CONTINUOUS GLUCOSE MONITORING AND INSULIN DELIVERY FOR MANAGING DIABETES

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Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENEFIT CONSIDERATIONS</td>
<td>1</td>
</tr>
<tr>
<td>COVERAGE RATIONALE</td>
<td>2</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>3</td>
</tr>
<tr>
<td>DESCRIPTION OF SERVICES</td>
<td>4</td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>5</td>
</tr>
<tr>
<td>U.S. FOOD AND DRUG ADMINISTRATION</td>
<td>15</td>
</tr>
<tr>
<td>CENTERS FOR MEDICARE AND MEDICAID SERVICES</td>
<td>17</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>17</td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>22</td>
</tr>
</tbody>
</table>

INSTRUCTIONS FOR USE
This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage.
Many states require benefit coverage of services that diagnose or treat diabetes mellitus, including glucose monitors, test strips, syringes, medications and related supplies. Specific required coverage varies from state to state.

**Repair and Replacement**

The enrollee-specific benefit document, either a Certificate of Coverage (COC) or Summary Plan Description (SPD), includes information regarding repair and replacement of Durable Medical Equipment. Many benefit documents also include language governing the coverage of Durable Medical Equipment that meets the enrollee’s basic need. Further information can be found in the Coverage Determination Guideline titled [Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies, and Repairs/Replacements](#). In all cases, the enrollee-specific benefit document must be used to determine coverage.

**COVERAGE RATIONALE**

**Insulin Delivery**

External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for the following:

- Patients with type 1 diabetes
  For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Insulin Infusion Pump ACG:A-0339 (AC).
- Patients with type 2 diabetes who currently perform ≥4 insulin injections and ≥4 blood glucose measurements daily

*Note:* Programmable disposable external insulin pumps are considered equivalent to standard insulin pumps.

Nonprogrammable transdermal insulin delivery systems are unproven and not medically necessary for treating patients with diabetes.

There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of transdermal insulin delivery in the management of patients with diabetes.

Implantable insulin pumps are investigational, unproven and not medically necessary.

No implantable insulin pumps have received U.S. Food and Drug Administration (FDA) approval at this time. While some preliminary studies reported improved glycemic control and fewer episodes of hypoglycemia in carefully selected patients, complications such as catheter blockage and infection were observed. Larger, randomized controlled trials are needed to determine the long-term impact of implantable insulin pumps on diabetes management.

Insulin infuser ports are unproven and not medically necessary for insulin delivery in patients with diabetes.

There is insufficient evidence demonstrating that the use of insulin infuser ports results in improved glycemic control beyond what can be achieved by using standard insulin delivery methods. In addition, an increase in complications, such as infection at the port site, has been reported when using these devices. Further well-designed, large-scale randomized controlled trials are needed to establish the safety and efficacy of these devices.

See the [Description of Services](#) section below for further details on the various types of insulin delivery systems.

**Continuous Glucose Monitors with or without Combined Insulin Pumps**

Short-term (3-7 days) continuous glucose monitoring by a healthcare provider for diagnostic purposes is proven and medically necessary for patients with diabetes.
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes: Medical Policy (Effective 04/22/2015)

Long-term continuous glucose monitoring for personal use at home is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who meet EITHER of the following criteria AND have demonstrated adherence to a physician ordered diabetic treatment plan:

- Have been unable to achieve optimum glycemic control as defined by the most current version of the American Diabetes Association (ADA) Standards of Medical Care in Diabetes; or
- Have experienced hypoglycemia unawareness and/or frequent episodes of hypoglycemia

Long-term continuous glucose monitoring for personal use at home is unproven and not medically necessary for patients with type 2 diabetes or gestational diabetes. There is insufficient evidence that the use of long-term continuous glucose monitoring leads to improvement of glycemic control in patients with type 2 or gestational diabetes.

For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Continuous Glucose Monitoring ACG:A-0126 (AC).

Remote Glucose Monitoring
Remote glucose monitoring is unproven and not medically necessary for managing patients with diabetes.
There is insufficient evidence in the clinical literature to conclude that remote glucose monitoring demonstrates improvement in clinical outcomes.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>95250</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording</td>
</tr>
<tr>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report</td>
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</tbody>
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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
</tr>
<tr>
<td>A9275</td>
<td>Home glucose disposable monitor, includes test strips</td>
</tr>
<tr>
<td>A9276</td>
<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply</td>
</tr>
<tr>
<td>A9277</td>
<td>Transmitter; external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td>A9278</td>
<td>Receiver (monitor); external, for use with interstitial continuous glucose monitoring system</td>
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CPT® is a registered trademark of the American Medical Association.
<table>
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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>E0607</td>
<td>Home blood glucose monitor</td>
</tr>
<tr>
<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
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</tbody>
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| E1399      | Durable medical equipment, miscellaneous  
            | NOTE: The i-port device is not durable medical equipment (DME) nor does it have a listed code |
| S1030      | Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code) |
| S1031      | Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code) |
| S1034      | Artificial Pancreas Device System (e.g., Low Glucose Suspend [LGS] Feature) Including Continuous Glucose Monitor, Blood Glucose Device, Insulin Pump And Computer Algorithm That Communicates With All Of The Devices |
| S1035      | Sensor; Invasive (e.g., Subcutaneous), Disposable, For Use With Artificial Pancreas Device System |
| S1036      | Transmitter; External, For Use With Artificial Pancreas Device System |
| S1037      | Receiver (Monitor); External, For Use With Artificial Pancreas Device System |

**Coding Clarification**

E1399 is often misused when reporting the i-port device; however, the i-port device is not durable medical equipment (DME) nor does it have a listed code. E1399 can apply to other unspecified DME devices.

**DESCRIPTION OF SERVICES**

Diabetes mellitus is one of the leading causes of death in the United States. If poorly controlled, diabetes can lead to complications such as heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, nerve damage and impotence. In gestational diabetes, fetal and maternal health can be compromised.

Improved glycemic control has been shown to slow the onset or progression of major complications. Management of diabetes involves efforts to maintain blood glucose levels near the normal range. Currently, self-monitoring of blood glucose (SMBG) and laboratory testing of glycosylated hemoglobin (A1C) to measure longer term glycemic control are the standard methods for glucose testing (AACE, 2011; ADA, 2015).

**Insulin Delivery**

An external insulin pump is an insulin delivery device that can be worn on a belt or kept in a pocket. Standard insulin pumps connect to flexible plastic tubing that ends with a needle inserted through the skin into the fatty tissue. Another type of insulin pump (OmniPod®) combines an insulin reservoir placed on the skin with a wireless device to manage dosing and perform SMBG. Both types of devices can be programmed to release small doses of insulin continuously (basal), or a bolus dose close to mealtime to control the rise in blood glucose after a meal. Newer patch devices (e.g., V-Go®) deliver preset dosages of insulin transdermally and lack programmability.

Implantable insulin pumps, with programmable infusion rates, provide continuous intraperitoneal insulin delivery. A blood glucose monitor is not an integral part of this type of system (ADA website).

An insulin infuser port is a device used to reduce the number of needle injections for patients with insulin-dependent diabetes. An insertion needle guides a soft cannula into the subcutaneous
tissue. Once applied, the insertion needle is removed, leaving the soft cannula under the skin to act as a direct channel into the subcutaneous tissue. Insulin is then injected through the cannula using a standard needle and syringe or insulin pen. Devices remain in place for up to 72 hours to accommodate multiple drug injections without additional needle sticks.

**Continuous Glucose Monitors (CGM)**

Continuous glucose monitoring (CGM) devices continuously monitor and record interstitial fluid glucose levels and have three components - a disposable subcutaneous sensor, transmitter and monitor. Some CGM systems are designed for short-term diagnostic or professional use. These devices store retrospective information for review at a later time. Other CGM systems are designed for long-term patient use and display information in real-time allowing the patient to take action based on the data (AMA, 2009). Glucose measurements provided during continuous monitoring are not intended to replace standard self-monitoring of blood glucose (SMBG) obtained using fingerstick blood samples, but can alert patients of the need to perform SMBG. These long-term devices are available with or without an integrated external insulin pump.

Remote glucose monitors provide real-time nocturnal glucose information. These devices transmit/receive information wirelessly by radiofrequency (RF) transmission.

**CLINICAL EVIDENCE**

**Insulin Delivery**

A systematic review and meta-analysis conducted by the Agency for Healthcare Research and Quality (AHRQ) (Golden et al., 2012) compared insulin pumps with multiple daily injections (MDI) and found no differences in glycemic control or weight gain, as well as insufficient evidence on hypoglycemic events, mortality, and other clinical outcomes. Although recent trials have provided some evidence of clinical benefit, these have suffered from methodological concerns and use of nonstandard outcomes. Findings from the evidence base of eight RCTs suggests a moderate level of certainty that insulin pumps provide a comparable net health benefit to multiple daily injections in patient with type 2 diabetes (ICER, 2014).

Reznik et al. (2014) conducted an international multicenter, randomized controlled trial comparing insulin pump treatment with multiple daily injections (MDI) for patients with poorly controlled type 2 diabetes. A total of 331 patients with an HbA1c of 8.0-12.0% were randomly assigned to pump treatment (n=168) or to continue with multiple daily injections (=163). Mean HbA1c at baseline was 9% in both groups. Neither patients nor investigators were masked to treatment allocation. The primary endpoint was change in mean HbA1c between baseline and end of the randomized phase. At 6 months, mean HbA1c had decreased by 1.1% in the pump treatment group and 0.4% in the MDI group. At the end of the study, the mean total daily insulin dose was 97 units with pump treatment versus 122 units for MDI with no significant difference in bodyweight change between the two groups. Two diabetes-related serious adverse events (hyperglycemia or ketosis without acidosis) resulting in hospitalization occurred in the pump treatment group compared with one in the MDI group. No ketoacidosis occurred in either group and one episode of severe hypoglycemia occurred in the MDI group. The authors concluded that in patients with poorly controlled type 2 diabetes, despite using multiple daily injections of insulin, pump treatment can be considered as a safe and valuable treatment option.

In a meta-analysis, Fatourechi et al. (2009) summarized the evidence on the effect of continuous insulin infusion (CSII) and multiple daily injections (MDIs) on glycemic control and hypoglycemia. Patients with type 1 diabetes using CSII had slightly lower HbA1c, with no significant difference in severe or nocturnal hypoglycemia. Adolescents and adults with type 1 diabetes enrolled in crossover trials had nonsignificantly fewer minor hypoglycemia episodes per patient per week with CSII than MDI; children enrolled in parallel trials had significantly more episodes. Outcomes were not different in patients with type 2 diabetes. Contemporary evidence indicates that compared to MDI, CSII slightly reduced HbA1c in adults with type 1 diabetes, with unclear impact on hypoglycemia. In type 2 diabetes, CSII and MDI had similar outcomes. The authors stated that
the effect in patients with hypoglycemia unawareness or recurrent severe hypoglycemia remains unclear because of lack of data.

Pickup and Sutton (2008) conducted a meta-analysis of 22 studies comparing severe hypoglycemia and glycemic control during continuous subcutaneous insulin infusion (CSII) and multiple daily insulin injections (MDI). The severe hypoglycemia rate in type 1 diabetes was markedly less during CSII than MDI, with the greatest reduction in those with most severe hypoglycemia on MDI and those with the longest duration of diabetes. The biggest improvement in HbA1c was in those with the highest HbA1c on MDI.

In a meta-analysis, Jeitler et al. (2008) compared the effects of continuous subcutaneous insulin infusion (CSII) with those of multiple daily insulin (MDI) injections on glycemic control, risk of hypoglycemic episodes, insulin requirements and adverse events in type 1 and type 2 diabetes mellitus. Twenty-two studies were included (17 on type 1 diabetes mellitus, two on type 2 diabetes mellitus, three on children). CSII therapy in adults and adolescents with type 1 diabetes resulted in a greater reduction of glycated hemoglobin. Total daily insulin requirements were lower with CSII than with MDI therapy. No beneficial effect of CSII therapy could be detected for patients with type 2 diabetes mellitus. No overall conclusions were possible for severe hypoglycemia and adverse events for any of the different patient groups due to rareness of such events, different definitions and insufficient reporting.

In a Cochrane review, Farrar et al. (2007) compared continuous subcutaneous insulin infusion (CSII) with multiple daily injections (MDI) of insulin for pregnant women with diabetes. The review found a lack of robust evidence to support the use of one particular form of insulin administration over another for pregnant women with diabetes. The data are limited because of the small number of trials appropriate for meta-analysis, small study sample size and questionable generalizability of the trial population. Conclusions cannot be made from the data available and therefore a robust randomized trial is needed. Assessed as up-to-date September 2011.

The Diabetes Control and Complications Trial (DCCT) demonstrated that tight glycemic control achieved with intensive insulin regimens significantly delayed the onset and slowed the progression of retinopathy, nephropathy or neuropathy in patients with type I or II diabetes. Elements of intensive therapy included testing blood glucose levels four or more times a day, injecting insulin at least three times daily or using an insulin pump, adjusting insulin doses according to food intake and exercise, following a diet and exercise plan and making monthly visits to a health care team (DCCT, 1993).

Clinical evidence evaluating the V-Go insulin delivery system is limited. Rosenfeld et al. (2012) performed an analysis of glycemic control in twenty-three patients who used the V-Go device. Clinical data was retrospectively collected before V-Go initiation, after 12 weeks of use, at the end of treatment and 12 weeks after discontinuation. Patient perceptions of device use were obtained through telephone surveys. The authors reported that glycemic control improved when patients were switched to the V-Go for insulin delivery and deteriorated when the V-Go was discontinued. No differences in hypoglycemic events were noted. Study limitations include its retrospective design, small sample size and short-term follow-up. Further well-designed, prospective studies are needed to establish the safety and efficacy of this device in managing patients with diabetes.

**Implantable Insulin Pumps**

Implantable insulin pumps (IIP) are a promising new technology for the treatment of insulin-dependent diabetes but at this time are only available in a clinical trial setting (Hayes, 2011; updated 2013).

**Insulin Infuser Ports**

Blevins et al. (2008) conducted a prospective, randomized controlled cross-over trial comparing the outcomes of insulin-dependent diabetics (n=74) who used the i-port compared to standard multi-injection insulin therapy. Type 1 (n=56) and type 2 (n=18) diabetics were randomly assigned
to one of four cohort groups. Cohort 1 (n=18) compared standard injections (SI) to single i-port, cohort 2 (n=20) compared single i-port to SI, cohort 3 (n=18) compared dual i-ports to single i-port and cohort 4 (n=18) compared single i-port to dual i-ports. At the end of the first three weeks, each group switched to the alternative method for an additional three weeks. Ten participants were lost to follow-up, six of which were due to device related issues (adhesive failure, discomfort, hyperglycemia, cannula bends and adverse events). Participant’s glycosylated albumin was not significantly different between SI, single i-port and dual i-port treatment regiments. A1c levels were similar among all cohorts at the initiation and completion of the study. Adverse events included erythema, suppuration, skin irritation, itching, and bruising at the i-port insertion site. Three events of severe hyperglycemia were also reported.

**Continuous Glucose Monitors**

The Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review of glucose monitoring methods for diabetes. Studies suggested that real-time continuous glucose monitoring (rt-CGM) was superior to self-monitoring of blood glucose (SMBG) in lowering HbA1c in nonpregnant individuals with type 1 diabetes, particularly when compliance was high, without affecting the risk of severe hypoglycemia. rt-CGM/CSII in the form of sensor-augmented pumps was superior to MDI/SMBG in lowering HbA1c in the research studies analyzed in this review; however, other combinations of these insulin delivery and glucose monitoring modalities were not evaluated (Golden et al., 2012).

A meta-analysis of fourteen randomized controlled trials (n=1188) evaluated the use of continuous glucose monitoring (CGM) in patients with type 1 diabetes. Compared to self-monitoring of blood glucose (SMBG), the use of CGM was associated with a greater reduction in HbA1c. The number of hypoglycemic events was not significantly different between the two groups, but duration of hypoglycemia was shorter for the CGM group, with an incremental reduction of hypoglycemia duration. Continuous glucose monitoring also resulted in a shorter duration of hyperglycemia than SMBG (Floyd et al., 2012).

In a randomized, controlled multicenter study, Battelino et al. (2011) assessed the impact of continuous glucose monitoring on hypoglycemia in patients with type 1 diabetes. A total of 120 children and adults on intensive therapy for type 1 diabetes and an A1c <7.5 were randomly assigned to a control group performing self-monitoring of blood glucose (SMBG) and wearing a masked continuous glucose monitor every second week for five days or to a group with real-time continuous glucose monitoring. Continuous glucose monitoring was associated with reduced time spent in hypoglycemia and a concomitant decrease in HbA1c in children and adults with type 1 diabetes.

The Juvenile Diabetes Research Foundation sponsored a multicenter, randomized controlled trial evaluating the use of continuous glucose monitoring in the management of type I diabetes mellitus. The investigators randomly assigned 322 adults and children who were already receiving intensive therapy for type 1 diabetes to a group with continuous glucose monitoring or to a control group performing home monitoring with a blood glucose meter. All the patients were stratified into three groups according to age and had a glycated hemoglobin level of 7.0 to 10.0%. The primary outcome was the change in the glycated hemoglobin level at 26 weeks. The changes in glycated hemoglobin levels in the two study groups varied markedly according to age group (P=0.003), with a significant difference among patients 25 years of age or older that favored the continuous-monitoring group (mean difference in change, -0.53%; 95% confidence interval [CI], -0.71 to -0.35; P<0.001). The between-group difference was not significant among those who were 15 to 24 years of age (mean difference, 0.08; 95% CI, -0.17 to 0.33; P=0.52) or among those who were 8 to 14 years of age (mean difference, -0.13; 95% CI, -0.38 to 0.11; P=0.29). Secondary glycated hemoglobin outcomes were better in the continuous-monitoring group than in the control group among the oldest and youngest patients but not among those who were 15 to 24 years of age. The investigators concluded that continuous glucose monitoring can be associated with improved glycemic control in adults with type 1 diabetes; however, further work is needed to identify barriers to effectiveness of continuous monitoring in children and adolescents.
The same JDRF study group also evaluated factors associated with successful use of continuous glucose monitoring (CGM) among participants with intensively treated type 1 diabetes. 232 participants randomly assigned to the CGM group (165 with baseline A1C ≥7.0% and 67 with A1C <7.0%) were asked to use CGM on a daily basis. The associations of baseline factors and early CGM use with CGM use ≥6 days/week in the 6th month and with change in A1C from baseline to 6 months were evaluated. The only baseline factors found to be associated with greater CGM use in month 6 were age ≥25 years (P < 0.001) and more frequent self-reported prestudy blood glucose meter measurements per day (P < 0.001). CGM use and the percentage of CGM glucose values between 71 and 180 mg/dl during the 1st month were predictive of CGM use in month 6 (P < 0.001 and P = 0.002, respectively). More frequent CGM use was associated with a greater reduction in A1C from baseline to 6 months (P < 0.001), a finding present in all age-groups. After 6 months, near-daily CGM use is more frequent in intensively treated adults with type 1 diabetes than in children and adolescents, although in all age-groups near-daily CGM use is associated with a similar reduction in A1C. Frequency of blood glucose meter monitoring and initial CGM use may help predict the likelihood of long-term CGM benefit in intensively treated patients with type 1 diabetes of all ages (JDRF, 2009a).

In a parallel study of 129 adults and children with intensively treated type 1 diabetes (age range 8-69 years), the JDRF study group reported that the evidence suggests that CGM is beneficial for individuals with type 1 diabetes who have already achieved excellent control with A1C <7.0% (JDRF, 2009b).

In a 6-month extension to the JDRF trial, the study group evaluated the long-term effects of continuous glucose monitoring (CGM) in 83 intensively treated adults (≥ 25 years of age) with type 1 diabetes. The group found that most adults continued to use CGM on a daily or near daily basis and had sustained benefits for improved glucose control noted by A1c levels and the amount of time sensor glucose values were in the target range. These benefits persisted despite less intensive follow-up, designed to approximate usual clinical practice, than during the 6-month randomized phase of the study (JDRF, 2009c).

In a Cochrane review, Langendam et al. (2012) assessed the effects of continuous glucose monitoring (CGM) systems compared to conventional self-monitoring of blood glucose (SMBG) in patients with Type 1 diabetes. Twenty-two randomized controlled trials (RCTs) comparing retrospective or real-time CGM with conventional self-monitoring of blood glucose levels or with another type of CGM system in patients with type 1 diabetes mellitus were included. The studies randomized 2883 patients with type 1 diabetes to receive a form of CGM or to use SMBG using fingerprick. The duration of follow-up varied between 3 and 18 months; most studies reported results for six months of CGM use. This review shows that CGM helps in lowering the HbA1c. In most studies the HbA1c value decreased in both the CGM and the SMBG users, but more in the CGM group. The difference in change in HbA1c levels between the groups was on average 0.7% for patients starting on an insulin pump with integrated CGM and 0.2% for patients starting with CGM alone. The most important adverse events, severe hypoglycemia and ketoacidosis did not occur frequently in the studies, and absolute numbers were low (9% of the patients, measured over six months). Diabetes complications, death from any cause and costs were not measured. There are no data on pregnant women with Type 1 diabetes and patients with diabetes who are not aware of hypoglycemia.

Chase et al. (2010) reported on the 12-month follow-up of 80 patients age 8–17 years who participated in the 6-month randomized JDRF study and the subsequent 6-month extension study. Outcomes included frequency of CGM use, HbA1c levels, rate of severe hypoglycemia and a CGM satisfaction scale. Seventy-six (95%) of 80 subjects were using CGM after 6 months (median use = 5.5 days/week) compared with 67 (84%) after 12 months (median use = 4.0 days/week). The 17 subjects using CGM ≥6 days/week in month 12 had substantially greater...
improvement from baseline in HbA1c than did the 63 subjects using CGM <6 days/week in month 12 (mean change - 0.8 +/- 0.6% vs. +0.1 +/- 0.7%). They also reported greater satisfaction with use of CGM. The incidence of severe hypoglycemic events was low during the 12 months of the study irrespective of the amount of CGM use. The study concluded that individuals who use CGM on a near-daily basis can have substantial improvement in glycemic control.

Chetty et al. (2008) performed a meta-analysis of randomized controlled trials comparing CGMS and SBGM in Type 1 diabetic patients. Seven studies with a total of 335 patients were included. Five studies were confined to the pediatric population (age<18 years). The authors concluded that while there was some indication of improved detection of asymptomatic nocturnal hypoglycemia in the CGMS group, there was insufficient evidence to support the notion that CGMS provides a superior benefit over SBGM in terms of HBA1c reduction.

**Adult Patients**

Szypowska et al. (2012) conducted a systematic review and meta-analysis to explore the potential beneficial effects of real-time continuous glucose monitoring (RT-CGM) on diabetes management compared with self blood glucose measurement (SBGM) in patients with type 1 diabetes (T1DM). Seven randomized controlled trials (n=948) were included. Combined data from all studies showed better HbA1c reduction in subjects using RT-CGM compared with those using SBGM. Patients treated with insulin pump and RT-CGM had a lower HbA1c level compared with subjects managed with insulin pump and SBGM (four RCTs, n=497) The benefits of applying RT-CGM were not associated with an increase in rate of major hypoglycemic episodes. The use of RT-CGM for over 60-70% of time was associated with a significant lowering of Hba1c. The authors concluded that RT-CGM is more beneficial than SBGM in reducing Hba1c in patients with type 1 diabetes. Further studies are needed to evaluate the efficacy of this system in the pediatric population, especially in very young children.

Vigersky et al. (2012) conducted a randomized controlled trial of 100 adults with type 2 diabetes, who were not on prandial insulin, to determine whether short-time, real-time continuous glucose monitoring (RT-CGM) had long-term glycemic effects. Intermittent RT-CGM over 12 weeks significantly improved glycemic control both during and for up to 1 year following the intervention. The authors concluded that additional studies are needed to confirm these results as well as determine the mechanism by which the improvement occurred, the minimum time for RT-CGM to be effective and the effect/timing of refresher courses of this intervention.

Hoeks et al. (2011) performed a systematic review of seven randomized controlled trials evaluating the effect of real-time continuous glucose monitoring systems in diabetes management. The analysis concluded that real-time continuous glucose monitoring has a beneficial effect on glycemic control in adult patients with diabetes, without an increase in the incidence of hypoglycemia. Studies in well-selected patient groups (pregnancy, history of severe hypoglycemia, type 2 diabetes) are lacking.

Cooke et al. (2009) presented the results of the Minimally Invasive Technology Role and Evaluation (MITRE) study in a randomized controlled trial (RCT) comparing the efficacy of two CGM devices in adult patients with insulin-dependent diabetes. The primary endpoint was long-term glucose control, as indicated by changes in A1C levels at 18 months. The patients were randomized to the MiniMed CGMS (n=102), the GlucoWatch G2 Biographer (n=100), standard control (n=102) or attention control (n=100). By month 18, the percentage of patients who had a relative reduction of A1C of at least 12.5% was 15% in the Biographer group, 27% in the CGMS group, 24% in the standard control, and 27% in the attention control group. The investigators found that CGMS has a small benefit but it does not last and the Biographer had a smaller effect on A1C than the MiniMed CGMS or standard treatments.

Two small studies evaluated poorly controlled patients with type 2 diabetes. Yoo et al. (2008) (n=65) reported significantly greater improvement in glycemic control in CGM patients compared with SMBG patients. Cosson et al. (2009) (n=48) evaluated both type 1 and 2 patients. Type 2
diabetic patients, but not type 1 patients, achieved significantly greater glycemic control following CGM intervention relative to controls.

In a small nonrandomized comparison study Garg et al. (2007) evaluated real-time CGM with DexCom STS (n=24). At 12 weeks a modest but significant improvement in A1C (0.4%) was observed in the CGM group compared to nonsignificant increase in A1C (0.3%) in the comparison group (n=23). Also, at 12 weeks there was a difference in A1C values between groups despite the fact that there was no change in insulin dose. The number of subjects achieving A1C values <7.5% was higher in the CMG group at 12 weeks. Improvements in metabolic control with CGM were not associated with increased hypoglycemia.

Similar results were reported by Bailey et al. (2007) who conducted an observational trial evaluating the DexCom STS in a heterogeneous patient population (n=139) including type 1 and type 2 diabetics. Overall, at the end of the 12-week study, the A1C was reduced by 0.4%. Decrease in A1C was more pronounced in patients with higher baseline levels. Patients did not report an increase in the time spent in hypoglycemia. Patients in the top quartile of CGM attention experienced a greater A1C reduction compared to those in the bottom quartile.

Zick et al. (2007) compared CGM with conventional measurements of hypoglycemia in a nonrandomized controlled trial. The proportion of patients who experienced hypoglycemia was significantly higher in those assessed with SMBG than with CGM, which may indicate an underreporting by SMBG. Mean daytime glucose values were similar between the two groups, but mean nocturnal glucose values were significantly lower in patients measured with CGM than in patients measured with SMBG.

One randomized controlled trial (Garg 2006a) evaluated the diagnostic performance and clinical effectiveness of the DexCom STS CGMS in 91 adult patients with either type 1 (n=75) or type 2 (n=16) insulin-requiring diabetes. Each subject participated in three, 72-hour cycles of monitoring. Results indicate that patients who were provided unblinded access to continuous glucose data and alerts/alarms were more effectively able to managing hypoglycemic and hyperglycemic events.

A similar study was conducted by Garg and Jovanovic (2006b) to evaluate the safety and efficacy of seven-day abdominal, transcutaneous, real-time CGM (DexCom STS) in a heterogeneous study group including type 1 (n=69) and type 2 (n=17) insulin-requiring diabetics. Study results showed that presenting real-time glucose values to patients was associated with a decrease in the time spent in the hyper- and hypoglycemic ranges while increasing the time spent in the euglycemic range. The greatest improvements were observed in patients with higher A1C baseline values.

Deiss et al. (2006b) reported on a 3-month study of 81 children and 81 adults with stable type 1 diabetes who had A1C levels of 8.1% or greater. Patients were randomized to continuous real-time monitoring with the Guardian RT, continuous monitoring for 3 days every 2 weeks, or SMBG. At 3 months, 50% of patients with continuous real-time monitoring had a decrease in A1C of at least 1% compared to 37% of those with intermittent continuous monitoring, and 15% of controls. An A1C reduction of at least 2% was seen in 26% of group 1 patients, 9% of group 2 patients and 4% of control group patients. The investigators reported that the patients did not record specific information regarding daily self-management activities but reported that changes were made. Therefore, delineation between the link between CGM and improvement in glycemic control could not be made.

Bode et al. (2004) evaluated the effectiveness of alarms based on real-time sensor glucose values provided by the MiniMed Guardian CGMS in 71 adult diabetics. Patient responses to the hypoglycemia alerts resulted in a significantly reduced duration of hypoglycemic events compared with controls, although overtreatment of hypoglycemia may have caused a small increase in the
frequency of hyperglycemic events.

The National Institute for Health and Care Excellence (NICE) states that continuous glucose monitoring systems have a role in the assessment of glucose profiles in adult Type I diabetes patients with consistent glucose control problems on insulin therapy, such as repeated hyper- or hypoglycemia at the same time of day or hypoglycemia unawareness unresponsive to conventional insulin dose adjustment (NICE, 2004; updated 2011).

**Pediatric Patients**

Mauras et al. (2012) assessed the benefit of continuous glucose monitoring (CGM) in young children aged 4 to 9 years with type 1 diabetes. A total of 146 children with type 1 diabetes (mean age 7.5 ± 1.7 years) were randomly assigned to CGM or to usual care. The primary outcome was reduction in HbA1c at 26 weeks by ≥0.5% without the occurrence of severe hypoglycemia. The primary outcome was achieved by 19% in the CGM group and 28% in the control group. Mean change in HbA1c was -0.1% in each group. Severe hypoglycemia rates were similarly low in both groups. CGM wear decreased over time, with only 41% averaging at least 6 days/week at 26 weeks. There was no correlation between CGM use and change in HbA1c. The authors concluded that CGM in 4- to 9-year-olds did not improve glycemic control despite a high degree of parental satisfaction with CGM. This finding may be related in part to limited use of the CGM glucose data in day-to-day management and to an unremitting fear of hypoglycemia.

The Diabetes Research in Children Network (DirecNet) Study Group examined the feasibility of daily use of a continuous glucose monitor, the FreeStyle Navigator CGMS in children with type 1 diabetes using insulin pumps. Mean A1C improved from 7.1% at baseline to 6.8% at 13 weeks of unblinded sensor use, and the percentage of glucose values in the target range increased from 52% to 60%. There was a modest increase in the percentage of sensor values that were <70 mg/dL. (Buckingham 2007) The DirecNet Study Group also conducted a similar study in 27 children with type 1 diabetes using multiple daily injections of insulin. Mean A1C level fell from 7.9 at baseline to 7.3 at 13 weeks (Weinzimer, 2008).

Golicki et al. (2008) performed a systematic review and meta-analysis of the evidence comparing the effects of continuous glucose monitoring with self-monitoring of blood glucose on glycemic control in children with type 1 diabetes. Combined data from five trials involving 131 patients showed that CGM did not significantly reduce HbA1c levels compared with control groups. The authors concluded that CGM was not better than self-monitoring of blood glucose with regard to improvement of metabolic control among type 1 diabetic children. They also stated that, due to the small number of participants and methodological limitations of the studies included, findings of this meta-analysis should be interpreted with caution.

NICE recommends that continuous glucose monitoring systems be available to children and young people with type 1 diabetes who have persistent problems with hypoglycemia unawareness or repeated hypoglycemia and hyperglycemia (NICE, 2004; updated 2011).

Deiss et al. (2006a) reported results of a small double-blinded, cross-over randomized trial in children with type 1 diabetes. During the first 12 weeks, group A (n=15) had access to the MiniMed CGMS data while group B (n=15) was blinded to the CGMS data. At the end of three months, the groups crossed over. The authors found that visual interpretation of CGMS data resulted in frequent changes in insulin therapy, but had no effect on metabolic control (no significant decrease in A1C levels) and duration of hyperglycemia.

The GuardControl study (Deiss 2006b) that included poorly controlled adults (n=81) and children (n=81) despite intensive insulin therapy showed that, within three months, real-time continuous glucose monitoring with the Guardian RT led to significantly improved A1C values. The study did not report age-specific outcomes. (Also see the Adult Patients section.)

Lagarde et al. (2006) conducted a small (n=27) randomized trial and reported that CGMS may
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes: Medical Policy (Effective 04/22/2015)

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improve metabolic control in children with type 1 diabetes since A1C levels decreased in the treatment group compared with the control group after 6 months. This decrease, however, was small.

**Gestational Diabetes**

In a prospective, open label randomized controlled trial, Murphy et al. (2008) evaluated the effectiveness of continuous glucose monitoring during pregnancy on maternal glycemic control, infant birth weight and risk of macrosomia in women with type 1 and type 2 diabetes. 71 women with type 1 diabetes (n=46) or type 2 diabetes (n=25) were allocated to antenatal care plus continuous glucose monitoring (n=38) or to standard antenatal care (n=33). The primary outcome was maternal glycemic control during the second and third trimesters from measurements of HbA1c levels every four weeks. Secondary outcomes were birth weight and risk of macrosomia. Women randomized to continuous glucose monitoring had lower mean HbA1c levels from 32 to 36 weeks’ gestation compared with women randomized to standard antenatal care. Compared with infants of mothers in the control arm those of mothers in the intervention arm had decreased mean birthweight, decreased median customized birthweight and a reduced risk of macrosomia. The authors acknowledged that, due to lack of blinding, they could not exclude the possibility of bias in clinical management. They also stated that because the number of women studied was small, larger multicentre trials are required to assess the impact of CGM during pregnancy.

Kestila et al. (2007) conducted a randomized controlled trial to compare CGMS (n=36) to SMBG (n=37) in detecting patients with gestational diabetes mellitus (GDM) who needed antidiabetic drug treatment. In 11 out of 36 patients (31%) monitored with CGMS antihyperglycemic drug therapy was introduced whereas only 3/37 (8%) in the SMBG group were drug-treated. The authors concluded that further large-scale studies are needed to evaluate whether CGMS guided initiation of antihyperglycemic therapy results in less macrosomia and perinatal complications related to GDM.

Buhling et al. (2005) reported that CGMS detected more frequent and longer periods of hyperglycemia. Compared with SMBG, CGMS also offered more differentiation between nondiabetic pregnant women, patients with gestational diabetes and patients with impaired glucose tolerance.

A second small study found that when CGMS was used to adjust insulin treatment, there was a reduction in undetected hyperglycemia and nocturnal hypoglycemic events. However, the study did not indicate a clinical difference in perinatal outcomes between CGMS and SMBG (Yoge, 2003).

**Insulin Pump and Continuous Glucose Monitoring Combined Systems**

Bergenstal et al. (2010) conducted a multicenter, randomized, controlled trial comparing the efficacy of sensor-augmented pump therapy (pump therapy) to that of multiple daily insulin injections (injection therapy) in 329 adults and 156 children (ages 7 through 70 years) with inadequately controlled type 1 diabetes. The primary end point was the change from the baseline glycated hemoglobin level. At one year, the researchers found that the pump-therapy group had glycated hemoglobin levels that were significantly lower than the injection-therapy group. The baseline mean glycated hemoglobin level, which was 8.3% in the two study groups, had decreased to 7.5% in the pump therapy group, compared with 8.1% in the injection therapy group. The proportion of patients who reached the glycated hemoglobin target (<7%) was greater in the pump-therapy group than in the injection-therapy group. The rates of severe hypoglycemia and diabetic ketoacidosis in the pump-therapy group did not differ significantly from the injection-therapy group. The study concluded that sensor-augmented pump therapy resulted in significant improvement in glycated hemoglobin levels, as compared with injection therapy.
multiple daily injections. The objective of the study was to compare the improvements in glycemic control associated with transitioning to insulin pump therapy in patients using continuous glucose monitoring versus standard blood glucose self-monitoring. One group was fitted with the Medtronic MiniMed Paradigm REAL-Time system (PRT group), an insulin pump with integrated continuous subcutaneous glucose monitoring (CGM) capability, with instructions to wear CGM sensors at least 70% of the time. Conventional insulin pump therapy was initiated in the other group. Outcome measures included A1C and glycemic variability. 115 patients completed the study. Between baseline and trial end, A1C improved significantly in both groups, with no significant difference between groups. When the 91 patients who were fully protocol-compliant (CGM sensor wear >or=70% of the time) were considered, A1C improvement was significantly greater in the PRT group. Hyperglycemia parameters decreased in line with improvements in A1C with no impact on hypoglycemia. The authors concluded that CGM-enabled insulin pump therapy improves glycemia more than conventional pump therapy during the first 6 months of pump use in patients who wear CGM sensors at least 70% of the time (Raccah, 2009).

In the first multicenter, randomized treat-to-target, Hirsch et al. (2008) evaluated the clinical effectiveness and safety of a device that combines an insulin pump with real-time continuous glucose monitoring (CGM), compared to using an insulin pump with standard blood glucose monitoring systems. The study enrolled 146 patients treated with continuous subcutaneous insulin infusion between the ages of 12 and 72 years with type 1 diabetes and initial A1C levels of >or=7.5%. Subjects were randomized to pump therapy with real-time CGM (sensor group [SG]) or to pump therapy and self-monitoring of blood glucose only (control group [CG]). A1C levels decreased from baseline in both groups; however, between-group differences did not achieve significance. Fourteen severe hypoglycemic events occurred (11 in the SG group and three in the CG group, P=0.04). A1C reduction was no different between the two groups. Subjects in the CG group had increased hypoglycemia area under the curve (AUC) and number of events during blinded CGM use; however, there was no increase in hypoglycemia AUC or number of events in the SG group. Subjects with greater sensor utilization showed a greater improvement in A1C levels.

Remote Glucose Monitoring
No studies were identified in the published clinical literature demonstrating improved clinical outcomes from managing nocturnal hypoglycemia with the use of remote glucose monitoring.

Ahmet et al. (2011) conducted a pilot study to determine the prevalence of nocturnal hypoglycemia (NH) in pediatric type 1 diabetes, to compare the prevalence of NH detected by continuous glucose monitoring (CGM) and self-monitored blood glucose (SMBG), and to compare the prevalence of NH using different thresholds. Twenty-five patients wore a continuous glucose monitor for 3 nights and also conducted SMBG. NH was defined with three thresholds: (1) <3.9 mmol/L; (2) <3.3 mmol/L; and (3) <2.9 mmol/L. The prevalence of NH with CGM was 68%, 52%, and 48% with the different thresholds. Of the 35 episodes of NH detected by CGM, 25 were not symptomatic and therefore not detected by SMBG. The mean difference in blood glucose between CGM and SMBG was -0.18 mmol/L (P = .35). The authors concluded that this study suggests that the prevalence of NH in pediatric patients with type 1 diabetes with conventional treatment may be as high as 68%, although this varied according to the method of detection and threshold used. Patients may benefit from CGM to detect asymptomatic NH. This study is limited by small sample size and a lack of randomization and control.

Professional Societies
American Diabetes Association (ADA)

Insulin Delivery
In a 2002 position statement the ADA states that both continuous subcutaneous insulin infusion (CSII) and multiple daily insulin injection therapy are effective means of implementing intensive diabetes management with the goal of achieving near normal level of blood glucose and improved lifestyle flexibility. Rapid-acting insulin analogs (such as lispro) are appropriate insulins
for insulin infusion pumps. Use of mixtures of insulins in pumps has not been evaluated and therefore is not recommended. Experience with insulin-pump therapy indicates that candidates for CSII must be strongly motivated to improve glucose control and willing to work with their health care provider in assuming substantial responsibility for their day-to-day care. Use of CSII requires care by skilled professionals, careful selection of patients, meticulous patient monitoring and thorough patient education (ADA, 2004a).

In a statement on the care of children and adolescents with type 1 diabetes, the ADA states that there is no best predetermined age to initiate insulin pump therapy. As with all diabetes management issues, individualized treatment plans that consider the needs of the patient as well as those of the family are best. Currently, there are fewer young children than preadolescents and adolescents using insulin pumps. Adult support at both home and school is essential for success with all diabetes management but especially with pump treatment until the child is able to manage the diabetes independently (Silverstein, 2005).

In a statement on gestational diabetes mellitus, the ADA states that insulin is the pharmacologic therapy that has most consistently been shown to reduce fetal morbidities when added to medical nutrition therapy (MNT). Selection of pregnancies for insulin therapy can be based on measures of maternal glycemia with or without assessment of fetal growth characteristics. When maternal glucose levels are used, insulin therapy is recommended when MNT fails to maintain self-monitored glucose at the following levels:

- Fasting plasma glucose less than or equal to 105 mg/dl (5.8 mmol/l); or
- 1-h postprandial plasma glucose less than or equal to 155 mg/dl (8.6 mmol/l); or
- 2-h postprandial plasma glucose less than or equal to 130 mg/dl (7.2 mmol/l)

Human insulin should be used when insulin is prescribed, and self-monitoring of blood glucose should guide the doses and timing of the insulin regimen. The use of insulin analogs has not been adequately tested in gestational diabetes mellitus (ADA, 2004b).

Insulin infusers create “portals” into which the patient injects insulin. With an infuser, a needle or catheter is inserted into subcutaneous tissue and remains taped in place, usually on the abdomen, for 48–72 hours. The insulin is injected into it, rather than directly through the skin into the fatty tissue. Some people are prone to infections with this type of product, so precautionary hygiene measures are necessary (ADA, 2008).

Continuous Glucose Monitoring
In the 2015 Standards of Medical Care in Diabetes, the ADA states that continuous glucose monitoring (CGM) may be a supplemental tool to SMBG in patients with hypoglycemia unawareness and/or frequent hypoglycemic episodes. When used properly, CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age greater than or equal to 25 years) with type 1 diabetes. Although the evidence for A1C lowering is less strong in children, teens and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device (ADA, 2015).

American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE)

Insulin Pumps
According to a 2014 AACE/ACE consensus statement, the ideal insulin pump candidate is:

- Patient with type 1 diabetes or intensively managed insulin-dependent type 2 diabetes
- Currently performing ≥4 insulin injections and ≥4 SMBG measurements daily
- Motivated to achieve optimal blood glucose control
- Willing and able to carry out the tasks that are required to use this complex and time-consuming therapy safely and effectively
- Willing to maintain frequent contact with their health care team
Continuous Glucose Monitoring

According to a 2010 AACE consensus statement, personal CGM is recommended for patients with type 1 diabetes and the following characteristics:

- Hypoglycemic unawareness or frequent hypoglycemia
- HbA1c over target, or with excess glycemic variability (e.g., hypoglycemia judged to be excessive, potentially disabling or life-threatening)
- Requiring HbA1c lowering without increased hypoglycemia
- During preconception and pregnancy

Although the evidence supporting the use of personal CGM is derived from studies in patients with type 1 diabetes, it is reasonable to expect that similar results would be seen in patients using basal-bolus insulin regimens or an insulin pump.

Endocrine Society

The Endocrine Society (Klonoff et al., 2011) recommends that long-term personal use CGM be used by the following:

- Adult patients with type 1 diabetes who have HbA1c levels of at least 7.0% and who have demonstrated that they can use these devices on a nearly daily basis
- Adult patients with type 1 diabetes who have HbA1c levels less than 7.0% and who have demonstrated that they can use these devices on a nearly daily basis

The guidelines also suggest the intermittent use of CGM systems designed for short-term retrospective analysis in adult patients with type 1 diabetes when there is a concern about the following:

- Nocturnal hypoglycemia, dawn phenomenon, and postprandial hyperglycemia
- Hypoglycemic unawareness
- Changes to a patient’s diabetes regimen (e.g., instituting new insulin or switching from multiple daily injections (MDI) to pump therapy)

There is also evidence that intermittent use of CGM systems designed for short-term retrospective analysis can provide additional insights in adults with type 2 diabetes mellitus regarding glucose levels and the time in target range.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Insulin Delivery

For information on external insulin pumps, see the following web site (use product code LZG).

No implantable insulin pumps have received FDA approval at this time.

The i-port® Injection Port was approved by the FDA on September 9, 2005 (K052389). The injection port is indicated for use by people requiring multiple daily subcutaneous injections of physician prescribed medications, including insulin. The device is designed for use on adults and children for up to 72 hours. Additional information available at: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K052389](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K052389). Accessed March 22, 2015.

The i-port Advance® Injection Port was approved by the FDA on February 16, 2012 (K120337). This model has the same indications as the original device but includes an automatic insertion component. Additional information available at: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K120337](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K120337). Accessed March 22, 2015.
The V-Go device (models V-Go20, V-Go30 and V-Go40) received FDA approval (K100504) on December 1, 2010. V-Go is a mechanical (no electronics), self-contained, sterile, patient fillable, single-use disposable insulin infusion device with an integrated stainless steel subcutaneous needle. The device is indicated for continuous subcutaneous infusion of insulin in one 24-hour time period and on-demand bolus dosing in 2-unit increments (up to 36 units per one 24-hour time period) in adult patients requiring insulin. Three models (20, 30 and 40 units/day) are available. The device is intended for use in patients with type 2 diabetes. Additional information available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K100504. A second FDA approval (K103825) came through on February 23, 2011. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K103825. Accessed March 22, 2015.

**Insulin Pump Models** (this is not an exhaustive list)
- Asante Snap
- MiniMed 530G with Enlite
- MiniMed Paradigm Real-Time Revel System
- OmniPod Insulin Management System
- OneTouch Ping
- Vibe

**Continuous Glucose Monitors**
The GlucoWatch noninvasive continuous glucose monitor is no longer marketed in the United States.


The mySentry remote monitoring system received FDA approval as a supplement (S075) to Premarket Approval P880022. The device is indicated for the remote monitoring of a single Paradigm REAL-Time Revel insulin pump (MMT-523/-723/MMT-523K/-723K). The real-time glucose values provided by the monitor are not intended to be used directly for making therapy adjustments. Rather, they provide an indication that may require a confirmation fingerstick measurement. All therapy adjustments should be based on measurements obtained using a blood glucose meter and not based on the value displayed by the monitor or Paradigm REAL-Time Revel insulin pump.

**Continuous Glucose Monitor Models** (this is not an exhaustive list)
- G4 Platinum
- Guardian Real-Time
- MiniMed 530G with Enlite
- MiniMed Paradigm Real-Time Revel System

**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare does not have a National Coverage Determination (NCD) for Continuous Glucose Monitoring Systems. However, refer to the NCD which addresses [Home Blood Glucose Monitors (40.2)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm). Local Coverage Determinations (LCDs) do not exist at this time.

Medicare may cover continuous subcutaneous insulin infusion (CSII) and related drugs/supplies for the treatment of diabetic patients when criteria are met. Medicare does not cover implantable infusion pumps for the infusion of insulin to treat diabetes. Refer to the National Coverage Determination (NCD) for [Infusion Pumps (280.14)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm). Local Coverage Determinations (LCDs)
exist. Refer to the LCDs for External Infusion Pumps and Implantable Infusion Pumps. Glucose Monitors

(Accessed March 18, 2015)

REFERENCES


ECRI Institute. Hotline Service. mySentry remote glucose monitor (Medtronic, Inc.) for accessing real-time continuous glucose and insulin pump information. April 2012.


Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes: Medical Policy (Effective 04/22/2015)


### POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/26/2015</td>
<td>Reorganized coverage rationale for insulin delivery; moved language pertaining to medical necessity review under indication for “patients with type 1 diabetes”</td>
</tr>
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</table>
| 04/22/2015 | Revised coverage rationale:  
  o Updated language pertaining to insulin delivery to indicate external insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for the following:  
    ▪ Patients with type 1 diabetes  
    ▪ Patients with type 2 diabetes who currently perform ≥4 insulin injections and ≥4 blood glucose measurements daily |
o Added language to indicate short-term (3-7 days) continuous glucose monitoring by a healthcare provider for diagnostic purposes is proven and medically necessary for patients with diabetes

o Replaced language indicating:
  ▪ “Long-term continuous glucose monitoring (greater than 72 hours), alone or in combination with an external insulin pump, is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who meet listed criteria” with “long-term continuous glucose monitoring for personal use at home is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who meet listed criteria”
  ▪ “Long-term continuous glucose monitoring is unproven and not medically necessary for patients with type 2 diabetes or gestational diabetes” with “long-term continuous glucose monitoring for personal use at home is unproven and not medically necessary for patients with type 2 diabetes or gestational diabetes”

o Removed language indicating:
  ▪ Devices classified by the U.S. Food and Drug Administration (FDA) as an artificial pancreas are unproven and not medically necessary
    - Study results fail to provide conclusive evidence that artificial pancreas devices lead to improved health outcomes, such as improved glycemic control or delay in diabetes-related complications, in patients with diabetes
    - Larger, randomized controlled trials are needed to determine the long-term impact of these devices on diabetes management
  ▪ As part of the ongoing effort to improve diabetes care, the National Diabetes Education Program, the American Association of Clinical Endocrinology and others have recommended the term "A1c" be used for GHB or hemoglobin A1c (HbA1c) measurement in health care practice to avoid confusion

- Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references
- Archived previous policy version 2015T0347Q