

# Protocol

## Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

(10120)

<b>Medical Benefit</b>		<b>Effective Date:</b> 04/01/19	<b>Next Review Date:</b> 01/20
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 07/07, 07/08, 07/09, 01/10, 01/11, 01/12, 01/13, 05/13, 01/14, 05/14, 03/15, 03/16, 03/17, 09/17, 11/17, 05/18, 01/19	

### ***Preauthorization is required for continuous, long-term monitoring.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

<b>Populations</b>	<b>Interventions</b>	<b>Comparators</b>	<b>Outcomes</b>
Individuals: <ul style="list-style-type: none"> <li>• With type 1 diabetes who are willing and able to use the device, and have adequate medical supervision</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Long-term (continuous) glucose monitoring</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Self-monitoring of blood glucose</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Morbid events</li> <li>• Quality of life</li> <li>• Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>• With type 1 diabetes</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Short-term (intermittent) glucose monitoring</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Self-monitoring of blood glucose</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Morbid events</li> <li>• Quality of life</li> <li>• Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>• With type 2 diabetes</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Long-term (continuous) glucose monitoring</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Self-monitoring of blood glucose</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Morbid events</li> <li>• Quality of life</li> <li>• Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>• With type 2 diabetes</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Short-term (intermittent) glucose monitoring</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Self-monitoring of blood glucose</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Morbid events</li> <li>• Quality of life</li> <li>• Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>• Who are pregnant with gestational diabetes</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Long-term (continuous) or short-term (intermittent) glucose</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Self-monitoring of blood glucose</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Morbid events</li> <li>• Quality of life</li> <li>• Treatment-related morbidity</li> </ul>

### **DESCRIPTION**

Tight glucose control in patients with diabetes has been associated with improved health outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every five to 10 minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to traditional self-monitoring of

blood glucose levels. Devices can be used on an intermittent (short-term) basis or a continuous (long-term) basis.

## SUMMARY OF EVIDENCE

### TYPE 1 DIABETES

For individuals who have type 1 diabetes who are willing and able to use the device, and have adequate medical supervision, who receive long-term continuous glucose monitoring (CGM), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Systematic reviews have generally found that at least in the short-term, long-term CGM resulted in significantly improved glycemic control for adults and children with type 1 diabetes, particularly highly compliant patients. A 2017 individual patient data analysis, pooling data from 11 RCTs, found that reductions in hemoglobin (HbA1c) levels were significantly greater with real-time CGM than with a control intervention. Two RCTs in patients who used multiple daily insulin injections and were highly compliant with CGM devices during run-in phases found that CGM was associated with a larger reduction in HbA1c levels than previous studies. One of the two RCTs prespecified hypoglycemia-related outcomes and reported that time spent in hypoglycemia was significantly less in the CGM group. One RCT in pregnant women with type 1 diabetes, which compared real-time CGM with self-monitoring of blood glucose, has also reported a difference in change in HbA1c levels, an increased percentage of time in the recommended glucose control target range, a smaller proportion of infants who were large for gestational age, a smaller proportion of infants who had neonatal intensive care admissions lasting more than 24 hours, a smaller proportion of infants who had neonatal hypoglycemia requiring treatment, and reduced total hospital length of stay all favoring CGM. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have type 1 diabetes who receive short-term (intermittent) glucose monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. The evidence for intermittent short-term monitoring on glycemic control is mixed, and there was no definite improvement in HbA1c levels. Studies have not shown an advantage for intermittent glucose monitoring in reducing severe hypoglycemia events, but the number of events reported is generally small and effect estimates imprecise. The evidence is insufficient to determine the effects of the technology on health outcomes.

### TYPE 2 DIABETES

For individuals who have type 2 diabetes who receive long-term CGM, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Only the DIAMOND RCT (N=158) has used real-time CGM in type 2 diabetes. Selected patients were highly compliant during a run-in phase. The difference in change in HbA1c levels from baseline to 24 weeks was -0.3% favoring CGM. The difference in the proportion of patients with a relative reduction in HbA1c level by 10% or more was 22% favoring CGM. There were no differences in the proportions of patients with an HbA1c level less than 7% at week 24. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. The treatment groups did not differ in any of the quality of life measures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have type 2 diabetes who receive short-term (intermittent) glucose monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Systematic reviews of three to four RCTs have found statistically significant benefits from CGM regarding glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reductions between groups may not be clinically significant. Also, the small number of RCTs and variabil-

ity among interventions make it difficult to identify an optimal approach to CGM or a subgroup of type 2 diabetes patients who might benefit. Moreover, studies of CGM in patients with type 2 diabetes have generally not addressed the clinically important issues of severe hypoglycemia and diabetic complications. Very few pregnant women with type 2 diabetes have been included in RCTs. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### GESTATIONAL DIABETES

For individuals who are pregnant with gestational diabetes who receive long-term CGM or short-term (intermittent) glucose monitoring, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. In the RCT, the type of glucose monitoring was unclear. Trial reporting was incomplete; however, there was no difference between the groups for most reported outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### POLICY

Continuous (i.e., long-term) monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique of diabetic monitoring, may be considered **medically necessary** when the following situations occur, despite use of best practices:

- patients with type 1 diabetes who have demonstrated an understanding of the technology, are motivated to use the device correctly and consistently, are expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider, and are capable of using the device to recognize alerts and alarms; or
- patients with type I diabetes mellitus who have recurrent, unexplained, severe, (generally blood glucose levels less than 50 mg/dl) hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk; or
- patients with poorly controlled type I diabetes mellitus who are pregnant. Poorly controlled type I diabetes mellitus includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

Intermittent monitoring (i.e., 72 hours) of glucose levels in interstitial fluid may be considered **medically necessary** in patients with type I diabetes mellitus whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines). Poorly controlled type I diabetes mellitus includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

Intermittent monitoring of glucose levels in interstitial fluid may also be considered **medically necessary** in patients with type I diabetes mellitus prior to insulin pump initiation to determine basal insulin levels.

Other uses of continuous and intermittent monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring are considered **investigational**.

#### POLICY GUIDELINES

Several insulin pump systems (e.g., Paradigm® REAL-Time System) have a built-in CGM. This protocol only evaluates the CGM; it does not evaluate insulin pumps. Insulin pump systems with a built-in CGM and a low glucose suspend (LGS) feature, are addressed in the Artificial Pancreas Device Systems Protocol.

Best practices in diabetes control include compliance with a regimen of four or more fingersticks each day and use of an insulin pump. However, some patients may do just as well with multiple insulin injections daily rather than an insulin pump. During pregnancy, three or more insulin injections daily could also be considered best practice for patients not on an insulin pump prior to the pregnancy.

Women with type I diabetes mellitus taking insulin who are pregnant or about to become pregnant with poorly controlled diabetes are another subset of patients to whom the policy statement on intermittent monitoring may apply.

Intermittent monitoring is generally conducted in 72-hour periods. It may be repeated subsequently depending on the patient's level of diabetes control.

The strongest evidence exists for use of CGM devices in patients age 25 and older. However, age may be a proxy for motivation and good control of disease, so it is also reasonable to select patients based on their ability to self-manage their disease, rather than their age.

Providers board certified in endocrinology and/or providers with a focus on the practice of diabetes care may be considered qualified to evaluate and oversee individuals for continuous (i.e., long-term) monitoring.

## MEDICARE ADVANTAGE

Therapeutic CGMs (continuous glucose monitor) and related supplies are considered **medically necessary** when all of the following coverage criteria (1-6) are met:

1. The patient has diabetes mellitus; and,
2. The patient has been using a BGM (blood glucose monitor) and performing frequent (four or more times a day) testing; and,
3. The patient is insulin-treated with multiple (three or more) daily injections of insulin or an approved continuous subcutaneous insulin infusion (CSII) pump; and,
4. The patient's insulin treatment regimen requires frequent adjustment by the patient on the basis of BGM or CGM testing results; and,
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the patient to evaluate their diabetes control and determined that criteria (1-4) above are met; and,
6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the patient to assess adherence to their CGM regimen and diabetes treatment plan.

If any of coverage criteria (1-6) are not met, the CGM will be denied as **not medically necessary**.

## BACKGROUND

### BLOOD GLUCOSE CONTROL

The advent of blood glucose monitors for use by patients in the home revolutionized the management of diabetes. Using fingersticks, patients can monitor their blood glucose levels both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight glucose control, defined as a strategy involving frequent glucose checks and a target hemoglobin A1c (HbA1c) level in the range of 7%, is now considered standard of care for diabetic patients. Randomized controlled trials assessing tight control have demonstrated benefits for patients with type 1 diabetes in decreasing microvascular complications. The impact of tight control on type 1 diabetes and macrovascular complications such as stroke or myocardial infarction is less certain. The

Diabetes Control and Complications Trial (2002) demonstrated that a relative HbA1c level reduction of 10% is clinically meaningful and corresponds to approximately a 40% decrease in risk for progression of diabetic retinopathy and 25% decrease in risk for progression of renal disease.<sup>1</sup>

Due to an increase in turnover of red blood cells during pregnancy, HbA1c levels are slightly lower in women with a normal pregnancy compared with nonpregnant women. The target A1c in women with diabetes is also lower in pregnancy. The American Diabetes Association recommends that, if achievable without significant hypoglycemia, the A1c levels should range between 6.0% to 6.5%; an A1c levels less than 6% may be optimal as the pregnancy progresses.<sup>2</sup>

Tight glucose control requires multiple daily measurements of blood glucose (i.e., before meals and at bedtime), a commitment that some patients may be unwilling or unable to meet. Also, the goal of tight glucose control has to be balanced with an associated risk of hypoglycemia. Hypoglycemia is known to be a risk in patients with type 1 diabetes. While patients with insulin-treated type 2 diabetes may also experience severe hypoglycemic episodes, there is a lower relative likelihood of severe hypoglycemia compared with patients who had type 1 diabetes.<sup>3,4</sup>

An additional limitation of periodic self-measurements of blood glucose is that glucose levels are seen in isolation, and trends in glucose levels are undetected. For example, while a diabetic patient's fasting blood glucose level might be within normal values, hyperglycemia might be undetected postprandially, leading to elevated HbA1c levels.

#### Management

Recently, measurements of glucose in the interstitial fluid have been developed as a technique to measure glucose values automatically throughout the day, producing data that show the trends in glucose levels. Although devices measure glucose in the interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).

Several devices have received approval from the U.S. Food and Drug Administration (FDA). The first approved devices were the Continuous Glucose Monitoring System (MiniMed), which uses an implanted temporary sensor in the subcutaneous tissues, and the GlucoWatch G2 Biographer, an external device worn like a wristwatch that measures glucose in interstitial fluid extracted through the skin by electric current (referred to as reverse iontophoresis).

Devices subsequently approved include those for pediatric use and those with more advanced software, more frequent measurements of glucose levels, or more sophisticated alarm systems. Devices initially measured interstitial glucose every five to 10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured ranges from every one to two minutes to five minutes, and most provide measurements in real-time directly to patients. While CGM potentially eliminates or decreases the number of required daily fingersticks, it should be noted that, according to the FDA labeling, monitors are not intended as an alternative to traditional self-monitoring of blood glucose levels but rather as adjuncts to monitoring, supplying additional information on glucose trends not available from self-monitoring. Also, devices may be used intermittently (i.e., for periods of 72 hours) or continuously (i.e., on a long-term basis).

In addition to stand-alone continuous glucose monitors, several insulin pump systems have built-in CGM. This protocol addresses CGM devices, not the insulin pump portion of these systems

#### REGULATORY STATUS

Several CGM systems have been approved by FDA through the premarket approval process (see Table 1).

Table 1. CGM Systems Approved by the Food and Drug Administration

Device	Manufacturer	Approval	Indications
Continuous Glucose Monitoring System (CGMS®)	MiniMed	1999	Three day use in physician's office
GlucoWatch G2® Biographer <sup>a</sup>		2001	Not available since 2008
Guardian®-RT (Real-Time) CGMS	MiniMed (now Medtronic)	2005	
Dexcom® STS CGMS system	Dexcom	2006	
Paradigm® REAL-Time System (second generation called Paradigm Revel System)	MiniMed (now Medtronic)	2006	Integrates a CGM with a Paradigm insulin pump
FreeStyle Navigator® CGM System	Abbott	2008	
Dexcom® G4 Platinum	Dexcom	2012	Adults 18 years and older; can be worn for up to seven days;
		2014	Expanded to include patients with diabetes two to 17 years
Dexcom® G5 Mobile CGM	Dexcom	2016 <sup>a</sup>	Replacement for fingerstick blood glucose testing in patients two years and older. System requires at least two daily fingerstick tests for calibration purposes, but additional fingersticks are not necessary because treatment decisions can be made based on device readings. <sup>5</sup>
Freestyle Libre® Pro Flash Glucose Monitoring System	Abbott	2017	Adults 18 years and older. Readings are only made available to patients in consultation with a health care professional. Does not require user calibration with blood glucose values.
Dexcom® G6 Mobile CGM	Dexcom	2018	For determining blood glucose levels in children ages 2 and older and adults with diabetes.

CGM: continuous glucose monitoring.

<sup>a</sup> As a supplement to the G4 premarketing approval.

FDA product codes: MDS, PQF

## RELATED PROTOCOL

Artificial Pancreas Device Systems

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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