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Avalere Health | An Inovalon Company

# Advancing Diabetes Care in the Era of CGM

## Dialogue Proceedings

April 2021



*Beyond Type 1*

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# Executive Summary

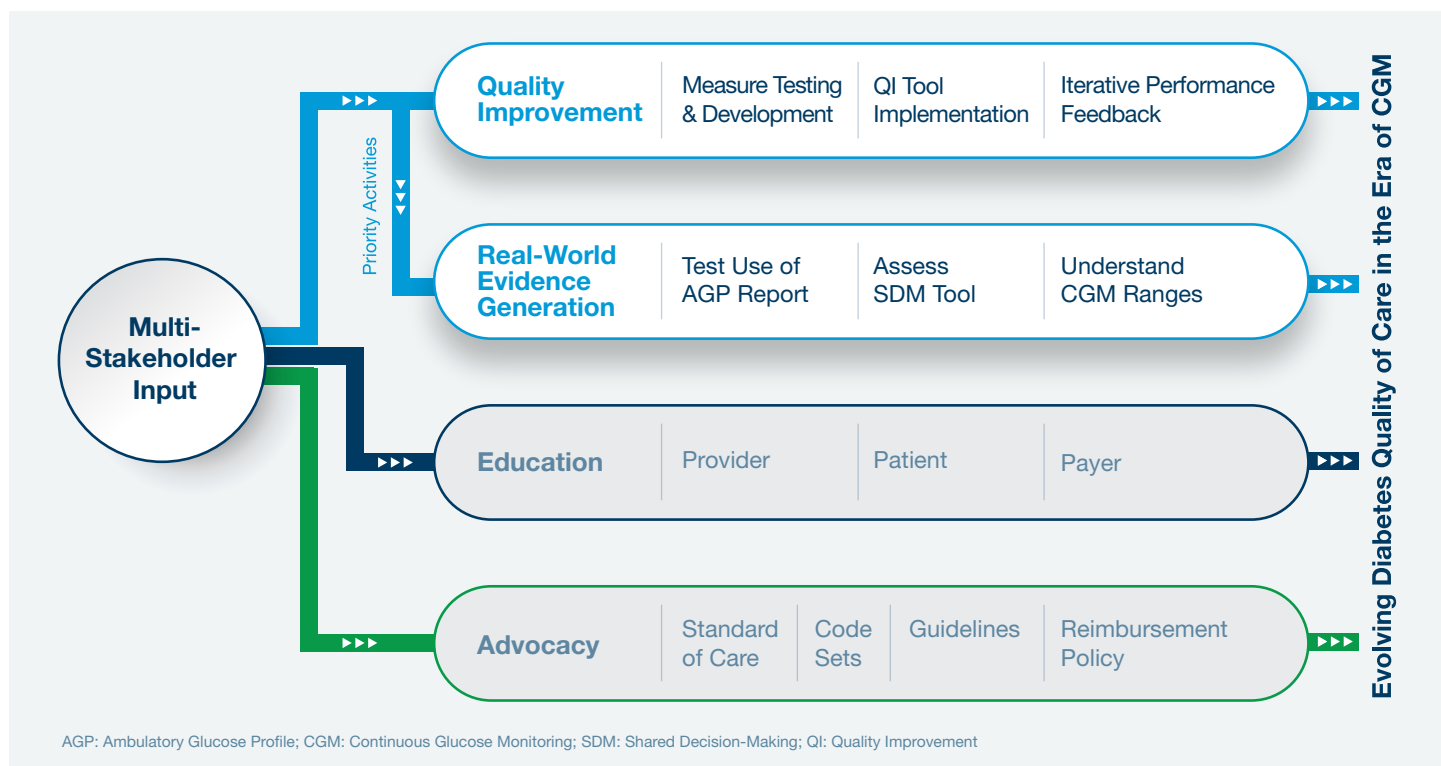
As one of the most common chronic conditions in the United States (US)—affecting approximately 10.5% of the US population and growing—diabetes (and the optimal management of this condition) remain a persistent healthcare challenge.<sup>i</sup> In order to document glycemic state and variations, most people with diabetes (PWD) perform self-monitoring of blood glucose (SMBG), which involves pricking the finger to provide blood glucose data at singular moments,<sup>ii</sup> and complete glycated hemoglobin (HbA1c) testing, which provides data about average glucose control over the past 2–3 months. Even with frequent, routine testing, neither provides complete data about blood glucose trends and fluctuations.<sup>iii</sup>

Continuous glucose monitoring (CGM) uses a wearable device to collect data and provide patients and clinicians with real-time feedback on blood sugar levels.<sup>iv</sup> Despite potentially providing PWD better data, current use of CGM technology is concentrated

among people with Type 1 diabetes (T1D).<sup>v</sup> Most people with Type 2 diabetes (T2D), which account for 95% of all diabetes patients, are managed by primary care physicians (PCPs), which have yet to widely adopt use of CGM.<sup>vi</sup>

Currently, no CGM-related diabetes quality measures and associated incentives exist, which may inhibit broader adoption. Developing such metrics has the potential to facilitate shared decision-making between patients, improve PWDs’ understanding and management of their diabetes, and offer providers more comprehensive data with which to assess quality of diabetes care. In November 2020, Avalere Health and Beyond Type 1 (BT1) convened a national dialogue meeting, “Advancing Diabetes Care in the Era of CGM,” to consider gaps in diabetes quality of care and identify actionable steps to address them.

**Figure 1. Priority Domains of the Framework /**





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The meeting was attended by PCPs, endocrinologists, quality experts, policy experts, and payers, all of whom are active in the diabetes space. Following an overview of ongoing CGM-related activities, Avalere, BT1, and participants discussed the central barriers to CGM use for PWD. A few barriers were identified as the most pressing to address, including low patient and provider education, inadequate provider reimbursement, high patient out-of-pocket costs, and access disparities.

Focusing on the need for quality improvement and evidence generation, participants considered a variety of solutions to address these barriers, including:

- Quality Improvement Initiatives
- Merit-Based Incentive Payment System (MIPS) Improvement Activities
- Alternative Payment Models

These solutions are interrelated, allowing them to be implemented in isolation or sequentially to progress from quality improvement programs and measure development and testing to overall health system transformation. After significant discussion, participants recommended first establishing a quality improvement initiative to set the stage for broader measure adoption and use.

In 2021, diabetes stakeholders will partner to build upon these recommendations by launching the initiative and developing initial CGM-related quality measures. The goal of these and subsequent efforts will be to leverage input from diverse diabetes stakeholders to establish an initiative that advances the quality of diabetes care in the era of CGM (Figure 1).

*Support for the dialogue was provided by Abbott.*

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# Background

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Diabetes is one of the most common chronic conditions in the United States (US). The Centers for Disease Control and Prevention (CDC) estimates that in 2018, 34.2 million people had diabetes, representing 10.5% of the US population.<sup>i</sup> Over the past 2 decades, age-adjusted prevalence of total diabetes among US adults has steadily increased, and approximately 88 million—or 1 in 3—US adults currently live with prediabetes. Of the 26.9 million people with diagnosed diabetes, 1.4 million adults report both having Type 1 diabetes (T1D) and using insulin.

The prevalence of diabetes varies significantly by race/ethnicity and education level. Diabetes is most prevalent in American Indian/Alaska Native (14.7%), Hispanic (12.5%), and non-Hispanic Black (11.7%) populations.<sup>ii</sup> Populations with lower levels of education—defined as less than a high school education—also experience greater prevalence of diabetes relative to populations with more than a high school education.

Diabetes is a growing driver of healthcare utilization and costs. In 2016, a total of 224,000 emergency department visits were reported among patients with diabetes experiencing hyperglycemic crisis, with an additional 235,000 reported for patients with diabetes experiencing hypoglycemia.<sup>ii</sup> According to an American Diabetes Association (ADA) analysis, 1 in 4 US dollars spent on healthcare in 2017 went towards the care of patients with diabetes. Across people with either T1D or Type 2 diabetes (T2D), direct healthcare spending on diabetes in 2017 totaled \$237 billion.<sup>iii</sup> As the prevalence, complications, and costs of care of diabetes continue to increase, innovative approaches have emerged to enhance diabetes management and prevent acute complications.

Self-monitoring of blood glucose (SMBG) and glycated hemoglobin (HbA1C) testing are commonly used in glycemic management for people with diabetes (PWD) as well as in clinical research to document glycemic states and variations.<sup>iv,v,vi</sup>

In a 2016 CDC survey, 60.9% of all adults with diagnosed diabetes reported self-monitoring their blood sugar at least once daily,<sup>vii</sup> while other estimates report over 75% of people with non-insulin-treated T2D regularly self-monitor their blood glucose.<sup>viii</sup>

SMBG involves pricking the finger to provide blood glucose data at singular moments.<sup>ix</sup> The efficacy of SMBG in improving HbA1C levels and preventing glycemic crises for various populations of people with diabetes has been widely debated.<sup>x,xi</sup> A1C testing provides information about average glucose control over the previous 2–3 months; both SMBG and A1C testing provide little data on blood glucose trends and fluctuations.<sup>xii</sup>

Relative to SMBG and A1C testing, continuous glucose monitoring (CGM) offers greater amounts of blood glucose information, providing a longitudinal patient glycemic profile without regular finger stick blood tests. CGM uses a wearable device to collect data and provide patients and clinicians with real-time feedback on blood sugar levels.<sup>xiii</sup>

Insurance coverage for CGM devices varies by payer depending on type of diabetes (Type 1 vs. Type 2) and type of CGM use (long term vs. short term). CGM is frequently covered for management of T1D but not T2D. For Medicaid-enrolled patients, coverage eligibility varies between states; 35 state Medicaid programs have at least some coverage for CGM, 14 of which provide coverage for both T1D and T2D.<sup>xiv</sup> For Medicare patients, CGM is covered to varying degrees under Part B depending on type of diabetes and type of CGM device.<sup>xv</sup>

CGM is classified as professional<sup>1</sup> or personal CGM.<sup>2</sup> Personal CGM is classified as either therapeutic or non-therapeutic CGM.<sup>xvi</sup> ADA recommends CGM use by all multiple daily injection (MDI) patients (T1D and T2D). ADA also recommends CGM for some T2D non-insulin patients.<sup>xvii</sup>

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1. Professional CGM (P-CGM) involves the patient wearing a provider-supplied CGM device for a period of time, during which robust blood glucose data are collected. Data are later analyzed by the provider and patient to identify patterns and potential treatment improvements.

2. Personal or Real-time CGM (RT-CGM) devices allow patients to access their blood glucose information automatically by transmitting data to compatible smart devices. Many CGM devices also allow patients to share their data with their providers and receive alerts for changing glucose levels.

First approved by the Food and Drug Administration (FDA) in 1999, CGM technology has experienced significant growth in both sophistication and use over the past 5 years, although overall use remains limited.<sup>xviii</sup>

Current use of CGM technology is heavily concentrated among people with T1D; in 2018, 30% of Americans with T1D were using a CGM device.<sup>xix</sup> T1D is often diagnosed at a younger age and managed by endocrinologists who may have access to patient educators and other specialized diabetes resources that support patient education and use of CGM. T2D, which accounts for 95% of all diabetes diagnoses, is often managed by primary care physicians and has yet to widely adopt use of CGM.<sup>xx</sup>

A lack of CGM-related diabetes quality measures and incentives may contribute to low adoption. Current diabetes quality measures rely predominantly on HbA1C metrics and provide limited insight into the state of a patient’s diabetes care. From 2013 to 2016, only 19.2% of US adults with diagnosed diabetes met combined diabetes care goals (HbA1C, blood pressure, cholesterol).<sup>3,xxi</sup> CGM, however, provides PWD additional data to inform other metrics, such as time in range (TIR), time below range, and glucose variability. There may be an opportunity to leverage these metrics to facilitate shared decision-making between patients and providers and to better assess quality of diabetes care.

# Developing Multi-Stakeholder Recommendations Through a National Dialogue

In recent years, CGM-related initiatives have focused on advocacy or patient and provider education.<sup>xxii,xxiii,xxiv</sup> To date, however, no actionable plans have been developed to advance quality of care in the era of CGM through quality measurement and evidence generation. To better understand gaps in diabetes care that could be addressed through CGM and develop actionable next steps to address these gaps, Avalere Health and Beyond Type 1 (BT1) convened a national dialogue, “Advancing Diabetes Care in the Era of CGM.”

The dialogue was held virtually and took place across 2 days on November 9 and 16, 2020. It brought together key stakeholders engaged in the delivery of care for PWD, active in diabetes policy or quality of care issues, and interested in improving care for PWD using CGM-based metrics. A diverse cross-section of stakeholders participated in the meetings, including healthcare providers, payers,

professional societies, and patient advocacy groups (Appendix A: List of Dialogue Participants).

The objectives of the dialogue were to:

- |   |  |
|---|--|
| 1 | Level set on current activities regarding standard use of CGM and diabetes quality measures  |
| 2 | Brainstorm and prioritize strategic initiatives to improve diabetes quality of care in the era of CGM (e.g., develop and test new quality measures)  |
| 3 | Develop actionable next steps for how best to advance diabetes quality of care in the era of CGM through evidence generation and quality measurement |

3. Hemoglobin A1C (<8%); blood pressure (<140/90 mmHg); cholesterol (non-high-density lipoprotein [non-HDL] <130 mg/dL)

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# State of CGM Usage and Diabetes Quality Measures

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To kick off the Dialogue, participants were invited to volunteer 1 opportunity to improve diabetes care. The wide range of responses included suggestions for improving coverage and reimbursement for CGM-related technologies and services, expanding patient access to CGM devices, and redesigning care delivery to allow for team-based care.

Three speakers presented on several CGM-related activities currently underway to advance diabetes care to provide additional context for the Dialogue and ensure a consistent understanding of the diabetes quality of care space among participants. These presentations highlighted ongoing FDA efforts to incorporate CGM metrics into regulatory decision-making, novel uses of CGM to address clinical treatment targets, and current challenges to CGM adoption (e.g., the lack of quality measures capturing time in range metrics).

Regarding ongoing FDA efforts, participants discussed the timeline for incorporating CGM metrics into FDA approval and regulatory processes. Noting the urgency of advancing both FDA and clinical quality efforts, participants agreed that FDA deliberation regarding the use of CGM metrics to inform regulatory decisions can happen in parallel with the development of external quality measures to support clinical care delivery.

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**“You get a world of data from CGM, and then we have to make a difference.”**

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**Physician**

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Participants were invited to add their insights throughout the presentations, and several points of discussion and additional observations emerged. Participants agreed that there is a need for broader use of CGM by patients with both T1D and T2D, particularly for the latter given the disproportionate burden of disease represented and

the potential for impact in that population. Participants also agreed that widespread use of CGM metrics such as time in range may be an effective and necessary driver of higher quality diabetes care. One participant noted the crucial importance of enhancing provider awareness of how to use and communicate CGM data for improving diabetes care. The applications of CGM beyond diabetes care were also noted, with examples of depression and stress detection highlighted as ways the technology can be leveraged to provide more robust and holistic patient care for PWD.

Beyond Type 1 shared patient insights about CGM-related diabetes care gaps from a digital poll of the BT1 app audience (Figure 2).

Avalere then presented evidence gaps identified from a 2019 scan of CGM-related quality measure activity and literature. Avalere’s analysis highlighted evidence gaps that may limit CGM adoption in diabetes care including the lack of long-term studies on time spent within glycemic ranges and of widely adopted shared decision-making (SDM) tools for clinicians and patients to support use of CGM.

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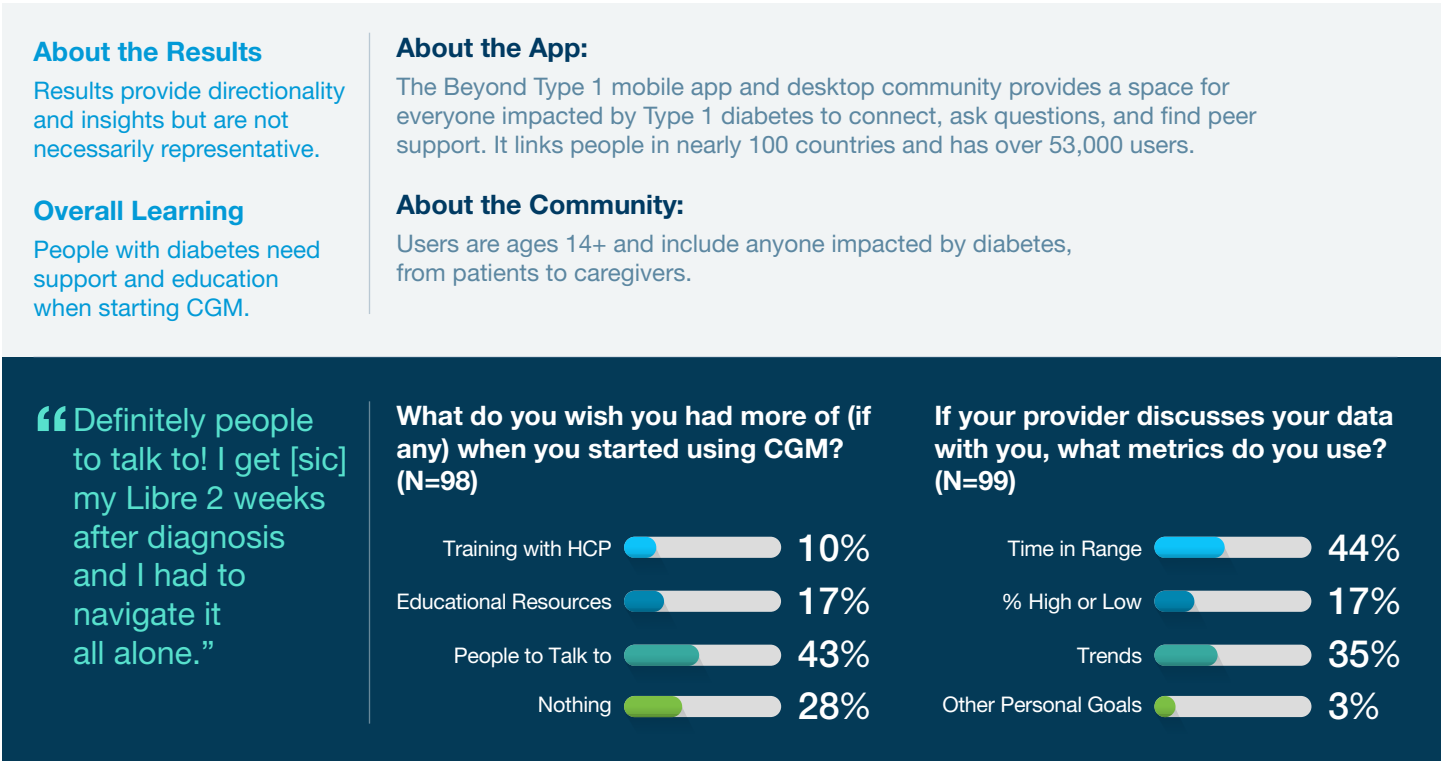
**“A1C levels don’t work great for patients; they work for measures. The ways they were written were not patient centered. A measure we’re lacking is patient-reported outcomes. CGM really lends itself to that kind of measure. How much better do patients feel with this kind of tech? How does this impact their lifestyle? How free do they feel?”**

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**Physician**

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Figure 2. Beyond Type 1 Digital Poll Results /



# Identifying and Prioritizing Barriers to CGM Use in Diabetes Care

Following the overview of ongoing CGM-related activities, participants reviewed and identified the central barriers to CGM use in diabetes care.

Though a number of barriers were discussed, a few challenges and care gaps were elevated as the most pressing to address.

Prioritized Gaps

1. There is need to engage more members of the diabetes care team (e.g., diabetes educators, PCPs, pharmacists) who can support and educate patients using CGM

2. There are patient-level access and cost barriers (e.g., out-of-pocket costs)
3. There is need for better guidance for providers to develop patient treatment plans (e.g., how to use CGM metrics, frequency of conducting professional CGM for a given patient, frequency of patient monitoring and engagement on real-time CGM report)

4. There are provider-level reimbursement barriers (e.g., reimbursement for time spent reviewing CGM readings)



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## Provider-Level Barriers /

Participants noted that, although educating patients about how to use CGM and understand CGM metrics takes time, current reimbursement mechanisms limit the amount of time providers can spend with their patients. Participants described how PWD often have multiple chronic conditions that need attention during the patient encounter with the provider, leaving limited time for providers to sufficiently educate patients on the use of CGM.

Along these lines, although endocrinologists, who predominantly oversee the care for patients with T1D, are more likely to have a supportive care team that includes a certified diabetes care and education specialist, PCPs have more limited staff resources and infrastructure. Participants noted the urgency to address these care team gaps, especially because PCPs oversee the majority of patients with T2D, who represent a significant majority of all PWD.

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“The average amount of time a PCP spends with a patient is around 5–10 minutes. That is not enough time to properly care for a diabetic patient.”

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**Physician**

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“The addition of a certified diabetes care and education specialist to a primary care practice can really be a great benefit.”

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**Diabetes Care & Education Specialist**

## Patient Barriers /

Regarding patient access to CGM, participants highlighted the need for provider and coverage support in expanding use of CGM. In order to access CGM, patients with T1D may face high out-of-pocket costs. Moreover, due to limited available evidence demonstrating the benefits of CGM for patients with T2D, many payers do not cover continuous CGM for this population at all.

Dialogue participants also discussed racial and ethnic disparities in access to CGM and specialized diabetes care and emphasized that CGM should be available to broader populations, including Black, Indigenous, and People of Color. The high out-of-pocket costs described above are exacerbated in these populations, further limiting their access to new technology. Participants called out the need for studies to incorporate diverse patient populations and for more data to highlight disparities in access to CGM, particularly among People of Color.

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“There’s a distinction between coverage and true out-of-pocket costs. Many people have ‘good coverage’ when their out-of-pocket costs are \$2,000–\$3,000 a year.”

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**Healthcare Executive**

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“The only quality data that CGM helps A1C come from real-time studies. If you want to stick to what exists in evidence, you throw out CGM and T2D and tons of people that benefit clinically. The guidelines are vague so that we can apply this evidence to these otherwise excluded populations.”

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**Physician**

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4. Patient insights were reflective of BT1 app “super-users.”



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## Prioritization of Gaps /

Following the discussion, participants aligned on a list of 10 gaps, taking into consideration their relevance to patients and providers and their feasibility of being mitigated through quality and evidence

generation strategies; 4 top-priority gaps emerged (see “Prioritized Gaps” above). Ideas and outputs were generated via videoconference, chat discussion, and polling exercises.

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### Additional Gaps

- There are not widely adopted shared decision-making tools for clinicians and patients to support informed patient use of CGM
- Patients and providers may not understand how to interpret and modify treatment plans using the AGP report
- There is need for long-term studies to understand the impact to patient outcomes (e.g., complications and comorbidities, hospitalizations, QoL) based on time spent within glycemic ranges using CGM
- There is need for additional evidence to support CGM use in patients with T2D
- There is need to better understand and collect data on patient-reported outcomes (e.g., fear of hypoglycemia, quality of life.) for CGM users
- There is not a consistent way to capture CGM data and metrics in EHRs

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# Solutions to Address Barriers in Diabetes Care

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After reviewing and prioritizing gaps, participants proposed potential solutions to address these gaps and advance diabetes quality of care. To help ground this conversation in the priority domains of the framework (Figure 1), Avalere shared case studies of innovative local and national initiatives that employ quality measurement and evidence generation strategies to improve quality of care. For example, Avalere described the Malnutrition Quality Improvement Initiative, which progressed from a local demonstration project to a national quality improvement initiative that provides clinicians with education and tools to improve the quality of malnutrition care and measures to assess their progress, benchmark their care, and identify opportunities for further improvement.

Avalere also described the CONCERT initiative, which initiated as a local pilot to test a system-level referral pathway for patients with irritable bowel disease. The goal was to one day support policy

changes that would enable the local demonstration to be implemented as an alternative payment model (APM) based on tested measures.

Participants identified a spectrum of solutions grounded in quality improvement and evidence generation (Figure 3). These solutions are interrelated and build on the same quality framework. Therefore, these solutions can be implemented in isolation or sequentially to progress from quality measure development, testing, and use to overall health system transformation.

All solutions drive toward developing measures that are ultimately adopted into CMS programs (e.g., the Quality Payment Program [QPP]), used to assess clinician performance and linked to payment. However, dialogue session participants emphasized the principle of “thinking big but starting small.” In particular, because broad use of CGM is relatively new, a number of test measures may need to be developed and tested

before CGM can be upheld as the standard of care for patients with diabetes. These measures could evolve over time into quality measures or serve as the foundation for future iteration of measures.

Moreover, the path to measure adoption and use takes time, so participants supported an incremental approach with key milestones throughout the process.

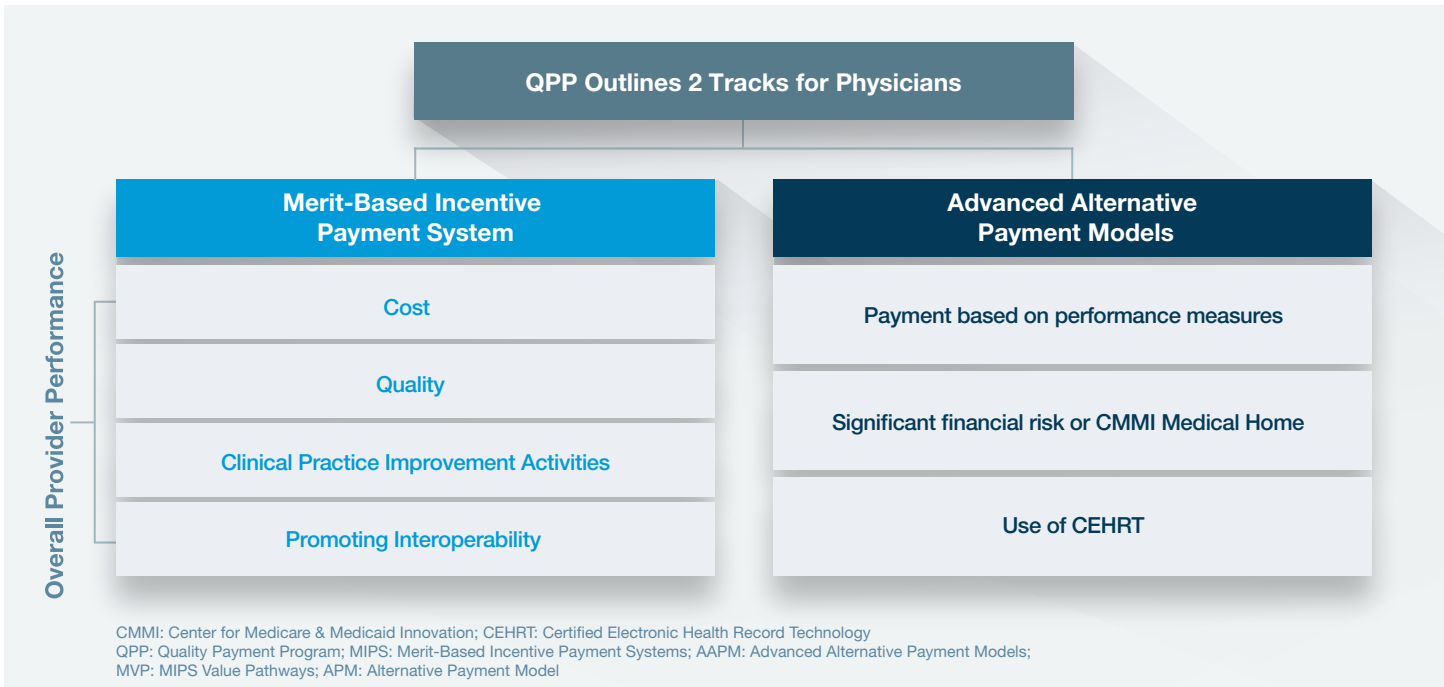
Figure 3. Spectrum of Solutions to Address the Gaps Prioritized in Prior Sessions /



The Quality Payment Program comprises of 2 components: the Merit-Based Incentive Payment

System and Advanced APMs (Figure 4).

Figure 4. Overview of QPP /



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# Quality Improvement Initiative

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Quality improvement initiatives are designed to address barriers to optimal care and drive performance improvement. These initiatives provide partners with the information, tools, and expert support needed to improve care and health outcomes, as measured using quality measures. Initiative leaders may provide technical assistance and other ongoing support to build knowledge and skills and implement interventions. The data generated by quality improvement initiatives can be used to refine an intervention prior to further deployment.

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“But a single narrative [to demonstrate value of CGM] is good. [...] There’s data out there that shows in some situations there’s value [to using CGM for more patients], but how much value?”

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## Payer

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A quality improvement initiative could be structured as a pilot study to expand use of CGM technology to broader populations receiving care in an outpatient practice. The pilot would leverage the skills and expertise of the broader diabetes care team, including diabetes educators and pharmacists, and implement tools (e.g., shared decision-making tools) to facilitate patient engagement around use of CGM technology and data. To support implementation, initiative leadership would develop a clinical practice workflow and toolkit, featuring new and existing tools (e.g., measures, benchmark reports).

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“The problem with [CGM-efficacy] data is that studies have to keep up with the pace of technological advancements.”

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## Physician

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Measurement is fundamentally central to a quality improvement initiative, and the outpatient practice would select, adopt, and test CGM or TIR-related quality measures to generate data and support measure refinement. Data generated by participating practices could also be used to assess which aspects of care are currently being provided well, and which require additional resources or education, thereby supporting rapid cycle improvements in care delivery.

Although a quality improvement initiative would not initially be relevant to all healthcare stakeholders (e.g., payers), it would tee up a pathway to value. Participants generally agreed that quality improvement focused on the use of CGM would be an important first step to advancing diabetes quality of care, provided that it complements other related efforts in the diabetes space.

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# Improvement Activities

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As 1 of the 4 components of MIPS, the Clinical Practice Improvement Activities performance category assesses clinicians' participation in clinical activities (e.g., shared decision-making, screening) that support the improvement of clinical practice, care delivery, and outcomes.<sup>xxx</sup>

In 2021, Improvement Activities comprise 15% of a clinician's overall MIPS score. In order to meet requirements for this category, clinicians must report between 1 and 4 improvement activities over a continuous 90-day period.<sup>xxxi</sup>

Each year, CMS calls on organizations, including professional associations, medical societies, and research groups, to submit improvement activities for inclusion in MIPS. CMS typically seeks improvement activities that can elevate the standard of care and exceed defined, commonly accepted guidelines for level of quality or attainment in clinical care or quality improvement guidelines.<sup>xxxii</sup> Although improvement activities undergo a rigorous review process, the submission requirements (e.g., level of evidence) to submit a successful improvement activity are generally lower than that of a quality measure.

Dialogue session participants agreed that MIPS improvement activities could be designed to support shared decision-making as well as patient and provider education. For example, many patients do not know how to interpret CGM reports, so one improvement activity may be "clinician reviews CGM reports with patients."

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**"[Improvement Activities are] the lowest bar in MIPS to jump over. ... For primary care, the return on investment is not great."**

**Physician**

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Participants indicated that implementing an improvement activity could be accomplished in the short term with low effort and could therefore represent an early "win." However, many expressed concerns that improvement activities would not yield significant provider behavior change. Improvement activities may be developed in parallel to initial measures and tested as part of a quality improvement initiative, but they are unlikely to achieve desired results if implemented in isolation.

## MIPS Overview /

Under MIPS, eligible clinicians are assessed on performance for 4 program components: Quality, Improvement Activities, Promoting Interoperability, and Cost. Clinicians submit data for all categories except Cost, for which CMS uses claims data to assess clinician performance.

CMS aggregates a clinician's performance on all 4 categories to arrive at an overall performance score, which determines payment adjustments applied to Medicare Part B claims.<sup>xxviii</sup>

Beginning in 2022, CMS indicated it would be implementing MIPS Value Pathways (MVPs) consisting of streamlined and complementary sets of measures and activities that are meaningful to clinicians. MVPs will be grouped by clinician specialty (e.g., endocrinology, family medicine) or patient diagnosis (e.g., T2D) with the goal of producing comparative performance data that are valuable to patients and caregivers.<sup>xxix</sup>



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# Alternative Payment Models

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An APM is a customized payment approach designed to incentivize healthcare providers who deliver high-quality, high-value care.<sup>xxxiv</sup> APMs can focus on specific clinical conditions, care episodes, or populations. All APMs aim to shift clinician payments away from fee-for-service models and into models that reward value over volume of services.<sup>xxxv</sup> However, not all APMs are considered Advanced APMs.<sup>xxxvi</sup>

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“An APM for diabetes would set payment goals that are reasonable for any physician who wants to get paid for the time it actually takes to properly care for a diabetic patient.”

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**Physician**

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Because APMs implement innovative payment approaches, they may be well-suited to address the provider-level reimbursement barriers identified by dialogue session participants, including lack of reimbursement for time spent reviewing CGM readings and educating patients about use of CGM as well as reimbursement for the diabetes care team. Under a flexible payment arrangement, such as global or capitated model, health systems can finance these high-value activities that have not traditionally been reimbursed under fee-for-service models.

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“[Diabetes care] should compensate based on time, regardless of what [conditions the patients] has. It has to be a holistic, primary care-focused APM. ”

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**Physician**

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Most participants felt that although designing and implementing an APM would address many key barriers to advancing diabetes quality of care in the era of CGM, additional evidence generation was needed to pursue this solution. For this reason, the APM solution would be well suited as a secondary effort that could build on efforts to generate evidence and measures, such as a quality improvement initiative.

## APM Overview /

Payment reform and proliferation of APMs are happening in both the public and private sector. Annually, CMS identifies which public and private sector APMs meet Advanced APM criteria (Figure 4). CMS offers a 5% incentive for achieving threshold levels of payments or patient counts through an Advanced APM.<sup>xxxiii</sup>

# Next Steps

After considering the merits and potential impact of each solution identified, it was determined that a quality improvement initiative should be established as an important first step to facilitating broader measure adoption and use. As noted above, implementing a quality improvement initiative would not preclude pursuit of the other potential solutions, either in parallel (e.g., alongside a MIPS improvement activity) or down the line (e.g., followed by an APM).

“We need to generate data and insights. Then, bring [the initiative] back to an APM.”

Payer

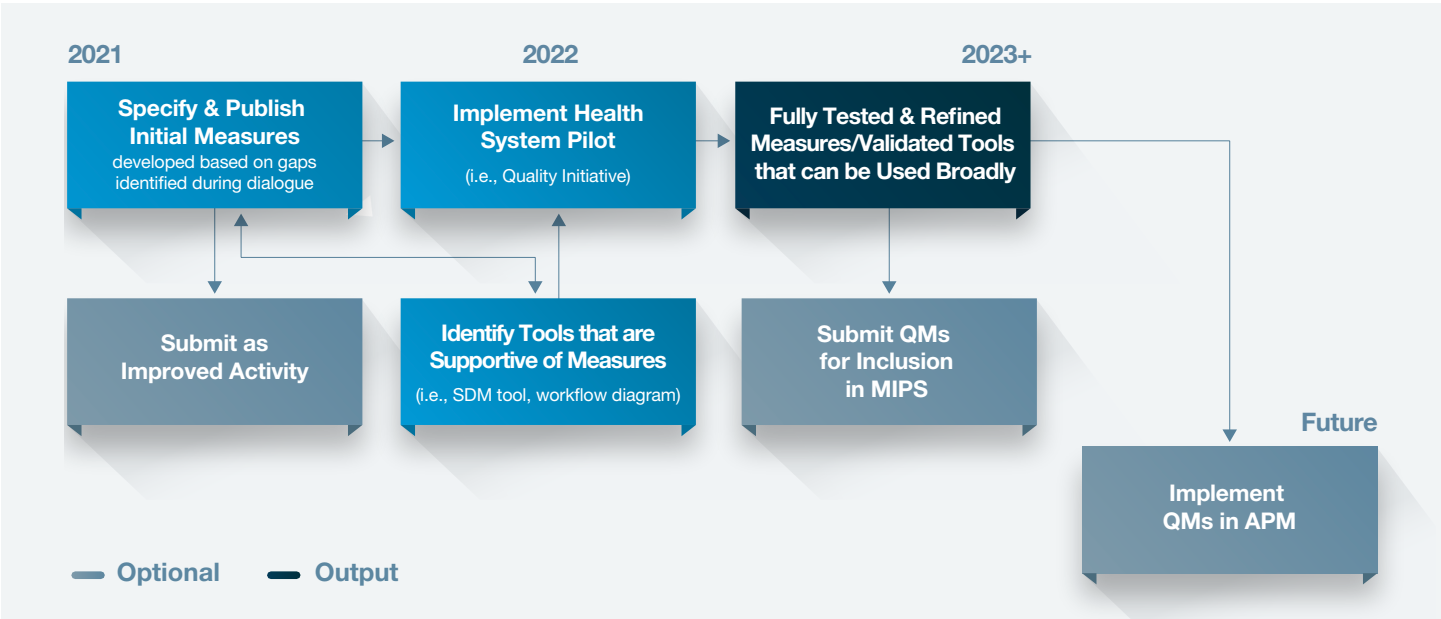
In 2021, Avalere will partner with other diabetes stakeholders to launch the initiative and build out measure concepts initially developed in 2020 with input from a technical expert panel (Appendix B: Measure

Concepts). As a first step, Avalere will establish initiative leadership, which will include an initial sponsor, project visionaries, and an advisory group. Additionally, the initiative leadership team will oversee the measure development process, identify tools that support measures, and initiate the quality improvement pilot in a health system (Figure 5). In future years, the initiative will aim to assess the feasibility of implementing the tools and test measures in health systems to set the stage for future tool and measure adoption (Figure 6).

“There is a continuum at the payer level. We need to create pathways to value and say, “We are going to reimburse you for these 6 measures” to try to get you prepared to take on more risk.”

Physician

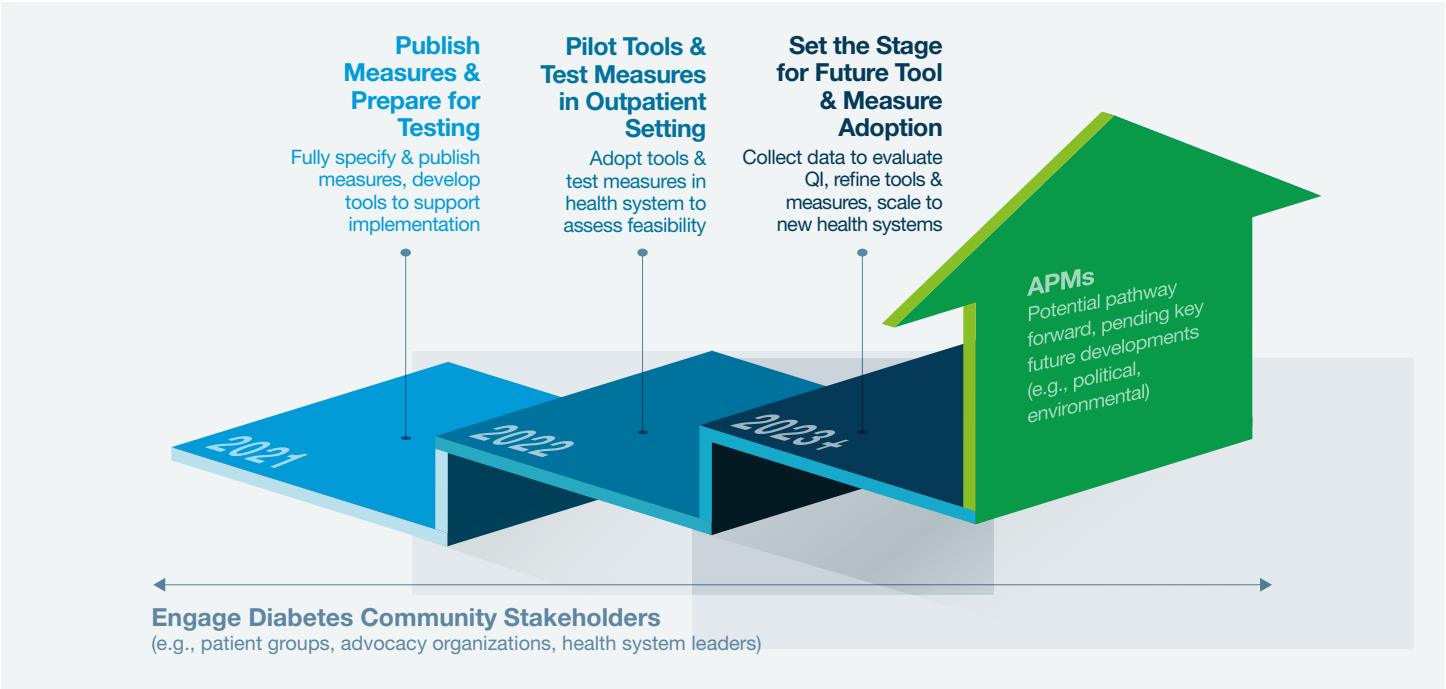
Figure 5. In 2021, Avalere Will Test Measures & Tools to Support Future Adoption in Accountability Programs /



This will lay the foundation for further evidence generation and inform any needed refinements to the measures. The initiative will be interdisciplinary and collaborative in nature, taking into account the needs and perspectives of stakeholders across the diabetes

landscape throughout the initiative to produce solutions that will benefit broad segments of the diabetes stakeholder space. Ultimately, this collaborative and cross-functional initiative will achieve the aims of advancing quality of diabetes care in the era of CGM.

Figure 6. The Path Forward /



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# Appendices

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## Appendix A: List of Dialogue Participants /

Name <sup>5</sup>	Organization
Alicia McAuliffe-Fogarty, PhD, CPsychol	Beyond Type 1
Amy Mullins, MD, CPE, FAAFP	American Academy of Family Physicians
Anne Peters, MD	University of Southern California, Keck School of Medicine
Campbell Hutton, MSPH	JDRF International
Charles Alexander, MD, FACP, FACE	JDRF International
Dave Walton, MBA	T1D Exchange
Gary Puckrein, PhD	National Minority Quality Forum
Howard Lando, MD, FACP, FACE	American Association of Clinical Endocrinologists
Kelly Close, MBA	Close Concerns and diaTribe
Kenneth Snow, MD, MBA	CVS Health
Osagie Ebekozen, MD, MPH, CPHQ	T1D Exchange
Patricia Scalzo, NP, CDE	Association of Diabetes Care & Education Specialists
Richard M. Bergenstal, MD	Park Nicollet, International Diabetes Center
Robert Gabbay, MD, PhD	American Diabetes Association
Sean Sullivan, PhD	Helmsley Charitable Trust
Todd Prewitt, MD, FAAFP	Humana

5. The meeting was held under the Chatham House Rule, and the views expressed were solely those of individual participants and not of their affiliated organization(s).



## Appendix B: Measure Concepts /

Rank	Concept	Description	Measure Type	Rationale for Measure
1	Type 1 or Type 2 diabetes patients who engaged in shared decision-making with a clinician regarding the use of a personal CGM. <sup>6</sup>	The percentage of patients ages 18 and older with a diagnosis of diabetes (Type 1 or Type 2) for whom a physician or other clinician engaged in SDM with the patient on the use of a CGM.	Process	<ul style="list-style-type: none"> <li>Measure would encourage clinicians to identify patients who would benefit from CGM and engage in SDM.</li> <li>SDM helps patients understand the benefits (and potential challenges) of CGM and the importance of consistent use.</li> <li>Measure could minimize payer concerns that patients use CGM inconsistently, which contributes to economic waste.</li> </ul>
2 <sup>7</sup>	CGM Metric: Patients that had a time below range (TBR) greater than recommended level. <sup>8,9</sup>	The percentage of patients, with a diagnosis of diabetes (Type 1 or Type 2) that met the appropriate ranges for TBR level 1 and level 2. <sup>10</sup>	Outcome	Measure would provide clinicians with data needed to support treatment plan modifications and improve patient outcomes.
2	CGM Metric: Patients that met the appropriate time in range (TIR) for the sub-population. <sup>11</sup>	The percentage of patients, with a diagnosis of diabetes (Type 1 or Type 2) that met the appropriate ranges for TIR	Outcome	Measure would provide clinicians with data needed to support treatment plan modifications and improve patient outcomes.
2	CGM Metric: Patients that had a time above range (TAR) greater than recommended level. <sup>12,13</sup>	The percentage of patients, with a diagnosis of diabetes (Type 1 or Type 2) that met the appropriate ranges for TAR level 1 and level 2	Outcome	Measure would provide clinicians with data needed to support treatment plan modifications and improve patient outcomes.
3	Patients on CGM who had a treatment plan developed or modified.	The percentage of patients ages 18 and older with a diagnosis of diabetes (Type 1 or Type 2) on a continuous glucose monitor (CGM) who had a treatment plan developed based on the CGM results.	Process	May result in earlier identification of noncompliance issues, which supports modification of the treatment plan as needed.
4	Patients who had their personal CGM results reviewed by a clinician.	The percentage of patients ages 18 and older with a diagnosis of diabetes (Type 1 or Type 2) on a CGM who had a treatment plan developed based on the CGM results.	Process	Enables clinicians to identify patients who are experiencing hypoglycemia and modify their treatment plan.

6. Patient must have had at least 2 severe hypoglycemic events, have hypoglycemia unawareness, have MDI or be on an insulin pump in the past 12 months to be included.

7. Avalere recommends developing at least 1 of the 3 CGM metrics listed here (all ranked #2 in this list). We prioritized TBR because it was identified at the dialogue session as a valuable metric. However, it will ultimately be the TEP's discretion which of the CGM metrics is the highest priority.

8. TBR (Level 1): The goal is to have <4% of their readings, or less than 1 hour, at a glucose level between 54 and 69 mg/dL for those that do not have high risk factors.

9. TBR (Level 2): The goal is to have <1% of their readings, or less than 15 minutes, at a glucose level <54 mg/dL for those that do not have high risk factors.

10. TEP to determine the age range that would be appropriate for all "CGM Metric" measure concepts.

11. A TIR is defined as having a reported glucose level between 70 and 180 mg/dL (i.e., range). Time is denoted in either percentage of time per day or hours/minutes per day. The percentage of time in range varies based on the group. For Type 1 or Type 2 patients that are 18 and older, the goal is to have greater than 70% of their readings or greater than 16 hours and 48 minutes in range in a day. However, the goal is relaxed for older adults (65 years and older), with a goal of having these patients with greater than 50% of their readings or greater than 12 hours in range in a day.

12. TAR (Level 1): The goal is to have <25% of their readings, or less than 6 hours, at >180 mg/dL for those that do not have high risk factors.

13. TAR (Level 2): The goal is to have <5% of their readings or less than 1 hour and 12 minutes at >250 mg/dL for those that do not have high risk factors.

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