therapy, the CGM requirement of intensive insulin therapy specifically targets those with T2D. Studies have demonstrated that use of CGM by T2D patients confers

significant reductions in HbA1c levels,[29,31,40-45] significant increases in time above range (%TIR),[29,40] significant decreases in time below range (%TBR),[19,48] and significant reductions in diabetes-related hospitalizations[39,49] regardless of insulin regimen. Although a substantial number of T2D Medicare beneficiaries are treated with less-intensive insulin regimens or non-insulin medications, they are at higher risk diabetes-related events (eg, hospitalizations and emergency room visits) than younger patients.[50-53]

The requirement for a documented history of frequent insulin dosage adjustment based on BGM values is burdensome for both healthcare providers and patients, and there is no evidence demonstrating its value as a predictor of successful CGM use. Moreover, this requirement ignores the broader utility of the CGM, which is the automated alarm/alert feature which warns patients of current or impending hypoglycemia/hyperglycemia, enabling them to take immediate remedial action. Finally, the specific wording of the requirement for "injecting" insulin fails to address other options for insulin administration (eg, insulin infusion using a pump and inhaled insulin).

"Deadlines" imposed for improved glycemic control. Some states require beneficiaries to show improved glycemic control within a specific time period. Given the numerous socioeconomic obstacles that challenge the Medicaid population, glycemic improvements may take longer in some patients. Moreover, the metrics of improvement will vary on an individual basis and may extend beyond glycemic control alone. The decision to continue CGM should be left to the clinical judgment of the prescribing healthcare provider.

Patient care must be provided by endocrinologists. Another significant obstacle to CGM access is the requirement for prescription from a board-certified endocrinologist. Of the 43 states and the District of Columbia that publish eligibility criteria for CGM coverage, seven require endocrinologists to prescribe or to provide consultation on a prescription (California, Georgia, Maryland, New York, South Carolina, South Dakota, Wisconsin).[23] This requirement does not consider the logistical obstacles patients may face if they have to travel long distances to receive care. For example, in Georgia, the vast majority of the practicing endocrinologists are located in the northwestern portion of the state. Moreover, there are only 65 board-certified endocrinologists who are enrolled to provide care to Medicaid beneficiaries, mostly in the large urban metropolitan area of Atlanta. This creates significant access limitations for patients living in rural areas or the southern portion of Georgia where diabetes prevalence is highest (Figure 1).

Moreover, this requirement does not align with the growing shortage of endocrinologists nationwide. As predicted by Vigersky et al,[104] the shortage of adult endocrinologists will increase to ~2700 by 2025 in the absence of any intervention. It will be up to primary care clinicians to fill the widening

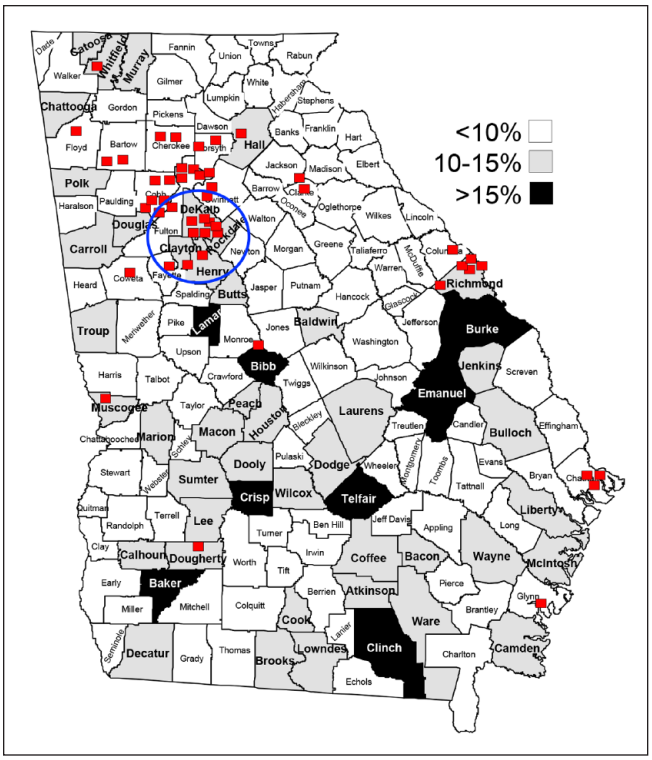

Figure 1. Endocrinologists enrolled in Medicaid vs diabetes prevalence by county.[103] Red squares—endocrinology office; blue circle—greater Atlanta metropolitan area.

supply-demand gap. Fortunately, efforts are currently in place at various medical institutions to provide CGM training to primary care physicians (PCP) through fellowship programs.[105] The implementation of such measures will further assist in increasing access and ensuring delivery of adequate care for patients with diabetes using these technologies.

Documentation requirements are onerous and potentially harmful. Changes in documentation requirements are needed. In addition to restrictive eligibility requirements, access to CGM is further hindered by the onerous documentation that healthcare providers are required to submit in order to obtain coverage for their patients. In a 2017 survey conducted by the American Medical Association (AMA), 92% of the 1000 clinicians surveyed reported that the documentation required to obtain authorization for medications and medical devices both delays patient treatment and negatively affects clinical outcomes.[106]

Recommendations for Reducing Patient/Provider Burden

Provide coverage for FDA-approved AID devices. Clinical evidence supporting the efficacy and safety of automated insulin delivery (AID) systems has grown over the last 5 years

with the introduction of commercially available, and soon to become available, AID systems. AID systems utilize a sophisticated algorithm that continuously modifies insulin delivery in response to glucose values obtained by CGM, residual insulin action, and other inputs, such as meal intake and exercise announcement. Numerous clinical trials and real-world studies have shown that use of AID systems significantly improve overall glycemic control and reduce severe hypoglycemia events in adults and children/adolescents with T1D.[107-118] Importantly, Medicaid currently provides insulin pump coverage for eligible beneficiaries. Without CGM, patients are not able to use AID pumps, which are the current and future best methods for management of insulin delivery in individuals treated with intensive insulin therapy.[22]

Simplify and streamline documentation. The focus of CGM eligibility documentation must be on simplifying administrative tasks and providing clear guidance to durable medical equipment (DME) suppliers and pharmacy coverage administrators. We recommend that state Medicaid programs develop and standardize a simple checklist to document each patient's diagnosed disease (T1D, T2D, CKD/ESRD) using ICD-9 and ICD-10 codes. A complete list of all relevant ICD codes should be included as a supplement to the checklist. Several options for documentation of problematic hypoglycemia should also be considered. (Table 5) Documentation of initial and follow-up consultations with healthcare providers would be documented as "yes" or "no."

Promote CGM acquisition as a pharmacy benefit. Most Medicaid patients currently receive their CGM devices through DME suppliers. However, they often encounter significant delays in processing their requests for CGM devices. These delays are multifactorial and detrimental to improving diabetes management. Many patients have competing needs and logistical barriers to receiving care, leading to recurrent hospitalizations for diabetes-related emergencies (DKA and hypoglycemia). During the time awaiting CGM approval, many of these patients remain at risk for diabetes-related admissions and readmissions, adding to the already existing disparities in care and health outcomes.

Moreover, the ongoing process for maintaining supplies through DME companies is difficult to navigate, especially for those coping with limited finances and multiple social pressures to maintain health and diabetes care. In the setting of these competing life demands (often including food insecurity), handling the process of ongoing DME requests or approvals required to get their supplies often results in intermittent use of CGM.

The opportunity to obtain their CGM supplies through pharmacy channels—a process that is more streamlined and improves continued access to devices—would have a significant impact on their ability to improve their glycemic control and clinical outcomes.

Table 5. Considerations for Documenting Problematic Hypoglycemia.

Presence of ≥1 glucose value indicating Level 2 (Severe) or nocturnal hypoglycemia events from available BGM data (prior 30 days).
Presence of ≥7 glucose values indicating frequent Level 1 (Moderate) hypoglycemia events from available BGM data (prior 30 days).
In the absence of BGM records, self-reported incidence/severity of hypoglycemia events.
Presence of Level 2/nocturnal hypoglycemia events and/or frequent Level 1 hypoglycemia events obtained from professional (short-term) CGM use.

Abbreviations: BGM, blood glucose monitoring; CGM, continuous glucose monitoring.

Summary

Diabetes continues to be a significant and growing health concern that threatens to overwhelm both public and private health systems. Because the prevalence of diabetes and its comorbidities is highest in people of color and/or low socioeconomic status, it is critical that these individuals have access to high-quality care for their diabetes.

Although a substantial and growing body of evidence demonstrates the clinical benefits of CGM in individuals with T1D and T2D regardless of their current therapy and prior glucose monitoring frequency,[19,39,41,42,46,49,102,119] CGM use is disproportionally low among individuals in racial/ethnic and low socioeconomic populations.[91,92]

Inappropriate, medically unfounded Medicaid eligibility criteria for CGM coverage deny access to CGM within a substantial population of beneficiaries with diagnosed diabetes, and further worsen disparities—particularly among minorities or patients in rural areas. Moreover, current policies are inconsistent with the established literature and current standards of care.[11,12]

Limiting access to CGM achieves neither cost-efficiencies nor clinical efficacies. We believe our evidence-based recommendations for modifying current eligibility criteria both streamlines the administrative processes for documenting medical necessity and expands access to our most vulnerable diabetes population.

Abbreviations

%TAR, percentage time above range; %TBR, percentage time below range; %TIR, percentage time in range; ADE, acute diabetes events; AID, automated insulin delivery; AMA, American Medical Association; BGM, blood glucose monitoring; CGM, continuous glucose monitoring; CKD, chronic kidney disease; CMS, Centers for Medicare & Medicaid Services; COVID-19, Coronavirus

Disease 2019; DME, Durable Medical Equipment; DKA, diabetic ketoacidosis; ESRD, end-stage renal disease; GDM, gestational diabetes; HbA1c, glycated hemoglobin; ICD, International Classification of Diseases; LCD, Local Coverage Determination; OR, odds ratio; Rx, pharmacy benefit; T1D, type 1 diabetes; T2D, type 2 diabetes.

Author Contributions

R.J.G., G.A., C.G.P., and J.B.M. wrote the manuscript. D.B., A.L.C., E.C. G.F., D.F.K., C.L., and G.E.U. provided input on the draft. All authors reviewed the final draft and approved its submission.

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Supplemental Material

Supplemental material for this article is available online.

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