HERC Coverage Guidance

Real-time continuous glucose monitoring (CGM) is recommended for coverage (weak recommendation) in adults with type 1 diabetes mellitus:

- who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit and
- who have baseline HbA1c levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM).

Real-time CGM is recommended for coverage (weak recommendation) in children and adolescents under age 21 with type 1 diabetes who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Real-time CGM (including the CGM-enabled insulin pump) is recommended for coverage (weak recommendation) in adults with type 1 diabetes on insulin pump management who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Real-time CGM is not recommended for coverage in adults with type 2 diabetes (weak recommendation).

Real-time CGM is not recommended for coverage in children and adolescents with type 2 diabetes (strong recommendation).

Retrospective CGM is not recommended for coverage in patients of any age with type 1 or type 2 diabetes (strong recommendation).

CGM is not recommended for coverage during pregnancy for type 2 diabetes or gestational diabetes (weak recommendation).

CGM is recommended for coverage for women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels (weak recommendation).

Note: Definitions for strength of recommendation are provided in Appendix A GRADE-Informed Framework Element Description.
RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as they seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of the Affordable Care Act and health system transformation, reaching these goals may require a focus on population-based health interventions from a variety of sectors as well as individually-focused clinical care. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that happen outside of the typical clinical setting.
The HERC selects topics for its reports to guide public and private payers based on the following principles:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC reports are based on a review of the relevant research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. For some conditions, the HERC has reviewed evidence and identified effective interventions, but has not made coverage recommendations because many of these policies are implemented in settings beyond traditional healthcare delivery systems.
GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are several elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. Assessments of confidence are from the published systematic reviews and meta-analyses, where available. Otherwise, the level of confidence in the estimate is determined by the HERC based on the assessment of two independent reviewers from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the HERC.

Coverage question: Should continuous glucose monitoring be recommended for coverage in adults with type 1 diabetes mellitus?

<table>
<thead>
<tr>
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<th>Resource allocation</th>
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<tbody>
<tr>
<td>Severe morbidity (Critical outcome)</td>
<td>Insufficient evidence</td>
<td>CGM adds significant cost to diabetes management, and generally does not eliminate the need for finger-stick testing before insulin dosage changes (one device that does so was approved by the FDA in December 2016). Health care savings that would offset the costs of CGM have not been demonstrated.</td>
<td>Blood glucose monitoring techniques that stabilize type 1 diabetes control would generally be highly valued by providers and patients, even if they involve increased attention and care. However, many might prefer established finger-stick monitoring</td>
<td>Studies that combine CGM and insulin pump management are appropriate and potentially important, but it is more difficult to establish the incremental benefit provided by CGM when both interventions are studied simultaneously.</td>
</tr>
<tr>
<td>Severe hypoglycemia (Critical outcome)</td>
<td>No difference in severe hypoglycemia at up to six months ●●○○ (Low confidence)</td>
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<tr>
<td>Quality of life (Important outcome)</td>
<td>No differences in various measures of quality of life ●●●○ (Moderate confidence)</td>
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<tr>
<td>Change in HbA1c (Important outcome)</td>
<td>No difference in HbA1c with retrospective CGM at up to six months of follow-up (MD -0.09%, 95% CI -0.44 to 0.26) ●●○○ (Moderate confidence)</td>
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### Coverage question: Should continuous glucose monitoring be recommended for coverage in adults with type 1 diabetes mellitus?

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<tr>
<td>Diabetic ketoacidosis</td>
<td>Greater improvement in HbA1c with real-time CGM at up to six months of follow-up (MD -0.30%, 95% CI -0.47 to -0.12) ●●○○ (Low confidence)</td>
<td>protocols with which they are familiar, given the limited evidence of benefit achieved by using the more complicated and invasive continuous monitoring.</td>
<td></td>
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<tr>
<td>(Important outcome)</td>
<td>No difference in ketoacidosis ●●○○ (Low confidence)</td>
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</table>

**Rationale:** There is insufficient evidence on long-term clinical outcomes related to the use of CGM, and CGM does not reduce severe hypoglycemia or ketoacidosis (although these were rare events in the studies). We found that use of real-time CGM in adults with DM1 results in greater improvements in HbA1c when compared with SMBG, although it is not clear that the benefits are clinically significant. Some evidence suggests that the greatest improvements in HbA1c are attained in patients who are on insulin pump management. We are recommending that use of CGM be limited to those most likely to benefit by using criteria and clinical recommendations established by payers and professional societies. Our recommendation is weak because of the limited evidence of benefit.

No improvement in HbA1c levels has been demonstrated with use of retrospective CGM at up to six months of follow-up.

**Recommendation:** Real-time CGM is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes mellitus:

- who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit and
- who have baseline HbA1c levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM).

Real-time CGM (including the CGM-enabled insulin pump) is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes on insulin pump management who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Retrospective CGM is not recommended for coverage in adults with type 1 diabetes *(strong recommendation)*.
## Coverage question: Should continuous glucose monitoring be recommended for coverage in adults with type 2 diabetes mellitus?

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Estimate of Effect for Outcome/ Confidence in Estimate</th>
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<tbody>
<tr>
<td>Severe morbidity</td>
<td>Insufficient evidence</td>
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<tr>
<td>(Critical outcome)</td>
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<tr>
<td>Severe hypoglycemia</td>
<td>Insufficient evidence</td>
<td></td>
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<td></td>
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<tr>
<td>(Critical outcome)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Quality of life</td>
<td>No difference in treatment satisfaction compared to SMBG</td>
<td>Resource allocation</td>
<td>CGM adds cost to type 2 diabetes management. There is insufficient evidence to assess possible offsetting health care savings.</td>
<td></td>
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<tr>
<td>(Important outcome)</td>
<td>●○○○ (Very low confidence)</td>
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<tr>
<td></td>
<td>Lower treatment satisfaction compared to internet blood glucose monitoring</td>
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<tr>
<td></td>
<td>●○○○ (Very low confidence)</td>
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<tr>
<td>Change in HbA1c</td>
<td>Greater improvement in HbA1c</td>
<td></td>
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</tr>
<tr>
<td>(Important outcome)</td>
<td>(MD -0.31% 95% CI -0.6 to -0.02)</td>
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<tr>
<td></td>
<td>●●○○ (Low confidence)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetic ketoacidosis</td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>(Important outcome)</td>
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### Rationale: We found insufficient evidence regarding the effects of CGM on long-term clinical outcomes or on severe hypoglycemia in type 2 diabetes, and CGM does not improve treatment satisfaction. We have low confidence that improvements in HbA1c levels seen in type 2 diabetes studies are clinically significant. Evidence was not found that demonstrated improved HbA1c or any other improved outcome with the use of retrospective CGM in adults with DM2. Given the prevalence of type 2 diabetes in the U.S. adult population, use of CGM would add significant cost without known population health benefit. Our recommendation for noncoverage of real-time CGM is a weak recommendation because additional studies could develop evidence that better supports its use in type 2 diabetes.
**Recommendation:** Real-time CGM is not recommended for coverage in adults with type 2 diabetes (*weak recommendation*). Retrospective CGM is not recommended for coverage in adults with type 2 diabetes (*strong recommendation*).

**Coverage question:** Should continuous glucose monitoring be recommended for coverage in children and adolescents with type 1 diabetes mellitus?

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<tbody>
<tr>
<td>Severe morbidity <em>(Critical outcome)</em></td>
<td>Insufficient evidence</td>
<td></td>
<td></td>
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<tr>
<td>Severe hypoglycemia <em>(Critical outcome)</em></td>
<td>No difference in severe hypoglycemia at 6 months (RR 0.63, 95% CI 0.27 to 1.46) ●●○○ <em>(Low confidence)</em></td>
<td></td>
<td></td>
<td>CGM studies of children and adolescents with type 1 diabetes generally exclude those younger than eight years of age, and hypoglycemia unawareness is frequent in younger children.</td>
</tr>
<tr>
<td>Quality of life <em>(Important outcome)</em></td>
<td>Greater parental satisfaction at 6 months (MD 0.3 on a scale of 1 to 3, 95% CI 0.21 to 0.39) ●●●● <em>(High confidence)</em></td>
<td></td>
<td>Parents of children with type 1 diabetes would place very high value in the reassurance provided by CGM. Benefits of CGM may include decreasing the frequency of fingerstick testing, remote access to glucose levels, and lessened nocturnal anxiety, all of which are highly valued by parents (who have primary responsibility for control of diabetes in younger children).</td>
<td></td>
</tr>
<tr>
<td>Change in HbA1c <em>(Important outcome)</em></td>
<td>No difference in HbA1c with real-time CGM at six months (MD -0.09, 95% CI -0.24 to 0.07) ●●●● <em>(High confidence)</em></td>
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<tr>
<td></td>
<td>No difference in HbA1c with retrospective CGM at six months (MD -0.3, 95% CI -0.67 to 0.07) ●●○○ <em>(Low confidence)</em></td>
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<tr>
<td>Diabetic ketoacidosis <em>(Important outcome)</em></td>
<td>Insufficient evidence</td>
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</table>
Coverage question: Should continuous glucose monitoring be recommended for coverage in children and adolescents with type 1 diabetes mellitus?

Rationale: We have high confidence that use of CGM in children with type 1 diabetes results in greater parental satisfaction. Expert testimony confirms that providers, parents, and these young patients highly value the benefits of improved monitoring capability, especially in reducing anxiety related to potential hypoglycemia during attempts to improve HbA1c levels. Although the evidence does not show benefit in critical or important outcomes, we recognize that published CGM studies generally do not include the youngest children with type 1 diabetes and do not address long-term developmental concerns. Our recommendation for coverage is based on strongly expressed values and preferences, and it is a weak recommendation that may be supplemented by further studies of CGM use in this population.

We have low confidence that the use of retrospective CGM results in no clinically significant improvement in HbA1c levels, and there is no evidence of benefit for other critical or important outcomes. Therefore, we recommend noncoverage. The recommendation is strong because of evidence of no benefit.

Recommendation: Real-time CGM is recommended for coverage (weak recommendation) in children and adolescents under age 21 with type 1 diabetes who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Retrospective CGM is not recommended for coverage in children and adolescents with type 1 diabetes (strong recommendation).

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<tbody>
<tr>
<td>Severe morbidity (Critical outcome)</td>
<td>Insufficient evidence</td>
<td>CGM adds significant cost to diabetes management, and offsetting benefits in reducing complications (such as hypoglycemia) have not been established.</td>
<td>It is unlikely that there would be strong preferences for the use of CGM in children and adolescents with type 2 diabetes, given the extra care</td>
<td></td>
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<tr>
<td>Severe hypoglycemia (Critical outcome)</td>
<td>Insufficient evidence</td>
<td></td>
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<tr>
<td>Quality of life (Important outcome)</td>
<td>Insufficient evidence</td>
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</table>
**Coverage question: Should continuous glucose monitoring be recommended for coverage in children and adolescents with type 2 diabetes mellitus?**

<table>
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<tr>
<th>Outcome</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Change in HbA1c</td>
<td>Insufficient evidence</td>
<td>and attention that this monitoring entails and the absence of studies establishing clinical benefit.</td>
<td></td>
<td></td>
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<tr>
<td>(Important outcome)</td>
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<tr>
<td>Diabetic ketoacidosis</td>
<td>Not applicable</td>
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<tr>
<td>(Important outcome)</td>
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**Rationale:** No systematic reviews or randomized controlled trials of CGM for children and adolescents with type 2 diabetes were identified in the search. There was insufficient evidence to draw conclusions about CGM for any outcomes in this population. Our recommendation for noncoverage is strong because of lack of evidence supporting the intervention, the additional cost, and the lack of clear values and preferences in favor of the intervention.

**Recommendation:** Real-time CGM is not recommended for coverage in children and adolescents with type 2 diabetes (*strong recommendation*). Retrospective CGM is not recommended for coverage in children and adolescents with type 2 diabetes (*strong recommendation*).

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**Coverage question: Should continuous glucose monitoring be recommended for coverage in pregnant women with preexisting or gestational diabetes mellitus?**

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</tr>
</thead>
<tbody>
<tr>
<td>Severe morbidity</td>
<td>No differences in maternal, obstetrical, or neonatal outcomes ●●○○ to ●●●● (Very low to low confidence)</td>
<td>Outcome improvements for diabetes in pregnancy, especially neonatal outcome improvements, could result in substantial treatment costs.</td>
<td>The value placed on CGM by pregnant women would be highly variable, but would likely be much higher for high-risk pregnancy outcomes.</td>
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<tr>
<td>(Critical outcome)</td>
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<tr>
<td>Severe hypoglycemia</td>
<td>No difference in severe hypoglycemia (RR 1.0, 95% CI 0.5 to 2.1) ●●○○ (Low confidence)</td>
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<td></td>
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<tr>
<td>(Critical outcome)</td>
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**Coverage question:** Should continuous glucose monitoring be recommended for coverage in pregnant women with preexisting or gestational diabetes mellitus?

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</thead>
<tbody>
<tr>
<td>Quality of life <em>(Important outcome)</em></td>
<td>Insufficient evidence</td>
<td>short-term and long-term cost savings. However, thus far improved outcomes have not been demonstrated, and use of CGM would add significant cost to diabetes management in pregnancy.</td>
<td>those with type 1 diabetes. Even in the absence of demonstrated significant clinical outcomes, many obstetrical providers would favor use of monitoring that potentially improves blood sugar control in pregnancy.</td>
<td></td>
</tr>
<tr>
<td>Change in HbA1c <em>(Important outcome)</em></td>
<td>Greater improvement in HbA1c at 32 to 36 weeks gestation (MD -0.6, 95% CI -0.9 to -0.3) ●●○ (Low confidence) No difference in HbA1c at 36 weeks gestation (MD -0.1, 95% CI not calculable, p=0.63) ●●●○ (Moderate confidence)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Diabetic ketoacidosis <em>(Important outcome)</em></td>
<td>Insufficient evidence</td>
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**Rationale:** There is conflicting evidence about the effect of CGM on HbA1c during the third trimester of pregnancy and no evidence regarding the use of these devices earlier in pregnancy or before conception. CGM does not appear to reduce severe hypoglycemia during the third trimester, and there is insufficient evidence to assess effects on quality of life or diabetic ketoacidosis. No benefits have been identified for maternal, obstetrical, or neonatal outcomes. In spite of these limitations, many patients and providers would favor monitoring (particularly in type 1 diabetes) that improves blood sugar control during pregnancy, even with associated additional cost. Despite the cost of these devices and the lack of evidence of clinical outcomes for this population, there is a clear rationale for using CGM to help control blood glucose levels to prevent the known fetal and maternal harms associated with type 1 diabetes during pregnancy or when pregnancy is anticipated.

**Recommendation:** CGM is not recommended for coverage during pregnancy for type 2 diabetes or gestational diabetes *(weak recommendation).*
CGM is recommended for coverage for women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels (weak recommendation).

Note: GRADE framework elements are described in Appendix A. A GRADE Evidence Profile is provided in Appendix B.
EVIDENCE OVERVIEW

Clinical Background

Diabetes mellitus is a metabolic disorder in which blood sugar (glucose) levels are elevated as a result of the body either failing to produce sufficient insulin or to use its own insulin properly (Centers for Disease Control and Prevention [CDC], 2015). Although the rate of new cases of diabetes in the United States has started to decline, diabetes remains a major public health issue: more than 29 million Americans are currently living with diabetes and 86 million Americans are living with prediabetes (CDC, 2016). Diabetes was the seventh leading cause of death in the U.S. in 2013 (CDC, 2016). Diabetes complications and associated conditions include heart disease, stroke, blindness, kidney disease, and amputations. More than 20% of health care expenditures are allocated to persons with diabetes (CDC, 2016).

There are several types of diabetes. Type 1 diabetes (DM1) accounts for 5% of diabetes cases and is typically diagnosed in children and young adults (American Diabetes Association [ADA], 2017d). In DM1, the immune system attacks cells in the pancreas that produce insulin. People with DM1 are thus reliant on daily insulin injections to stay alive (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2016).

In children, DM1 has been associated with mild impairment in neurocognitive functioning across several domains; in particular, severe hypoglycemia is associated with statistically significant impairment in short-term verbal memory (Naguib, Kulinskaya, Lomax, & Garralda, 2009). Additionally, psychological distress is common among parents of children with DM1 and higher levels of psychological distress are associated with poorer diabetes management (Whittemore, Jaser, Chao, Jang, & Grey, 2012).

Type 2 diabetes (DM2) accounts for approximately 90% to 95% of diabetes cases (CDC, 2015). DM2 can develop at any age as a result of the body failing to make or use insulin properly, but is most common in adults (NIDDK, 2016).

Gestational diabetes (GDM) develops in 2% to 10% of pregnancies and can cause health issues for mothers and their babies if untreated (CDC, 2015).

Diabetes is typically treated with healthy eating, physical activity, medications to lower blood glucose levels, insulin injections, and blood glucose testing. It is important for people with diabetes to take responsibility for their daily care and maintain blood glucose levels within target range (CDC, 2015).

Indications

Blood glucose monitoring is a critical tool for patients in managing their diabetes. Target ranges for levels of blood glucose are individualized based on duration of diabetes, age and life expectancy, comorbid conditions, known cardiovascular disease or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations. The ADA typically recommends an HbA1c target of 7% (i.e., 154 mg/dL average glucose) for adults with diabetes who are not pregnant. Results from measuring blood glucose levels often inform changes to the patient’s treatment plan, especially if blood glucose levels are abnormally high or low or fluctuating rapidly (ADA, 2017a).
Hypoglycemia is a condition characterized by abnormally low blood glucose levels (usually defined as below 70 mg/dL), which can lead to a seizure or unconsciousness if left untreated. Individual reactions to hypoglycemia vary; signs and symptoms include shakiness, anxiety, irritability, confusion, rapid heartbeat, dizziness, nausea, hunger, headache, and fatigue. Hypoglycemia unawareness is when blood glucose levels fall below 70 mg/dL, but there are no symptoms (ADA, 2017c). Hyperglycemia or high blood glucose occurs when the body has too little insulin or when the body cannot use insulin properly. If left untreated, hyperglycemia can lead to ketoacidosis (i.e., a diabetic coma), a life-threatening condition requiring immediate treatment (ADA, 2017b).

Given the importance of blood glucose testing and insulin administration to the management of diabetes, multiple technologies are available to aid persons with diabetes in maintaining their blood glucose levels within a safe range. The most common way to check glucose levels is the finger-stick test, which involves pricking a fingertip with a lancing device to obtain a blood sample and then using a glucose meter to measure the blood glucose level (NIDDK, 2008). More recently developed technologies include insulin pumps, which are computerized devices that can deliver a steady flow of insulin; continuous glucose monitoring (CGM) devices; and CGM-enabled insulin pumps (United States Food and Drug Administration [FDA], 2016b).

**Technology Description**

CGM systems consist of a small sensor inserted under the patient’s skin to measure glucose levels in the interstitial fluid. The device automatically takes readings, typically in one-minute or five-minute intervals (NIDDK, 2008). CGM devices can be categorized into two primary types: retrospective and real-time. In retrospective CGM, data must be downloaded from the device before analysis. Real-time CGM systems, approved by the FDA in 2005, consist of a transmitter and receiver connected to the glucose sensor, which enables the patient to see measurements instantaneously. Real-time CGM also allows for the option to set alarms, which can alert patients to hypoglycemia, hyperglycemia, or rapid variations in glucose levels (Golden et al., 2012).

The accuracy of CGM systems has improved during the last decade and measurement error has been reduced from approximately 20% to 10% (Rodbard, 2016). In December 2016, the FDA announced its expansion of approved use for one CGM system, the Dexcom’s G5 Mobile Continuous Glucose Monitoring System; the device is now approved as a replacement for the finger-stick test for diabetes treatment decisions for individuals ages two and older. Previously, all approved CGM devices including the Dexcom system were approved only to supplement and not replace finger-stick testing (FDA, 2016a).

**Key Questions and Outcomes**

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods, please see Appendix C.

1. What is the evidence of effectiveness of CGM in improving outcomes in people with diabetes?
2. What are the indications for retrospective and real-time CGM?
3. Is there evidence of differential effectiveness of CGM based on:
   a. Type 1 vs. Type 2 DM?
   b. Insulin pump (integrated with CGM or standalone) vs. multiple daily insulin injections (MDII)?
   c. Frequency and duration of CGM?
   d. Persistently poor glycemic control?

Critical outcomes selected for inclusion in the GRADE table are severe morbidity (e.g., microvascular and macrovascular complications) and severe hypoglycemia. Important outcomes selected for inclusion in the GRADE table are quality-of-life, change in HbA1c, and ketoacidosis.

**Evidence Review**

**Adults with DM1**

*Langendam et al., 2012*

This is a high-quality systematic review of 22 randomized controlled trials (RCTs) of CGM in patients with DM1. The review included studies of adults and children and studies of real-time and retrospective CGM. Seven of the studies involved only patients with poorly controlled diabetes (HbA1c >8.0%). The authors noted several concerns regarding risk of bias in the studies, including inadequate allocation concealment, lack of blinding, and industry sponsorship or involvement.

The main comparison for the review examined the use of CGM-augmented insulin pump therapy to self-monitoring blood glucose (SMBG) with MDII in insulin pump-naïve patients (all age groups). For this comparison, there were no statistically significant differences in severe hypoglycemia at six months (risk ratio [RR] with CGM 3.26, 95% CI 0.38 to 27.82, very low-quality evidence); ketoacidosis at six months (RR with CGM 2.45, 95% CI 0.1 to 58.45, very low-quality evidence), or quality of life at six months as measured by the SF-36 (very low-quality evidence). Patients treated with CGM-augmented insulin pump therapy had greater improvement in HbA1c at six months (-0.7% compared to -0.1 to -0.2% in the control groups, moderate-quality evidence).

The overall meta-analytic estimates for the effects of real-time CGM in patients with DM1 (adults and children) were as follows:

- There was low-quality evidence of no difference in severe hypoglycemia at six months (7.9% with CGM vs. 7.5% with controls, RR 1.05, 95% CI 0.63 to 1.77).
- There was low-quality evidence of no difference in ketoacidosis at six months (2% with CGM vs. 2.3% with controls, RR 0.85, 95% CI 0.32 to 2.26).
- There was very low-quality evidence of no differences in patient or parental quality of life at six months.
- There was moderate-quality evidence that CGM reduced HbA1c more than controls at six months (mean difference -0.2%, 95% CI -0.1% to -0.4%).
The following observations were made about retrospective CGM systems in adults:

- One study found no difference in the change in HbA1c between study arms and another study found a statistically non-significant difference in favor of GCM (-0.3%, 95% CI -0.9% to 0.3%).
- One study found no difference in severe hypoglycemia (one event in each group).

The following observations were made about real-time CGM systems in adults:

- At three months, the mean difference in change in HbA1c ranged from -0.12 to -1.12 in favor of CGM (five trials, two with statistically significant improvements).
- At six months, the mean difference in change in HbA1c ranged from -0.05 to -1.10 in favor of CGM (three trials, two with statistically significant improvements).
- At 12 months, the mean difference in change in HbA1c was -0.6 based on a single trial with a statistically significant improvement.
- For a single trial that reported on the categorical outcome of >0.5% reduction in HbA1c at six months, the RR was 4.25 (95% CI 1.76 to 10.22, 46% vs. 11% absolute risk) in favor of CGM.
- In four trials that examined severe hypoglycemia at three to 12 months, there were no statistically significant differences between the groups.
- Of four trials that investigated ketoacidosis at three to 12 months, there were no statistically significant differences between the groups.
- In two trials that reported on quality of life at six months, there were no statistically significant differences between the groups.

The authors included several pre-specified subgroup analyses. No studies involved patients with impaired awareness of hypoglycemia. Among the seven studies that enrolled patients with poorly controlled DM1 (HbA1c >8.0%), the three retrospective CGM studies reached conflicting conclusions, and the four real-time CGM studies offered “limited evidence” for improved glycemic control. In one study that examined protocol adherence, patients who used the CGM sensor at least 70% of the time had greater improvements in HbA1c than CGM users who demonstrated lower adherence (mean change in HbA1c at six months of -0.96% vs. -0.81%).

Benkhadra et al., 2017

This is a high-quality systematic review and individual patient data meta-analysis of RCTs of real-time CGM in adults and children with DM1. The authors identified 11 trials and judged the overall risk of bias in these trials to be moderate (mostly stemming from concerns about allocation concealment, blinding, and industry sponsorship). The patient characteristics were similar at baseline; the average baseline HbA1c was 8.2% in adults and 8.3% in children and adolescents.

The meta-analytic estimates were stratified by age. For participants over the age of 15, CGM resulted in a greater reduction in HbA1c compared to controls (mean difference -0.356%, 95% CI -0.551% to -0.160%, p<0.001). For participants ages 12 and under or ages 13 to 15, there were no statistically significant differences in HbA1c between the CGM and control groups. Severe hypoglycemia was not assessed in this review, but the meta-analysis found no statistically significant differences in the incidence of any hypoglycemic event (glucose <70 mg/dL) in the overall population or any of the
stratified age groups. A sensitivity analysis that excluded two trials of older real-time CGM technology did not alter the conclusions.

National Institute for Health and Care Excellence (Guideline 17), 2015

This is a good-quality systematic review commissioned by the National Institute for Health and Care Excellence to inform the 2015 update of the comprehensive guideline on diagnosis and management of DM1 in adults. The authors identified 11 parallel RCTs and three crossover RCTs that compared retrospective or real-time CGM to SMBG. The authors assessed GRADE ratings for the outcomes.

For trials comparing retrospective CGM to SMBG, there was moderate-quality evidence of no statistically significant difference in HbA1c at up to six months of follow-up (mean difference -0.09, 95% CI -0.44 to 0.26), and low-quality evidence of no statistically significant difference in severe hypoglycemia.

For trials comparing real-time CGM to SMBG, there was very low-quality evidence of a statistically significant improvement in HbA1c at up to six months of follow-up (mean difference -0.30%, 95% CI -0.47 to -0.12). There was very low-quality evidence of no statistically significant difference between real-time CGM and SMBG with respect to severe hypoglycemia at up to six months follow-up (12 fewer events per 1,000 patients with CGM, 95% CI -37 to 63 per 1,000). There was moderate-quality evidence of no significant difference between real-time CGM and SMBG with respect to overall and various subscale measures of quality of life.

Beck et al., 2017

This is a moderate-quality RCT of real-time CGM (using the Dexcom G4 Platinum system) in adults with DM1 using MDII. The trial was conducted at 24 endocrinology practices in the United States. Adults over age 25 with DM1 were eligible to participate in the trial if their HbA1c level was between 7.5% and 10% and they had not used a CGM device in the preceding three months. There was a two week run-in period during which eligible participants were required to demonstrate 85% adherence to use of the CGM sensor in addition to twice-daily calibration with a blood glucose meter. Fourteen eligible participants were excluded from randomization during the run-in period. Ultimately, 158 adults were randomly assigned (2:1 randomization) to CGM or continued SMBG. Randomization was stratified by HbA1c level. The authors did not describe blinding of patients, clinicians, or outcomes assessors. The primary outcomes were changes in HbA1c at 12 and 24 weeks as measured by a central laboratory.

The groups were generally similar at baseline, and the average HbA1c in both groups was 8.6%. A greater proportion of patients in the control group had reported at least one episode of severe hypoglycemia in the previous 12 months (17% vs. 8%). At 24 weeks, the mean change in HbA1c was greater in the CGM group (-0.6%, 95% CI -0.8% to -0.3%, p<0.001). The percentage of patients achieving HbA1c of <7.0% at 24 weeks was 18% in the CGM group and 4% in the control group (p=0.01). There were two episodes of severe hypoglycemia in each group, and no episodes of ketoacidosis in either group. In the exploratory analyses, age, baseline HbA1c, education level, and type of study site (community or academic) did not have significant interactions with the 24-week HbA1c treatment effect.
**Hommel et al., 2014**

This is a report on quality of life, treatment satisfaction, medical resource use, and indirect costs from a fair-quality randomized crossover trial of real-time CGM in adults and children with DM1 treated with continuous subcutaneous insulin infusion (CSII). Patients ages 6 to 70 were eligible to participate in the study if they had DM1 for more than one year and had been on CSII for more than six months with suboptimal control (defined as HbA1c 7.5% to 9.5%). Patients were required to pass a five-question multiple-choice test concerning pump therapy and general understanding of diabetes to be eligible. During a four week run-in period, eligible patients wore the CGM system (MiniMed Paradigm) for two weeks, followed by two weeks during which blinded CGM data was collected. At the end of the run-in period, eligible patients were required to pass a 10-question test about sensor use in order to enter the trial. Ultimately, 153 patients were randomized in a 1:1 ratio to six months of sensor ON or sensor OFF, followed by a four-month washout period before crossing over to the other arm. Patients had clinical follow-up every six weeks during the study periods. Blinding of patients, clinicians, or outcomes assessors was not described in the report.

The groups were similar at baseline and the average HbA1c values were 8.5% and 8.3% for the OFF/ON and ON/OFF sequence, respectively. For adult participants, overall treatment satisfaction (measured by the Diabetes Treatment Satisfaction Questionnaire [DTSQ]) was higher in the sensor ON arm (p=0.012). There were no statistically significant differences between the sensor ON and sensor OFF groups with respect to diabetes-related hospitalizations (p=0.21). In a per-protocol analysis, children with >70% adherence during the sensor ON period had significantly fewer missed school days compared to the sensor OFF group (0.38 vs. 1.24 days per child per six months, p=0.005).

**Lind et al., 2017**

This is a fair-quality open-label randomized crossover trial of real-time CGM conducted at 15 clinical sites in Sweden. Patients over the age of 18 with DM1 for at least one year were eligible if they had HbA1c >7.5% and were being treated with MDII; patients receiving treatment with CSII were excluded. All eligible patients were subject to a six-week run-in period, which included two weeks of masked CGM data collection. Patients who “did not believe they would wear the sensor more than 80% of the time” or who did not perform a sufficient number of calibrations were excluded. Ultimately, 161 patients were randomized to real-time CGM or SMBG (four times daily) for 26 weeks, followed by a 17-week washout period, and then crossover to the other arm for an additional 26 weeks. The trial was not blinded.

The groups were similar at baseline, and the average HbA1c was 8.5% at the time of randomization. Nineteen patients (12%) had incomplete follow-up and were excluded from the analysis. The patients with incomplete follow-up were more likely to be younger, have a higher baseline HbA1c, and to have had an episode of severe hypoglycemia in the preceding year compared to those with complete follow-up. For the primary outcome of change in HbA1c, patients in the CGM arm had statistically significantly greater improvements than those in the control arm (mean difference -0.43%, 95% CI -0.57 to -0.29). Severe hypoglycemia was rare, occurring in five patients in the control arm and one patient in the CGM arm (numeric data only). Mean well-being (measured by the WHO-5 scale) and treatment satisfaction (measured by DTSQ) were statistically significantly higher in the CGM arm.
New et al., 2015
This is a fair-quality randomized controlled trial comparing real-time CGM with alarms, real-time CGM without alarms, and SMBG. Adults ages 18 to 65 with DM1 or DM2 treated with MDII or CSII and who had not used a CGM system in the preceding six months were eligible. After a 20 day run-in period during which masked CGM was performed, patients with at least 50% adherence to sensor use (n=145) were randomized to CGM with alarms, CGM without alarms, and SMBG (1:1:1, stratified by type of diabetes). The trial was not blinded.

The groups were similar at baseline, and the average HbA1c was around 8.2%. Most participants (about 85%) had DM1. Although they were not the primary outcomes, HbA1c and quality of life measures were reported. Severe hypoglycemia and ketoacidosis were not reported. There were no statistically significant differences between the three groups with respect to change in HbA1c. As for quality of life measures, only the comparison of CGM with alarms versus SMBG for the physical component score of the Short-Form-8 Health Survey reached statistical significance (favoring CGM with alarms, p=0.024).

Riveline et al., 2012
This is a poor-quality randomized trial comparing patient-led real-time CGM, physician-driven real-time CGM, and SMBG in adults and children with DM1 treated with MDII or CSII. Eligible patients were aged 8 to 60 years, had HbA1c ≥ 8.0%, and were performing SMBG at least twice daily. Eligible participants were subject to a 10-day run-in period to assess suitability for CGM use. Randomization technique and allocation concealment were not described. Of 257 eligible participants, 60 failed the screening during run-in, and these patients were more likely to be younger, have a lower educational level, and have a history of ketoacidosis compared to the group that was randomized. Ultimately, 197 patients were randomized, but 19 were excluded from the analysis because of missing HbA1c data.

The groups were generally similar at baseline, although the patient-led CGM group included a greater number of patients with an episode of severe hypoglycemia in the previous year. At 12 month follow-up, the reduction in HbA1c was similar in the two CGM groups. The combined CGM groups had greater improvement in HbA1c (-0.48%, 95% CI -0.63 to -0.33) than the SMBG group (0.02%, 95% CI -0.18 to 0.23). However, the improvement in HbA1c in the combined CGM groups was only present in patients on CSII (-0.67%, 95% CI -1.01 to -0.33); for patients on MDII, the difference in HbA1c between the combined CGM groups and the SMBG group was not statistically significant (-0.28%, 95% CI -0.67 to 0.10). After adjustment for age and a history of severe hypoglycemia in the previous year, there were no differences in episodes of severe hypoglycemia between the groups. For quality of life outcomes, patients in the combined CGM groups had statistically significant improvements in the physical component score of the SF-36 and the treatment satisfaction scale of the Diabetes Quality of Life (DQoL) score compared to those in the SMBG group; there were no statistically significant differences between the CGM and the SMBG groups on the global DQoL or mental component of the SF-36.

Tumminia et al., 2015
This is a poor-quality single-center randomized crossover trial of adults with DM1 treated with MDII or CSII. Twenty patients with DM1 (10 on MDII and 10 on CSII) and HbA1c >8.0% were randomly assigned
to real-time CGM or SMBG for six months, followed by a two-month washout period and crossover to the other arm for an additional six months. The randomization technique and allocation concealment are not well described. The trial was not blinded.

It is unclear whether the groups were similar at baseline because the authors only reported baseline characteristics by the use of MDII or CSII. For their analysis, the authors excluded six patients (30%) who did not use CGM at least 40% of the time during the prescribed portion of the study. Among the remaining 14 patients, the improvement in HbA1c was greater during the CGM period of the study (-0.78%) than during the SMBG portion of the study (-0.14%). Both the MDII-treated patients and the CSII-treated patients had greater improvement during the CGM period compared to the SMBG period. There were no episodes of severe hypoglycemia during the study. One patient on CSII was hospitalized for ketoacidosis during the SMBG portion of the study.

van Beers et al., 2016
This is a fair-quality open-label randomized crossover trial of CGM compared to SMBG in adults with DM1 and impaired hypoglycemia awareness who were treated with MDII or CSII. After a six-week run-in period that included diabetes education and a two-week period of masked CGM, patients were randomly assigned to CGM or SMBG for 16 weeks, followed by a 12-week washout period and crossover to the other arm for an additional 16 weeks. The authors described appropriate randomization techniques and allocation concealment. Ultimately, 52 patients were randomized. The average HbA1c at randomization was 7.5%.

Two secondary outcomes that were reported are relevant to this summary. The number of patients with at least one severe hypoglycemic event was 19% in the CGM phase compared to 35% in the SMBG phase (OR 0.48, 95% CI 0.2 to 1.04, p=0.062). There was no difference in HbA1c at the study endpoint between the CMG and SMBG phases (7.3% in both groups). Although the data were not presented in the paper, the authors observed no difference in quality of life measures between the CGM and SMBG phases.

Adults with DM2
National Institute for Health and Care Excellence (Guideline 28), 2016
This is a good-quality systematic review commissioned by the National Institute for Health and Care Excellence (NICE) to inform the 2016 update of the comprehensive guideline on diagnosis and management of DM2 in adults. The authors identified two RCTs with 165 total patients that compared SMBG with CGM to conventional SMBG alone. One trial was conducted in the United States and one was conducted in South Korea. The average HbA1c at baseline was 8.3% in one study and 8.9% in the other. Patients in these trials could be on oral antidiabetic medications, insulin, or both. In the meta-analysis of these two trials, the authors found very low-quality evidence that SMBG with CGM results in a statistically significant improvement in HbA1c at up to 52-weeks follow-up with a mean difference of -0.46% (95% CI -0.87 to -0.06). No other important or critical outcomes were reported.

Poolsup et al., 2013
This is a good-quality systematic review and meta-analysis of randomized trials of CGM in children with DM1 or adults with DM2. The authors identified four RCTs comparing CGM to SMBG in adults with DM2
Continuous Glucose Monitoring in Diabetes Mellitus

Although all studies used a real-time CGM monitor, two studies used the data retrospectively. Two of the trials were judged as high quality and two were deemed low quality. All of the participants in the studies had a baseline HbA1c >8%. Two of the studies only included patients on oral antidiabetic agents, and the other two studies included patients on oral agents, insulin, or both. The authors found no indication of publication bias and there was limited heterogeneity, with an I² = 0%. In the fixed-effects meta-analysis, CGM resulted in statistically significantly improvement in HbA1c with a mean difference of -0.31% (95% CI -0.6 to -0.02). Because of the small number of trials, sensitivity analysis comparing retrospective and real-time CGM was not performed. No other important or critical outcomes were reported.

New et al., 2015

The description of this trial can be found above. Overall, 15% of the patients in this trial had DM2. However, the results for glycemic control as measured by HbA1c were not separately reported by the type of diabetes.

Sato et al., 2016

This is a poor-quality open-label randomized controlled trial of retrospective CGM compared to usual care (including SMBG) for adults with DM2. All patients (n=34) wore a CGM system for the duration of the trial. In the intervention group, the information from the CGM device was interpreted by the study team, which subsequently provided counseling and treatment guidance to the patient and treating clinician; in the control group, patients and physicians were blinded to the CGM data and based clinical decisions on HbA1c and SMBG information. The authors did not describe the randomization technique or allocation concealment. Patients, treating clinicians, and study personnel were not blinded. It is unclear whether patients in each arm had similar numbers of clinical encounters during the study. There were baseline differences between the two groups with respect to gender distribution and age; the average baseline HbA1c in both groups was 8.2%. There were no statistically significant differences in change in HbA1c between the two groups; at up to eight months follow-up, the mean HbA1c was 8.2% in the CGM group and 7.9% in the control group. However, the average total daily insulin dose increased by 2.2 IU in the CGM group compared to 0.2 IU in the control group. Severe hypoglycemia was not measured, but the authors noted that the time spent at a glucose level of <70 mg/dL was “almost” 0% in both groups. There was no statistically significant difference in treatment satisfaction between the two groups.

Tang et al., 2014

This is a fair-quality parallel randomized controlled trial comparing real-time CGM to internet-blood glucose monitoring (IBGM) in adults with DM2. The primary outcomes for this trial were related to treatment satisfaction. Fifty-seven patients were initially enrolled and randomized, but seven patients in the CGM group dropped out immediately after randomization. Five additional patients withdrew from the CGM group; some cited inconvenience or discomfort from their treatment. Five patients in the IBGM group withdrew during the study. Thus, 40 patients with HbA1c >7.0% treated with insulin or insulin with oral agents were randomized to real-time CGM or to three times daily SMBG and facilitated internet communication with their provider. The groups were similar at baseline. The primary outcome
was treatment satisfaction as measured by the DTSQ. Fifteen patients in the CGM group and 17 patients in the IBGM group completed the survey at trial completion. Overall, treatment satisfaction was statistically significantly higher in the IBGM group compared to the CGM group (p<0.001). Although glycemic outcomes were not a primary endpoint in this study, there was no statistically significant difference in the change in HbA1c between the CGM and IBGM groups at six months follow-up (-0.9% vs. -1.07%, p=0.312).

**Tildesley et al., 2013**
This is a report from the trial described immediately above with respect to glycemic control outcomes measured at six months. Only the seven patients who dropped out of the CGM group immediately after randomization were excluded from the analysis. Available data for the remaining 50 participants was analyzed in an intention-to-treat fashion. The baseline mean HbA1c in the CGM group was 8.80% and improved to 7.49% at six months; in the IBGM group, the baseline mean HbA1c was 8.79% and improved to 7.96% at six months. The between-group difference in change in HbA1c was not statistically significant (p=0.08). There were no episodes of severe hypoglycemia in either group.

**Children and Adolescents with DM1**

**Langendam et al., 2012**
A description of this systematic review and meta-analysis and results from the combined group of adults and children can be found above.

The following observations were made about retrospective CGM systems in children:

- In five trials, the mean difference in change in HbA1c ranged from -0.5% to 0.1%, with wide confidence intervals around the estimates due to small sample sizes.
- In four trials that reported severe hypoglycemia, events were rare, occurring in two children in a CGM group and one child in an SMBG group.
- In one trial that reported on quality of life, there were no significant differences between the CGM and SMBG groups on the DCCT quality of life questionnaire.

The following observations were made about real-time CGM systems in children:

- In one trial, the mean difference in change in HbA1c was -0.2% (95% CI -0.3% to 0.0%) at three months. At six and 12 months, the difference in HbA1c between CGM and SMBG was not statistically significant.
- In one trial with a categorical outcome of HbA1c improvement of -0.5% at three months, that goal was achieved in 46% of patients in the CGM group compared to 28% of patients in the SMBG group (RR 1.68, 95% CI 1.02 to 2.78). The results were sustained at six months, with the goal achieved in 54% in the CGM group and 31% in the SMBG group (RR 1.73, 95% CI 1.10 to 2.72).
- In one trial, improvements in HbA1c were only observed in children with sensor use >60% of the time.
Severe hypoglycemia and ketoacidosis were both rare events in these trials. In one trial, there were five severe hypoglycemic events in the CGM arm compared to seven events in the SMBG arm at six months (RR 0.74, 95% CI 0.25 to 2.19).

In two studies that reported on quality of life outcomes, there were no statistically significant differences between the groups on the PedsQL or WHO-5 questionnaires.

The following observations were made about real-time CGM systems in adolescents:

- In two trials, the mean difference in change in HbA1c at three months was -0.3% (95% CI -0.8% to 0.1%) and -0.2% (95% CI -0.4% to 0.0%).
- In one trial with a categorical outcome of HbA1c improvement of -0.5% at three months, there was no difference between the CGM and SMBG groups (36% and 37%, respectively).
- Severe hypoglycemia and ketoacidosis were both rare events in these trials. In one trial, there were three severe hypoglycemic events in the CGM arm compared to five events in the SMBG arm (RR 0.56, 95% CI 0.14 to 2.22).

National Institute for Health and Care Excellence (Guideline 18), 2016

This is a good-quality systematic review and meta-analysis commissioned by NICE to inform the 2016 update of the comprehensive guideline on diagnosis and management of DM1 in children and adolescents. The authors identified seven RCTs comparing CGM and SMBG (five from the Langendam review and two additional trials). The authors assessed GRADE ratings for the outcomes. The results for children and adolescents with a diagnosis of DM1 at least one year before study enrollment were reported separately from those of children with a recent diagnosis of DM1 (within one year of study enrollment).

Among children and adolescents with DM1 diagnosed at least one year before study enrollment:

- There was high-quality evidence of no statistically significant difference between real-time CGM and SMBG with respect to HbA1c at six months (MD -0.09, 95% CI -0.24 to 0.07).
- There was low-quality evidence of no statistically significant difference between retrospective CGM and SMBG with respect to HbA1c at six months (MD -0.3, 95% CI -0.67 to 0.07).
- There was low-quality evidence of no statistically significant difference between CGM and SMBG with respect to severe hypoglycemia at six months (RR 0.63, 95% CI 0.27 to 1.46).
- There was high-quality evidence of statistically significantly greater parental satisfaction with CGM compared to SMBG at six months (MD 0.3 on a scale of 1 to 3, 95% CI 0.21 to 0.39).

Among children and adolescents with a recent diagnosis of DM1 (within one year of study enrollment):

- There was moderate-quality evidence of no statistically significant difference between real-time CGM and SMBG with respect to HbA1c at six months (MD -0.10, 95% CI -0.46 to 0.66).
- There was moderate-quality evidence of no statistically significant difference between real-time CGM and SMBG with respect to HbA1c at 12 months (MD -0.10, 95% CI -0.46 to 0.66).
- There was low-quality evidence of no statistically significant difference between CGM and SMBG with respect to the rate of severe hypoglycemia at 12 months (-4.6%, 95% CI -5.1% to 5.5%).
• There was high-quality evidence of no statistically significant differences between CGM and SMBG with respect to parental satisfaction at six or 12 months.

**Benkhadra et al., 2017**
The description of this systematic review and individual patient data meta-analysis can be found above. In the stratified meta-analysis, real-time CGM was not found to produce statistically significant improvements in HbA1c in participants age ≤12 or age 13 to 15.

**Poolsup et al., 2013**
The description of this systematic review and meta-analysis can be found above. The authors identified 10 RCTs (total n=817) comparing CGM to SMBG in children with DM1. Seven of the studies were judged to be high quality and three studies low quality. The authors stated that there was significant heterogeneity in the study results. Overall, CGM was not better than SMBG with respect to HbA1c (pooled mean difference -0.13%, 95% CI -0.38% to 0.11%, p=0.27). When the five trials of real-time CGM were considered separately, CGM resulted in greater improvement in HbA1c compared to usual care (pooled mean difference -0.18%, 95% CI -0.35% to -0.02%, p=0.02). There were no statistically significant differences among subgroups in baseline HbA1c or trial quality.

**Hommel et al., 2014**
The description of this trial can be found above. The results for children included in the trial are as follows. Pediatric quality of life was measured by the PedsQL scale and its subscales using both the child’s self-rating and the parent’s proxy rating. There were no statistically significant differences in the child’s self-rated quality (overall or in any subscale) between the sensor ON and sensor OFF periods. There were statistically significant improvements in the parent’s proxy ratings, but the magnitude of the differences was not deemed to be clinically relevant. Additionally, in a per-protocol analysis, children with >70% adherence during the sensor ON period had significantly fewer missed school days compared to the sensor OFF group (0.38 vs. 1.24 days per child per six months, p=0.005).

**Riveline et al., 2012**
This description of this trial can be found above. Overall, 14% of the patients in this trial were age 18 and younger. However, the results were not stratified by age.

**Children and Adolescents with DM2**
No systematic reviews or randomized controlled trials of CGM for children and adolescents with DM2 were identified in the search.

**Diabetes During Pregnancy**

**National Institute for Health and Care Excellence (Guideline 3), 2015**
This is a good-quality systematic review and meta-analysis commissioned by NICE to inform the 2015 update of the comprehensive guideline on diagnosis and management of diabetes in pregnant women. The authors identified five studies comparing CGM to SMBG (three RCTs and two within-participant studies). Two of the included studies enrolled pregnant women with DM1, two studies enrolled
pregnant women with either DM1 or DM2, and one study enrolled women with GDM. Four of the studies used retrospective CGM and one used real-time CGM. In the SMBG groups, women measured capillary blood glucose between four and eight times each day. The authors assessed the GRADE rating for the outcomes.

There was low-quality evidence from one study that CGM resulted in greater improvement in HbA1c at 32 to 36 weeks gestation (MD -0.6, 95% CI -0.9 to -0.3). There was moderate-quality evidence from one study of no statistically significant difference between CGM and SMBG with respect to HbA1c at 36 weeks gestation (MD -0.1, 95% CI not calculable, p=0.63). There was moderate-quality evidence from one study of no statistically significant difference between CGM and SMBG with respect to severe hypoglycemia (RR 1.0, 95% CI 0.5 to 2.1).

There was low- to very low-quality evidence of no statistically significant differences between CGM and SMBG with respect to the risk of Caesarean delivery, preterm birth, miscarriage, early neonatal death, need for neonatal intensive care unit admission, or large for gestational age.

**Wei et al., 2015**

This is a high-quality open-label randomized controlled trial comparing CGM to SMBG in women with GDM. At the outset of the trial, 117 women with GDM at 24 to 28 weeks gestation were randomized to CGM or SMBG; four participants in the CGM arm were lost to follow-up or dropped out, and seven participants in the SMBG group were found to be ineligible after randomization. Ultimately, 51 participants received CGM (24 during the second trimester and 27 during the third trimester), and 55 participants were managed by SMBG. Follow-up and insulin management were standardized across all groups.

The groups were similar at baseline. There were no statistically significant differences in any obstetrical or neonatal outcomes (including perinatal death, Caesarean delivery, preterm birth, gestational age at delivery, five-minute Apgar scores, macrosomia, neonatal hypoglycemia, or large or small for gestational age). As expected in women with GDM, the baseline HbA1c values were relatively low (5.7% and 5.8% in the CGM and SMBG groups respectively). There were no statistically significant differences in the change in HbA1c between the CGM and SMBG groups during the trial.

**Integrated Sensor-Augmented Pump Therapy for DM1**

**Riemsma et al., 2016**

This is a good-quality health technology assessment of integrated sensor-augmented pump therapies for adults and children with DM1. The authors included 19 RCTs that compared integrated sensor-augmented pump therapy with CSII + SMBG, CSII + CGM (non-integrated), MDII + SMBG, and MDII + CGM. Both head-to-head data and indirect comparisons (through network meta-analysis) were presented when appropriate. The results were separated by adults and children with DM1. Eleven of the trials were deemed to be at high risk of bias, four trials had an unclear risk of bias, and four trials had a low risk of bias (overall assessment of high risk of bias for the body of literature). Follow-up periods ranged from three to 24 months.
The head-to-head comparison of the MiniMed Veo pump to other integrated CSII + CGM systems in adults at three months follow-up produced the following findings:

- There was no significant difference in the change in HbA1c (difference 0.05%, 95% CI -0.05 to 0.15).
- There were statistically significantly fewer overall and nocturnal hypoglycemic events in the MiniMed Veo group (p<0.001), but severe hypoglycemia was not specifically reported.
- There were no cases of diabetic ketoacidosis in either group.
- Quality of life measures were not reported.

The head-to-head comparison of integrated CSII + CGM systems to non-integrated CSII + CGM in adults at six months follow-up produced the following finding:

- There was no statistically significant difference in the change in HbA1c (difference -0.0364%, SE 0.1412, p=0.80)

The head-to-head comparison of CSII + CGM to MDI + SMBG in adults at three months produced the following findings:

- One study found no statistically significant difference in the change in HbA1c (difference -0.68%, p=0.071).
- One study found a statistically significant difference in change in HbA1c in favor of CSII + CGM (-0.97%, p=0.02).
- There were no statistically significant differences in the number of hypoglycemic events or diabetic ketoacidosis.

The head-to-head comparison of CSII + CGM to MDI + SMBG in adults at six months produced the following findings:

- There was a statistically significant difference in the change in HbA1c in favor of CSII + CGM (-1.1%, 95% CI -1.47 to -0.73).
- There was no statistically significant difference in the number of hypoglycemic events.
- There was a small but statistically significant improvement in quality of life as measured by the SF-36 in favor of CSII + CGM (difference 7.9, 95% CI 0.5 to 15.3).

The head-to-head comparison of CSII + CGM to MDI + SMBG in adults at 12 months produced the following findings:

- There was a statistically significant difference in the change in HbA1c in favor of CSII + CGM (-0.6%, 95% CI –0.8 to -0.4).
- There was no statistically significant difference in the rate of severe hypoglycemic events.
- There was a small but statistically significant improvement in quality of life as measured by the SF-36 in favor of CSII + CGM (difference 3, 95% CI 1.36 to 4.64).

Indirect comparisons between studies in adults are summarized in the tables below. Cells in bold indicate that the difference is statistically significant.
**Indirect comparisons for change in HbA1c at three months in adults**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Integrated CSII + CGM WMD (95% CI)</th>
<th>CSII + SMBG WMD (95% CI)</th>
<th>MDII + SMBG WMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiniMed Veo</td>
<td>0.04 (-0.07 to 0.15)</td>
<td>0.41 (-0.31 to 1.13)</td>
<td>-0.43 (-0.95 to 0.1)</td>
</tr>
<tr>
<td>Integrated CSII + CGM</td>
<td>0.37 (-0.34 to 1.08)</td>
<td></td>
<td>-0.47 (-0.98 to 0.04)</td>
</tr>
<tr>
<td>CSII + CGM</td>
<td></td>
<td></td>
<td><strong>-0.84 (-1.33 to -0.35)</strong></td>
</tr>
</tbody>
</table>

**Indirect comparisons for diabetic ketoacidosis at three months in adults**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Integrated CSII + CGM RR (95% CI)</th>
<th>CSII + SMBG RR (95% CI)</th>
<th>MDII + SMBG RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiniMed Veo</td>
<td>No events</td>
<td>No events</td>
<td>No events</td>
</tr>
<tr>
<td>Integrated CSII + CGM</td>
<td>0.26 (0.01 to 8.53)</td>
<td>0.32 (0.04 to 2.86)</td>
<td></td>
</tr>
<tr>
<td>CSII + CGM</td>
<td></td>
<td></td>
<td>1.25 (0.08 to 19.22)</td>
</tr>
</tbody>
</table>

**Indirect comparisons for severe hypoglycemia at three months in adults**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>CSII + SMBG RR (95% CI)</th>
<th>MDII + SMBG RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated CSII + CGM</td>
<td>0.33 (0.03 to 3.87)</td>
<td>0.19 (0.02 to 1.51)</td>
</tr>
<tr>
<td>CSII + CGM</td>
<td></td>
<td>0.63 (0.17 to 2.31)</td>
</tr>
</tbody>
</table>

**Indirect comparisons for change in HbA1c at six months in adults**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>CSII + SMBG WMD (95% CI)</th>
<th>MDII + SMBG WMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated CSII + CGM</td>
<td>-0.05 (-0.31 to 0.21)</td>
<td><strong>-1.1 (-1.46 to -0.74)</strong></td>
</tr>
<tr>
<td>CSII + SMBG</td>
<td></td>
<td>-0.10 (-0.52 to 0.32)</td>
</tr>
</tbody>
</table>

**Indirect comparisons for quality of life (by DTSQ) at six months in adults**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>CSII + SMBG WMD (95% CI)</th>
<th>MDII + SMBG WMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated CSII + CGM</td>
<td><strong>5.90 (2.22 to 9.58)</strong></td>
<td><strong>8.60 (6.28 to 10.92)</strong></td>
</tr>
<tr>
<td>CSII + SMBG</td>
<td></td>
<td>2.70 (-0.16 to 5.56)</td>
</tr>
</tbody>
</table>
The head-to-head comparison of MiniMed Veo to CSII + SMBG in children and adolescents at six months produced the following finding:

- There was no statistically significant difference in the change in HbA1c (0.07, 95% CI -0.2 to 0.3).

The head-to-head comparison of integrated CSII + CGM to CSII + SMBG in children and adolescents at six months produced the following finding:

- There was no statistically significant difference in the change in HbA1c (0.4894, SE 0.2899, p=0.10).

The head-to-head comparison of integrated CSII + CGM to MDI + SMBG in children and adolescents at 12 months produced the following findings:

- There was a statistically significant change in HbA1c in favor of integrated CSII + CGM (-0.5, 95% CI -0.8 to -0.2).
- There were no statistically significant differences in severe hypoglycemia, DKA, or quality of life (as measured by the PedsQL scale).

The indirect comparison between studies in children is shown in the table below.

### Indirect comparisons for change in HbA1c at six months in children

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Integrated CSII + SMBG WMD (95% CI)</th>
<th>CSII + SMBG WMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiniMed Veo</td>
<td>0.38 (-0.16 to 0.92)</td>
<td>-0.04 (-0.26 to 0.18)</td>
</tr>
<tr>
<td>Integrated CSII + SMBG</td>
<td></td>
<td>-0.42 (-0.92 to 0.08)</td>
</tr>
</tbody>
</table>

### EVIDENCE SUMMARY

#### Adults with DM1

There is evidence that real-time CGM in adults with DM1 results in greater improvements in HbA1c when compared with SMBG. Some evidence suggests that the greatest improvements in HbA1c are attained in patients who use CSII. CGM does not reduce severe hypoglycemia or ketoacidosis, but these were rare events in the studies. CGM does not improve quality of life. There was insufficient evidence about the effects of CGM on long-term clinical outcomes from diabetes.

#### Adults with DM2

There is evidence that CGM in adults with DM2 reduces HbA1c. CGM does not improve treatment satisfaction. There was insufficient evidence about the effects of CGM on hypoglycemia or long-term clinical outcomes from diabetes.

#### Children with DM1

Neither real-time nor retrospective CGM results in improvements in HbA1c in children with DM1. CGM does appear to result in greater parental satisfaction at up to six months. CGM does not reduce severe
hypoglycemia or ketoacidosis, but these were rare events in the studies. There was insufficient evidence about the effects of CGM on long-term clinical outcomes from diabetes.

**Children with DM2**

There was insufficient evidence to draw conclusions about CGM for any outcomes in this population.

**Pregnant Women**

There is conflicting evidence about the effect of CGM on HbA1c at various time points during pregnancy. CGM does not reduce severe hypoglycemia. There were no differences in any of the studied maternal, obstetrical, or neonatal outcomes.

**Integrated Sensor-Augmented Pump Therapy**

There was limited evidence that the use of the MiniMed Veo integrated CSII + CGM system results in fewer overall and nocturnal hypoglycemic events compared to other integrated CSII + CGM systems. Based on indirect comparisons, integrated CSII + CGM systems result in greater improvement in HbA1c at six months when compared to MDI + SMBG, but not when compared to CSII + SMBG. Integrated CSII + CGM systems result in greater patient satisfaction than CSII + SMBG or MDI + SMBG.

**POLICY LANDSCAPE**

**Quality measures**

A search of the [National Quality Measures Clearinghouse](https://www.nqf.org) did not identify any measures directly related to CGM for diabetes.

**Payer coverage policies**

**Private Payers**

Coverage policies for CGM for patients with diabetes were assessed for [Aetna](https://www.aetna.com), [Cigna](https://www.cigna.com), [Moda](https://www.modalife.com), and [Regence](https://www.regence.com). Aetna, Cigna, and Moda cover short-term and long-term use of CGM for certain patients when set criteria are met. Regence considers subcutaneous insertion and removal of an implantable interstitial glucose sensor to be investigational medical technology.

**Coverage for Short-Term Use of CGM**

Aetna defines short-term use of CGM as 72 hours to one week, and covers no more than two short-term CGM periods within a 12-month period. Cigna and Moda both define short-term use as 72 hours or less. Cigna permits no more than six separate sessions in a 12-month period.

Aetna covers short-term CGM for diagnostic use for persons with diabetes who have hypoglycemia unawareness or repeated hypoglycemia and hyperglycemia at the same time each day. Cigna provides coverage for short-term CGM for persons with difficult-to-control insulin-treated diabetes, including patients who have hypoglycemic or hyperglycemic episodes unresponsive to therapy adjustments, in addition to patients with asymptomatic nocturnal hypoglycemia. Moda specifies coverage for short-
term CGM for persons with diabetes and at least one of the following: HbA1c values greater than 6.0 and less than 8.5; wide variations in blood glucose levels at least four times per day and insulin administration at least three times per day; unexplained frequent hypoglycemic episodes in people with diabetes who take insulin; repeated hypoglycemic or hyperglycemic episodes at the same time each day; episodes of ketoacidosis or hospitalizations for uncontrollable glucose; preconception or pregnancy with a history of suboptimal glycemic control; and patients who are initiating insulin or an insulin pump regimen for the first time.

**Coverage for Long-Term Use of CGM**

Aetna covers long-term therapeutic use of CGM as an adjunct to finger-stick testing of blood glucose for adults ages 25 and older with DM1 and for certain younger persons with DM1 who have two or more episodes of severe hypoglycemia in a period of 30 days, despite frequent self-monitoring and appropriate insulin adjustments. Cigna covers long-term use of CGM as necessary for persons with diabetes who have at least one of the following: a history of diabetic ketoacidosis; a positive autoantibody test; fasting C-peptide level ≤110% of the lower limit of normal according to the lab measurement method and a concurrently obtained fasting glucose ≤225 mg/dL; or renal insufficiency with a creatinine clearance ≤50 ml/minute and a fasting C-peptide level ≤200% of the lower limit of normal according to the lab measurement method. Moda may cover long-term use of CGM for persons ages 7 and older who have diabetes and either use an insulin pump or receive at least three daily insulin injections who have a history of hypoglycemic unawareness or wide fluctuations in blood glucose levels requiring four or more finger sticks per day and frequent insulin dosage adjustments. Moda requires the patient to complete a comprehensive diabetic program with a written statement from the ordering physician indicating the patient’s readiness for CGM, in addition to evidence of the patient’s compliance and understanding of the previous diabetic regimen.

**Coverage for CGM Replacement**

Cigna covers the replacement of an existing CGM device or component as medically necessary for persons with diabetes when provided documentation confirming need for replacement (i.e., device is malfunctioning, is no longer under warranty, and cannot be repaired), as well as evidence of an evaluation by the health care provider managing the patient’s diabetes, including a recommendation for continued use of CGM.

**Medicaid**

[Washington Medicaid](#) covers FDA-approved CGM devices for patients ages 18 and younger who have received prior authorization and an invoice. Before requesting prior authorization for CGM, patients should be diagnosed with insulin-dependent diabetes, be followed by an endocrinologist, and have one or more severe episodes of hypoglycemia or be enrolled in an Institutional Review Board-approved trial. Washington Medicaid does not cover closed-loop systems and requires verification of blood glucose with SMBG prior to insulin adjustment. [Washington Medicaid](#) covers short-term SMBG use for a 72-hour monitoring period with expedited prior authorization.
Medicare

No Medicare National Coverage Determination was identified for CGM for patients with diabetes. One Medicare Local Coverage Determination (LCD) was identified (effective 1/12/2017), which applies to all 50 states and Washington D.C. CGM is covered by Medicare with the following requirements:

- The beneficiary has been using a BGM and performing testing four or more times a day
- The beneficiary is insulin-treated with three or more daily injections of insulin or a Medicare-covered CSII pump
- The beneficiary’s insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results
- Within six months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate diabetes control and determined that the requirements above are met

The LCD requires the treating practitioner to have an in-person visit with the beneficiary every six months to assess adherence to the CGM regimen and diabetes treatment plan.

On January 12, 2017, the Centers for Medicare & Medicaid Services issued Ruling 1682R, defining which CGM devices are covered under the durable medical equipment benefit. Medicare covers CGM devices that have been approved by the FDA to replace blood glucose monitors for diabetes treatment decisions. To date, the Dexcom G5 is the only device to receive such FDA approval. Medicare does not cover CGM devices approved by the FDA for use as adjunctive devices to complement, but not replace, information obtained from blood glucose monitors.

Professional Society Guidelines

Recommendations from nine guidelines that address CGM for persons with diabetes are outlined below. The guidelines consistently recommend that CGM be considered for certain patients with DM1, especially for individuals with DM1 who have severe or frequent episodes of hypoglycemia or hypoglycemia unawareness.

The guideline “American Diabetes Association Standards of Medical Care in Diabetes—2016” makes the following recommendations regarding CGM for persons with diabetes (ADA, 2016):

- CGM can be a useful tool to lower HbA1c in selected adults ages 25 and older with DM1 when used properly and in conjunction with intensive insulin regimens.
- CGM may help lower HbA1c in children, teens, and younger adults; however, evidence for these groups is not as strong as for adults and success correlates with adherence to ongoing use of the device.
- CGM may be useful as a supplement to SMBG for persons with hypoglycemia unawareness or frequent hypoglycemia episodes.
- Patient readiness for CGM should be assessed on a case-by-case basis because adherence to CGM varies by individual.
- Robust diabetes education, training, and support for CGM are necessary for its optimal implementation and continuous use.
• Access to CGM should be continued after turning 65 years of age for patients who have been using CGM successfully.

The “American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement” makes the following recommendations regarding CGM for persons with diabetes (Bailey et al., 2016):

• CGM is recommended for adults and children with DM1, particularly for individuals with a history of severe hypoglycemia and hypoglycemia unawareness, and to assist in correcting hyperglycemia in patients not within target range for blood glucose level.
• Before CGM use, patients should have knowledge of the basics of sensor insertion, calibration, and real-time data interpretation. More in-depth training and more frequent follow-up is recommended for CGM users who are children.
• Current evidence is limited for CGM use for patients with DM2 who are receiving insulin or sulfonylureas; trials assessing the use of CGM for these patients are ongoing.
• No recommendation is provided regarding the use of CGM for persons with DM2 who have a low risk of hypoglycemia.
• Evidence is unclear regarding the benefits of CGM in pregnant persons with preexisting diabetes; additional studies are ongoing. CGM should primarily be considered a teaching tool when used during pregnancy, and should be used to evaluate peak postprandial blood glucose, fine-tune insulin dosing, and identify foods associated with blood glucose fluctuations. Additionally, CGM can be used as a supplement to blood glucose monitoring during pregnancy, in particular for monitoring nocturnal hypoglycemia or hyperglycemia and postprandial hyperglycemia.

The guideline “2016 Continuous Glucose Monitoring: A Consensus Conference of the American Association of Clinical Endocrinologists and American College of Endocrinology” makes the following recommendations regarding CGM for persons with diabetes (Fonesca, et al., 2016):

• Current evidence supports the use of CGM for children and adults with DM1.
• CGM may also benefit patients with insulin-dependent DM2 and pregnant women with diabetes.

The guideline “2016 Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline” makes the following recommendations regarding CGM for persons with diabetes (Peters, et al., 2016):

• Real-time CGM is recommended for adults with well-controlled DM1 and for adults with DM1 who have HbA1c levels above target. Patients should be willing and able to use a CGM device on a nearly daily basis.
• Short-term use of real time CGM is suggested for adult patients with DM2 who have HbA1c levels greater or equal to 7% and are both willing and able to use a CGM device.
• Education, training, and ongoing support to help achieve and maintain individualized glycemic goals is suggested for adults with diabetes using CGM.
The NICE 2016 guideline, “Type 1 Diabetes in Adults: Diagnosis and Management,” which is based on a NICE systematic review discussed in the evidence overview of this coverage guidance, makes the following recommendations regarding CGM for persons with diabetes (NICE, 2016b):

- Do not offer real-time CGM routinely to adults with DM1.
- Consider real-time CGM for adults with DM1 who are willing to commit to using it at least 70% of the time and calibrate it as needed, and who have at least one of the following (despite optimized use of insulin therapy and conventional blood glucose monitoring): more than one episode a year of severe hypoglycemia that has no obviously preventable cause; complete hypoglycemia unawareness; frequent asymptomatic hypoglycemia that interferes with daily activities; extreme fear of hypoglycemia; or hyperglycemia that persists despite frequent testing (but only continue CGM if HbA1c can be sustained at 7% or below, or if there has been a fall in HbA1c of 2.5% or more).
- For adults with DM1 using CGM, the principles of flexible insulin therapy should be applied with either multiple daily injections of insulin or continuous subcutaneous insulin infusion therapy.
- Real-time CGM should be provided by a center with expertise in CGM use as a tool to optimize HbA1c levels and reduce the frequency of hypoglycemic episodes.

Guidelines Specific to Diabetes in Children and Adolescents

The International Society for Pediatric and Adolescent Diabetes 2014 Clinical Practice Consensus Guideline, “Assessment and Monitoring of Glycemic Control in Children and Adolescents with Diabetes,” makes the following recommendations regarding CGM for persons with diabetes (Rewers, et al., 2014):

- CGM may particularly benefit individuals with hypoglycemic unawareness because CGM devices can be set to alert patients when glucose is below a specified range or when glucose falls at a rapid rate. However, it is currently recommended that CGM values are confirmed by SMBG for real-time adjustments of insulin dosing.

The NICE 2016 guideline, “Diabetes (Type 1 and Type 2) in Children and Young People: Diagnosis and Management,” which is based on a NICE systematic review discussed in the evidence overview of this coverage guidance, makes the following recommendations regarding CGM for persons with diabetes (NICE, 2016a):

- Offer ongoing real-time CGM monitoring with alarms to children and young people with DM1 who have at least one of the following: frequent severe hypoglycemia, impaired awareness of hypoglycemia associated with adverse consequences (e.g., seizures or anxiety), or inability to recognize or communicate about symptoms of hypoglycemia.
- Consider ongoing real-time CGM for neonates, infants, and preschool children; children and young people who undertake high levels of physical activity; and children and young people who have comorbidities (i.e., anorexia nervosa) or who are receiving treatment (e.g., corticosteroids) that impedes control of blood glucose levels.
- Consider intermittent CGM to improve blood glucose control in children and young people who have hyperglycemia that persists despite insulin adjustment and additional support.
Guidelines Specific to Diabetes during Pregnancy

The 2013 “Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline” makes the following recommendations regarding CGM for persons with diabetes (Blumer, et al., 2013):

- It is suggested that CGM be used during pregnancy for women with overt or gestational diabetes when SMBG is not sufficient to assess glycemic control.

The NICE 2015 guideline, “Diabetes in Pregnancy: Management from Preconception to the Postnatal Period,” which is based on a NICE systematic review discussed in the evidence overview of this coverage guidance, makes the following recommendations regarding CGM for persons with diabetes (NICE, 2015):

- Do not offer CGM routinely to pregnant women with diabetes.
- Consider CGM for pregnant women on insulin therapy who either have severe hypoglycemia or unstable blood glucose levels, or to gain information about changes in blood glucose levels.
- Ensure available support for pregnant women using CGM from a health care professional with expertise in CGM use.

REFERENCES

Evidence Sources


National Institute for Health and Care Excellence. (2016a). Diabetes (type 1 and type 2) in children and young people: Diagnosis and management. Retrieved from
Continuous Glucose Monitoring in Diabetes Mellitus

Approved 8/10/2017


**Other Citations**


Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

### Appendix A. GRADE Informed Framework – Element Descriptions

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance of benefits and harms</td>
<td>The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.</td>
</tr>
<tr>
<td>Quality of evidence</td>
<td>The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted.</td>
</tr>
<tr>
<td>Resource allocation</td>
<td>The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted.</td>
</tr>
<tr>
<td>Values and preferences</td>
<td>The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted.</td>
</tr>
<tr>
<td>Other considerations</td>
<td>Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.</td>
</tr>
</tbody>
</table>

### Strong recommendation

**In Favor:** The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

**Against:** The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

### Weak recommendation

**In Favor:** The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

**Against:** The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

### Confidence in estimate rating across studies for the intervention/outcome

**High:** The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

**Moderate:** The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies...

---

1 Includes risk of bias, precision, directness, consistency and publication bias
studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

**Low:** The subcommittee’s confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

**Very low:** The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.
## Appendix B. GRADE Evidence Profile

<table>
<thead>
<tr>
<th>Quality Assessment (Confidence in Estimate of Effect)</th>
<th>Adults with T1DM</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Studies</td>
<td>Study Design(s)</td>
</tr>
<tr>
<td>Severe morbidity</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Severe hypoglycemia</td>
<td>3 RCTs</td>
</tr>
<tr>
<td>Quality of life</td>
<td>1 RCT</td>
</tr>
<tr>
<td>Change in HbA1c</td>
<td>Retrospective CGM 2 RCTs</td>
</tr>
<tr>
<td>Real-time CGM 6 RCTs</td>
<td>Serious risk of bias</td>
</tr>
</tbody>
</table>
### Quality Assessment (Confidence in Estimate of Effect)

#### Adults with T1DM

<table>
<thead>
<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
<th>Risk of Bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic ketoacidosis</td>
<td>5</td>
<td>RCTs</td>
<td>Serious risk of bias</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious Imprecision</td>
<td>None</td>
</tr>
</tbody>
</table>

**Note:** The original assessment in the NICE review was very serious inconsistency due to a high level of statistical heterogeneity. Subsequent RCTs of RT-CGM in type 1 diabetics have shown similar improvements in HbA1c that overlap with the 95% CI of the meta-analytic estimate from NICE. Thus we regard concerns over inconsistency as less serious based on the additional studies.

### Quality Assessment (Confidence in Estimate of Effect)

#### Adults with T2DM

<table>
<thead>
<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
<th>Risk of Bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe morbidity</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Severe hypoglycemia</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Quality of life</td>
<td>Treatment satisfaction</td>
<td>2</td>
<td>Serious</td>
<td>No serious inconsistency</td>
<td>Serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
</tr>
</tbody>
</table>
### Quality Assessment (Confidence in Estimate of Effect)
#### Adults with T2DM

<table>
<thead>
<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
<th>Risk of Bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in HbA1c</td>
<td></td>
<td>Serious</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Low confidence in estimate of the effect ●●○○</td>
</tr>
<tr>
<td>Diabetic ketoacidosis</td>
<td></td>
<td></td>
<td></td>
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</table>

### Quality Assessment (Confidence in Estimate of Effect)
#### Children and adolescents with T1DM

<table>
<thead>
<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
<th>Risk of Bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe morbidity</td>
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<td>No serious risk of bias</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
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<td>Insufficient evidence</td>
</tr>
<tr>
<td>Severe hypoglycemia</td>
<td></td>
<td>No serious risk of bias</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>Low confidence in estimate of the effect ●●○○</td>
</tr>
<tr>
<td>Quality of life</td>
<td></td>
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<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>High confidence in the estimate of the effect ●●●●</td>
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</table>
### Quality Assessment (Confidence in Estimate of Effect)
#### Children and adolescents with T1DM

<table>
<thead>
<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
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<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
<th>Quality</th>
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<tbody>
<tr>
<td>Change in HbA1c</td>
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<td></td>
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<tr>
<td>Retrospective CGM 2</td>
<td>RCTs</td>
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<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Low confidence in estimate of the effect ●●○○</td>
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<tr>
<td>Real-time CGM 2</td>
<td>RCTs</td>
<td>No serious risk of bias</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>High confidence in the estimate of the effect ●●●●</td>
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#### Diabetic ketoacidosis

<table>
<thead>
<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
<th>Risk of Bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe morbidity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Severe hypoglycemia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Quality of life</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Change in HbA1c</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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### Quality Assessment (Confidence in Estimate of Effect)

#### Children and adolescents with T2DM

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<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
<th>Risk of Bias</th>
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<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
<th>Quality</th>
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</thead>
<tbody>
<tr>
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### Quality Assessment (Confidence in Estimate of Effect)

#### Pregnant women

<table>
<thead>
<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
<th>Risk of Bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RCTs</td>
<td>Serious risk of bias (all studies)</td>
<td>Varies by outcome</td>
<td>Varies by outcome</td>
<td>Varies by outcome</td>
<td>Varies by outcome</td>
<td>Very low to low confidence in estimate of the effect</td>
</tr>
<tr>
<td>Severe morbidity</td>
<td>Maternal, obstetrical, and neonatal outcomes</td>
<td>1 to 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>●◌◌◌ to ●●◌◌</td>
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</tbody>
</table>

#### Severe hypoglycemia

<table>
<thead>
<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
<th>Risk of Bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RCT</td>
<td>Serious risk of bias</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Moderate confidence in the estimate of the effect ●●●○</td>
</tr>
<tr>
<td>No. of Studies</td>
<td>Study Design(s)</td>
<td>Risk of Bias</td>
<td>Inconsistency</td>
<td>Indirectness</td>
<td>Imprecision</td>
<td>Other Factors</td>
<td>Quality</td>
</tr>
<tr>
<td>----------------</td>
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<td>---------------</td>
<td>--------------</td>
<td>-------------</td>
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<tr>
<td><strong>Quality of life</strong></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>RCT</td>
<td>Serious</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>Moderate confidence in the estimate of the effect ●●●◌</td>
</tr>
<tr>
<td><strong>Change in HbA1c</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 32 to 36 weeks gestation</td>
<td>RCT</td>
<td>Serious risk of bias</td>
<td>No serious inconsistency</td>
<td>Serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>Low confidence in estimate of the effect ●●○○</td>
</tr>
<tr>
<td>At 36 weeks gestation</td>
<td>RCT</td>
<td>Serious risk of bias</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>Moderate confidence in the estimate of the effect ●●○ ○</td>
</tr>
<tr>
<td><strong>Diabetic ketoacidosis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Insufficient evidence</td>
</tr>
</tbody>
</table>
APPENDIX C. METHODS

Scope Statement

Populations

Children, adolescents, and adults with type 1 or type 2 diabetes mellitus (DM) on insulin therapy, including pregnant women

Population scoping notes: None

Interventions

Continuous blood glucose monitoring, either retrospective or real time

Intervention exclusions: None

Comparators

Self-monitoring blood glucose (SMBG) and/or routine HbA1c monitoring

Outcomes

Critical: Severe morbidity (e.g., microvascular and macrovascular complications), severe hypoglycemia

Important: Quality-of-life, change in HbA1c, ketoacidosis

Considered but not selected for the GRADE table: Myocardial infarction, cerebrovascular accident, amputations, neuropathy, retinopathy, nephropathy (we chose to generalize these into “severe morbidity” to simplify consideration), diabetes-related hospitalizations, emergency department visits

Key Questions

KQ1: What is the evidence of effectiveness of CGM in improving outcomes in people with diabetes?

KQ2: What are the indications for retrospective and for real-time CGM?

KQ3: Is there evidence of differential effectiveness of CGM based on:
   a. Type 1 vs. Type 2 DM?
   b. Insulin pump (integrated with CGM or standalone) vs. multiple daily insulin injections (MDII)?
   c. Frequency and duration of CGM?
   d. Persistently poor glycemic control?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines meeting the criteria for the PICO above. Searches of core sources were limited to citations published after 2012.

The core sources searched included:
A MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, using the search terms for Diabetes Mellitus and continuous glucose monitoring. The search was limited to publications in English published since 2012. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the most recent systematic review selected for each indication.

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice guidelines was also conducted, using the following sources:

- Australian Government National Health and Medical Research Council (NHMRC)
- Centers for Disease Control and Prevention (CDC) – Community Preventive Services
- Choosing Wisely
- Institute for Clinical Systems Improvement (ICSI)
- National Guidelines Clearinghouse
- New Zealand Guidelines Group
- NICE
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Preventive Services Task Force (USPSTF)
- Veterans Administration/Department of Defense (VA/DOD)

**Inclusion/Exclusion Criteria**

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, or clinical practice guidelines.
### APPENDIX D. APPLICABLE CODES

<table>
<thead>
<tr>
<th>CODES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT Codes</strong></td>
<td></td>
</tr>
<tr>
<td>83036</td>
<td>Hemoglobin; glycosylated (A1C)</td>
</tr>
<tr>
<td>83037</td>
<td>Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use</td>
</tr>
<tr>
<td>95250-1</td>
<td>Glucose monitoring by SQ device</td>
</tr>
<tr>
<td>97802-97804</td>
<td>Medical nutrition therapy</td>
</tr>
<tr>
<td>98960-98962</td>
<td>Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face, with the patient (could include caregiver/family) each 30 minutes</td>
</tr>
<tr>
<td>99078</td>
<td>Physician educational services rendered to patients in a group setting (eg, prenatal, obesity, or diabetic instructions)</td>
</tr>
<tr>
<td><strong>HCPCS Level II Codes</strong></td>
<td></td>
</tr>
<tr>
<td>A4230-2</td>
<td>Insulin infusion pump supplies</td>
</tr>
<tr>
<td>A4233-6</td>
<td>Batteries for home blood glucose monitors</td>
</tr>
<tr>
<td>A4253</td>
<td>Blood Glucose test strips, box of 50</td>
</tr>
<tr>
<td>A4255</td>
<td>Platforms for home blood glucose monitor, 50/box</td>
</tr>
<tr>
<td>A4256</td>
<td>Calibrator solutions/chips</td>
</tr>
<tr>
<td>A4258</td>
<td>Spring-powered device for lancet, each</td>
</tr>
<tr>
<td>A4259</td>
<td>Lancets, per box of 100</td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable</td>
</tr>
<tr>
<td>A9276</td>
<td>Disposable sensor, CGM system</td>
</tr>
<tr>
<td>A9277</td>
<td>External transmitter, CGM system</td>
</tr>
<tr>
<td>A9278</td>
<td>External receiver, CGM system</td>
</tr>
<tr>
<td>E0607</td>
<td>Blood glucose monitor</td>
</tr>
<tr>
<td>E0784</td>
<td>Insulin infusion pump</td>
</tr>
<tr>
<td>E2100</td>
<td>Blood glucose monitor with voice synthesizer</td>
</tr>
<tr>
<td>E2101</td>
<td>Blood glucose monitor with integrated lancet</td>
</tr>
<tr>
<td>G0108-G0109</td>
<td>Diabetes outpatient self-management training services</td>
</tr>
<tr>
<td>G0270-G0271</td>
<td>Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease)</td>
</tr>
<tr>
<td>S1030-1</td>
<td>Continuous non-invasive glucose monitoring device, purchase/rental</td>
</tr>
<tr>
<td>S9140</td>
<td>Diabetic management program, follow-up visit to non-MD provider</td>
</tr>
<tr>
<td>S9141</td>
<td>Diabetic management program, follow-up visit to MD provider</td>
</tr>
</tbody>
</table>

Note: Inclusion on this list does not guarantee coverage