

# RT-**CGM** and T2D

Managed Care/Payer Working Group

MANAGED CARE INSIGHTS BRIEF

## Payer Perspectives on the Value of Real-Time Continuous Glucose Monitoring in Managing Clinical and Economic Outcomes in Type 2 Diabetes





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## Key Takeaways

- Payers are acutely aware of the disease burden associated with type 2 diabetes (T2D), affecting up to 12% of plan members and accounting for an estimated 30% of plan costs
- T2D remains a challenging disease state beset by poor outcomes and high cost; lifestyle modification and patient engagement are crucial to quality improvement
- Payers and providers know *why* patients impacted by social determinants of health (SDOH) experience worse outcomes, but are constantly seeking exactly *how* to address these challenges
- Real-time continuous glucose monitoring (rtCGM) provides a means by which to improve patient engagement and self-management across a diverse population of plan members, including those impacted by SDOH
- Recent studies published in *JAMA* demonstrate the value of rtCGM for improving glycemic control and reducing resource utilization in insulin-treated T2D across both a randomized, controlled trial (RCT) and a real-world cohort analysis
- Prospective and retrospective analyses reinforce cost savings associated with rtCGM and demonstrate the value derived through appropriate coverage and prescribing
- These studies, in conjunction with consensus recommendations from leading endocrinology organizations, have led to more liberal coverage criteria for CGM in insulin-treated T2D by the Centers for Medicare and Medicaid Services and commercial payers
- Pharmacy coverage of rtCGM can elicit immediate cost savings for payers in addition to easing the administrative burden on both payers and providers while enhancing access among members



## Introduction

Type 2 diabetes (T2D) imposes significant clinical and economic burdens across variable US health plan populations characterized by diverse age, race/ethnicity, socioeconomic status, and health literacy. T2D affects more than 30 million Americans, and its optimal treatment is complicated by requisite lifestyle modification and intensive self-management protocols.<sup>1</sup> At least 42 individual factors can affect blood glucose, and patients often spend a total of 4 hours per day or more on their self-care routines with minimal provider contact.<sup>2,3</sup> The result of this current suboptimal management environment is that only 6% of individuals with diabetes live a life free from disease-related complications.<sup>4</sup> Furthermore, diverse racial/ethnic populations and those in low-income groups are disproportionately affected by T2D, thereby experiencing greater morbidity and worsening outcomes.<sup>5</sup>

In addition to the micro- and macrovascular complications associated with poor glycemic management, approximately 30% of individuals with T2D are treated with some form of insulin, increasing the risk of complications and resource utilization associated with hypoglycemia.<sup>5</sup> Severe hypoglycemia (SH) represents a barrier to optimal glycemic management, a considerable detriment to member quality of life, and a substantial drain on health care resources.<sup>6</sup> Across all lines of business, SH increases resource utilization, with 90% of events resulting in emergency department (ED) visits, 50% involving an emergency medical service (EMS) claim, and approximately one-third resulting in hospitalization averaging nearly \$11,000.<sup>7</sup> This phenomenon is common among members with T2D, and the risk of SH increases with longer duration of disease.<sup>8</sup> Furthermore, after experiencing SH, members with T2D demonstrate a greater tendency to utilize health care resources than those with T1D.<sup>6</sup> The true impact of these events is often underestimated by payers, with only approximately 5% of self-reported events among pharmacologically treated patients being captured by health care utilization-based surveillance.<sup>9</sup>

## Advancing T2D Management with Continuous Glucose Monitoring

Continuous glucose monitoring (CGM) represents a significant advancement in the precision management of T2D, providing members with the ability to receive a virtually uninterrupted stream of information about the current physiology of their disease. Real-time CGM (rtCGM) takes this technology a step further, providing active, ongoing feedback according to which members can make medication and lifestyle adjustments without actively scanning a sensor. Real-time CGM also provides alerts and notifications of impending high and/or low glucose, allowing for proactive rather than reactive adjustment on the part of the user to prevent hyper/hypoglycemic events. These features are coupled with the availability of cloud-based data sharing with providers and family members to extend the care circle and enhance patient engagement in the challenging discipline of T2D management. To date, rtCGM has demonstrated improvements over blood glucose monitoring (BGM) in terms of traditional metrics, such



as HbA1c, in addition to more sophisticated measures, such as time in range (TIR), time above range (TAR), and time below range (TBR).<sup>10,11,12,13</sup> TIR, specifically, has been endorsed by leading professional organizations in endocrinology and translates to improvements in tangible outcomes, such as micro/macrovascular complications and hypoglycemia.<sup>14,15</sup>

## A Growing Body of Evidence Supports the Value of rtCGM in T2D

Owing to improved glycemic outcomes and reduced resource utilization, rtCGM has demonstrated real-world cost savings in plan members with T2D in prospective and retrospective analyses. In the Intermountain Healthcare/SelectHealth network, 99 members (n=93 T2D, mixed regimens) were randomized for analysis, including 50 assigned to rtCGM and 49 assigned to BGM.<sup>16</sup> Real-time CGM users demonstrated significantly reduced HbA1c ( $P=0.001$ ), total visits ( $p = .009$ ), ED encounters ( $P=0.018$ ), and labs ordered ( $P=0.001$ ). Among SelectHealth non-Medicare Advantage members, savings amounted to \$417 per member per month (PMPM) for rtCGM users compared with BGM users. Similarly, a retrospective cohort analysis including 571 patients with T2D treated with intensive insulin therapy (IIT) and non-intensive therapies (NIT) from the Optum Research Database demonstrated a reduction of \$424 PPPM in diabetes-related medical care costs after initiating rtCGM.<sup>17</sup> PPPM reductions were driven, in part, by reductions in diabetes-related inpatient medical costs, including inpatient hospital stays and hospital days.

## The Latest Findings Supporting Expanded Coverage of rtCGM for Insulin-Treated T2D

Results of two new studies published in *JAMA* highlight the role of rtCGM in the optimal management of T2D. In tandem, the results of these studies exemplify the rigor of a randomized controlled trial (RCT) complemented by real-world evidence from usual care settings.

**The MOBILE Study** followed 175 adults with basal insulin-treated T2D over 32 weeks at 15 primary care centers.<sup>18</sup> The primary endpoint was a significant 1.1% HbA1c reduction from baseline in the rtCGM group without a significant increase in insulin doses or non-insulin medications. From a quality-focused perspective, 61.5% more participants in the rtCGM group were able to achieve a HEDIS-compliant HbA1c <8% than participants in the BGM group. Real-time CGM users also demonstrated improvements in terms of TIR (70-180 mg/dL; 3.6 more hours/day) and time spent in hypoglycemia (>250 mg/dL; 3.6 fewer hours/day) compared with BGM users. Overall, the rtCGM group demonstrated greater glycemic improvement despite the administration of fewer medications (insulin, non-insulin medications) than the BGM group. Furthermore, rtCGM reduced the incidence of hypoglycemia events/week, and the clinical benefits of rtCGM were consistent across diverse racial/ethnic backgrounds comprising 52% of the study population.



**A real-world study conducted by Kaiser Permanente of Northern California** used a propensity score-matched cohort analysis to compare rtCGM with BGM (12 months pre/post rtCGM initiation) among 30,407 members with insulin-treated T2D.<sup>19</sup> Real-time CGM resulted in a statistically significant advantage over BGM, including a 0.56 reduction in HbA1c. This HbA1c difference favored rtCGM across all ages (33-79 years), baseline HbA1c levels (7.1%-11.6%), education levels, and diabetes numeracy. In terms of resource utilization, rtCGM resulted in a 51% reduction in ED visits and hospitalizations, a reduction in outpatient visits, and an increase in telephonic visits. These latter findings demonstrate increased patient engagement without increased in-person visits, representing potential cost savings. In addition, improvement in HEDIS-compliant HbA1c was demonstrated for rtCGM across several measures, including a 12.5% increase in members with HbA1c <7%, a 17.7% increase in members with HbA1c <8%, and a 10.8% decrease in members with HbA1c >9%.

According to researchers and leading clinicians, the recently published studies demonstrate the benefit of rtCGM in members with T2D is at least equal to that in members with type 1 diabetes (T1D).<sup>20</sup> In fact, the blood sugar control associated with rtCGM in these studies was noted as being similar to that attained by starting a new diabetes medication. Therefore, in addition to providing superior glycemic control and reducing costs through the avoidance of outpatient visits, ED visits, and hospitalizations, rtCGM demonstrates value for payers as an alternative to increased pharmacotherapy utilization. As a result, these clinicians are calling for increased access to rtCGM for insulin-treated members with T2D.<sup>5</sup>

## **Leveraging rtCGM Benefit Design and Coverage Criteria to Improve Outcomes and Reduce Costs in T2D**

In 2021, an expert panel of clinicians representing the American Diabetes Association (ADA), Endocrine Society, and American Academy of Clinical Endocrinologists (AACE) determined that current payer CGM coverage criteria through the durable medical equipment (DME) benefit are both overly restrictive and not supported by scientific evidence.<sup>21</sup> The panel noted that use of CGM in patients with T2D confers significant benefit in HbA1c, TIR, TBR, and hospitalizations regardless of insulin regimen. However, most physicians cite that prior authorizations delay patient treatment and negatively impact clinical outcomes.<sup>15</sup> Therefore, many patients who would benefit from CGM do not meet current criteria, and care disparities compound these challenges. The latest consensus guidelines from ADA and AACE strongly recommend CGM for patients on intensive insulin therapy and recommend CGM for patients on other forms of insulin therapy.<sup>22,23</sup>



In light of these guidelines and mounting evidence, the Centers for Medicare and Medicaid Services (CMS) eased its restrictions on CGM coverage for insulin-using Medicare beneficiaries with respect to daily fingerstick requirements.<sup>24</sup> Many commercial payers have likewise enacted more amenable criteria for CGM, including coverage under the pharmacy benefit instead of the DME. These payers often realize immediate cost savings under the pharmacy benefit, in addition to the savings that will presumably result from improved outcomes and reduced resource utilization facilitated by CGM uptake among clinically appropriate plan members with insulin-treated T2D. This coverage can be enacted by comparing the fee schedule for CGM through the DME to contracted rates via the pharmacy benefit. Finally, a smart edit featuring an automated look back in claims data for a previous insulin prescription can be used as the criterion for approval with real-time adjudication, easing the administrative burden for payers and providers and streamlining access for members. These steps serve as a basic blueprint for payers to apply the latest evidence in advancing T2D management with optimal outcomes and cost reduction.

Collectively, the recently published studies delineating improved clinical outcomes and cost savings associated with rtCGM in insulin-treated T2D—in conjunction with consensus treatment recommendations—indicate that more widespread coverage of diabetes technology is warranted. By easing current restrictions on rtCGM, removing fingerstick test requirements, and applying a diagnosis of T2D with any prior insulin prescription as the sole criteria for coverage, payers can position this intervention for appropriate prescribing under the pharmacy benefit and realize immediate savings in addition to increased patient engagement, enhanced self-management, and improved outcomes in a costly and refractory disease state.



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