Medical Policy Reference Manual
Medical Policy

2.01.045 Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

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Description

Blood glucose monitoring by fingerstick has been used in the management of diabetes for several years. Patients could monitor their blood glucose level both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Recently, measurements of glucose in interstitial fluid have been developed as a technique of automatically measuring glucose values throughout the day, producing data that show the trends in glucose measurements, in contrast to the isolated glucose measurements of the traditional blood glucose measurements (American Diabetes Association).

Externally worn Continuous Glucose Monitoring (CGM) Systems are monitoring devices which continuously sample and measure glucose levels in the interstitial fluid by the use of a glucose sensor inserted into the subcutaneous tissue using a needle-like introducer. CGM systems record the glucose level periodically and store the data for later review. CGM systems are not intended to take the place of the patient's regular treatment regimen of checking their blood sugar levels by sampling of blood using a finger stick. Rather, the continuous glucose monitoring system is designed to measure fluctuations in the overall glucose levels during an extended period including times of sleep, activity, mealtimes, and so forth. The data from the continuous glucose monitoring system is then used by the specialist in diabetes treatment to modify the patient's insulin dosages, the time it should be given, and the optimum times for the patient to test their blood sugar levels. The ultimate goal of diabetes control is to maintain a level of glycosylated hemoglobin (HbA1C) at 7% or lower. Improved metabolic control, then, leads to reduction in the onset of complications of diabetes.

One type of noninvasive continuous glucose monitoring device, the GlucoWatch G2 Biographer®, was approved by the U.S. Food and Drug Administration (FDA) but was removed from the market in 2007.

In 2018, the FDA approved the Eversense Implantable CGM device that uses a fully implanted sensor with a removable transmitter that sends data to a smart device.

Intermittent glucose monitoring (diagnostic test):

Intermittent monitoring of interstitial fluid glucose (i.e., minimum of 72 hours) for diagnostic testing has been proposed for type I diabetics whose diabetes is poorly controlled despite current best practices. Intermittent monitoring has also been used for type I diabetics prior to initiation of an insulin pump. The rationale for doing the study is that some diabetic patients present special challenges in controlling their glucose levels. They may experience nighttime hypoglycemic episodes even though their evening blood glucose prior to sleep was within prescribed limits or, they may have hyperglycemic periods during the daytime hours.

Continuous glucose monitoring (i.e., long-term):

Other CGM-type systems have been approved recently which are intended for long-term use for diabetic management. These devices are targeted primarily at type I diabetics who are poorly controlled, with a history of recurrent, severe, and dangerous hypoglycemic episodes. They have also been proposed for pregnant type I diabetics who are poorly controlled, with hypoglycemic episodes, hypoglycemic unawareness, or recurrent diabetic ketoacidosis.

Policy

Intermittent monitoring, that is for a minimum of 72 hours of glucose levels in interstitial fluid for *diagnostic testing,* is considered **medically necessary** for type I and type II diabetics who meet at least *one* of the following criteria:

- the patient exhibits inadequate diabetes control, despite multiple daily injections of insulin or use of an insulin pump, and frequent monitoring of blood glucose by using a home glucometer or
- has unexplained large fluctuations in daily pre-prandial glucose values or
- has unexplained, frequent hypoglycemic episodes or
- has had at least one recent episode of emergent treatment for ketoacidosis or acute hypoglycemia or
- is diabetic and newly pregnant, or intends to become pregnant within a short time or
- is being evaluated prior to using injectable insulin for the first time or using an insulin pump, to determine basal insulin levels.

Continuous monitoring of glucose levels in interstitial fluid as a technique of *diabetes management* is considered **medically necessary** for type I and type II diabetics.

Continuous glucose monitoring utilizing GlucoWatch G2 Biographer® (S1030, S1031) is considered **experimental / investigational** as it does not meet TEC criteria # 2 - 5. **NOTE: The GlucoWatch G2 Biographer® glucose monitoring system is no longer available in the United States as of July 31, 2007.**

Policy Guidelines

A CGM system should be prescribed by a physician or nurse practitioner who is knowledgeable in the treatment of diabetes and is familiar with how to manage treatment based on the data obtained from the monitor.

The intermittent diagnostic device is generally worn for a minimum of 72 hours. The allowed benefit is the same, regardless of the number of days worn.

Continuous glucose monitoring using an implantable glucose sensor is appropriate for the management of type I or type II diabetes mellitus for an individual who:

- Has demonstrated an understanding of the technology
- Is motivated to use the device correctly and consistently
- Is expected to be adherent to comprehensive diabetes treatment plan supervised by a qualified provider
- Is capable of using the device to recognize alerts and alarms

Rationale:

The published evidence has established a correlation between interstitial fluid glucose and serum glucose levels and HbA1C levels. Data has also established that Continuous Glucose Monitoring can be useful in the management of difficult type I diabetics such as those with unexplained wide fluctuations in glucose levels, patients with insulin pumps, and those with a history of emergent care related to ketoacidosis or hypoglycemic episodes.

A search of the literature from 2002-2005 indicated subsequent studies have been published for the GlucoWatch G2 Biographer®. The most recent studies suggest that there is insufficient data to demonstrate an improvement in net health outcomes as a result of using the GlucoWatch G2 Biographer®.

Update 2008:

A search of the peer-reviewed literature was performed for the period of December 2005 through December 2008.

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

Currently there are four FDA-approved monitors available, with varying capabilities for high and low glucose alarms, data gathering, and data display. None are approved for use as a basis to determine insulin dosages, but rather as adjuncts for self-monitoring of blood glucose levels using conventional devices. The devices currently available include the Guardian REAL-time® and Paradigm REAL-time® (Medtronic Minimed), the DexCom SEVEN (DexCom, Inc.) and the FreeStyle Navigator® (Abbott Diabetes Care, Inc.) All four are approved for use in diabetic patients age 18 and older. Pediatric versions of the two Minimed systems received a separate approval in March of 2007 for use in children and adolescents aged 7-17.

The GlucoWatch G2 Biographer® (Cygnus, Inc.) is an FDA-approved monitoring device that will not be considered in this review as the manufacturer is no longer marketing the device as of July 31, 2007.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

Evidence from previous studies have established that measurement of glucose levels in interstitial fluid correlate with direct measurement of glucose in the blood. CGM of interstitial fluid therefore can provide a fairly accurate indication of blood glucose levels. The question then becomes whether CGM can be used to improve the health outcomes of diabetics by allowing for more precise regulation and identifying episodes of hyper- or hypoglycemia. A number of studies have been conducted to test whether CGM improves glycemic control. Many of these are randomized, small studies which assigned patients to self-monitoring of blood glucose (SMBG) or SMBG with adjunctive CGM. None of the studies provided more than 6 months of follow-up. A flaw in the studies is a lack of standardization of the duration of the CGM monitoring period, which ranged from 3 consecutive days to 40 days spread over 3 months. Another flaw is a lack of blinding to hypoglycemic events in the controls group, which limits the ability to draw conclusions whether CGM reduces incidences of hypoglycemia.

Studies of pediatric patients using CGM have demonstrated mixed results. Chase et al (2001) did not find CGM enabled significant decreases in glycosylated hemoglobin in pediatric patients. In contrast, a later study by Chase and colleagues (2003), as well as Ludvigsson and Hanas (2003) did report that CGM allowed for reduction of hyperglycemia. The two Chase studies also reported a significant increase in detection of hypoglycemia episodes but did not report the impact on outcomes. A later study by Deiss et al (2006) reported that CGM data resulted in frequent changes in insulin dosages but had no effect on overall metabolic control. A 2006 study by Yates and colleagues reported no statistically significant improvements in HbA1C levels in patients using CGM than in controls.

Clinical studies of adult patient populations likewise have shown mixed results. One study by Chico et al (2003) did not find statistically significant decreases in glycosylated hemoglobin levels in a randomized population (n=75). Another (Larsen et al, 2004) compared glucose levels in diabetic and non-diabetic control patients using CGM. The authors report that 41% of hypoglycemic episodes that were identified by the patient were not detected by the CGM, and that CGM may have falsely reported hypoglycemic events. In contrast, a manufacturer-sponsored study by Garg and colleagues (2006) reported that patients who had unblinded access to the CGM data were able to more effectively manage hyper- and hypoglycemic events. Similar results were reported in a study by Bode et al (2004). In one of the larger randomized controlled studies (n=128), Tanenberg and colleagues (2004) found that patients in CGM and SMBG groups experienced significant reductions in HbA1C levels at 12 weeks compared to baseline, but that the differences between the two groups were not significant.

Overall, there is insufficient evidence to support conclusions regarding whether CGM improves diabetic metabolic control, or improves detection of hyper- or hypoglycemia, due to methodological flaws in the studies. Although the CGM appears to detect asymptomatic incursions of hyper- and hypoglycemia, this observation does not necessarily translate into improved metabolic control, nor is there evidence regarding the clinical significance of this information over time.

3. The technology must improve the net health outcome:

The available evidence is promising that CGM may detect hyperglycemia incursions which would allow for improved metabolic control. However, there is conflicting evidence that that actually happens. Moreover, the published studies to date were conducted with short follow-up period, so it is not possible to conclude that CGM would improve diabetic management over time. Finally, the studies have not established selection criteria for patients who may be better managed by adding CGM to SMBG, or whether doing so demonstrates improvement in net health outcomes.

In a 2007 position statement, the American Diabetes Association (ADA) concluded that although CGM can be used to determine glucose patterns and detect hypoglycemia, its role in improving diabetes outcomes has not been established.

4. The technology must be as effective as any established alternatives:

CGM is indicated as an adjunctive procedure to SMBG, not as a replacement for it.

5. The improvement must be attainable outside the investigational settings:

An improvement in net health outcomes has not been demonstrated in the investigational settings.

Update 2020:
Revision. Studies performed on implantable continuous glucose monitoring systems (Eversense®) have demonstrated accurate glucose readings throughout the 90-day sensor life. Expert opinion and scientific research, including the results of the PRECISE II and PRECISION studies, have suggested that implantable glucose sensors have acceptable accuracy and safety. Therefore, this policy is being revised to include coverage of implantable continuous glucose monitoring systems as medically necessary.

Update 2018:
On January 12, 2017, the Centers for Medicare & Medicaid Services (CMS) issued a ruling that classified CGM systems into therapeutic and non-therapeutic systems. Therapeutic CGM are defined as CGM used as a replacement for fingerstick blood glucose testing for diabetes treatment decisions i.e., non-adjunctive use. Non-therapeutic CGM are devices used as an adjunct to blood glucose monitoring (BGM) testing (i.e., primary therapeutic decisions regarding diabetes treatment must be made with a standard home BGM, not the CGM).

Two additional CGM devices have been approved by U.S.FDA through the PMA process since the last review.

In September 2017, the Freestyle Libre® Pro Flash Glucose Monitoring System (Abbott) was approved and is indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons age 18 and older with diabetes. Readings are only made available to patients through consultation with a health care professional. The device does not require user calibration with blood glucose values. This device is externally worn and measures glucose levels in the interstitial fluid. The Freestyle Libre® Pro Flash Glucose Monitoring System is considered an acceptable alternative to other continuous glucose monitoring systems for medically necessary indications.

On June 21, 2018, the Eversense Implantable CGM System was approved. This is an *implantable device* indicated for continually measuring glucose levels in adults (18 years and older) with diabetes for up to 90 days. The Eversense differs from traditional CGM devices in that it is uses a fully implanted sensor with a removable transmitter that sends data to a smart device. In addition, the Eversense CGM sensor is replaced every 90 days via a 5-minute in-office minimally invasive procedure.

Kropff et al (2017) published the findings of a 180-day prospective, multicenter pivotal trial evaluating the accuracy and longevity of the Eversense implantable CGM sensor (PRECISE trial). Seventy-one participants aged 18 years and older with type 1 and type 2 diabetes used the CGM system at home and in the clinic. Eighty-one percent of hypoglycemic events were detected by the CGM system within 30 min. No device-related serious adverse events occurred during the study.

Christensen and colleagues (2018) reported on the PRECISE II, a multicenter U.S. pivotal trial that evaluated the accuracy and safety of an updated Eversense system, which included a modified algorithm and a new sensor configuration, in individuals with T1D and T2D. The system was found to have a favorable safety profile for its intended use but the need for long-term surveillance studies was identified to ensure that the safety profile remains favorable with multiple sensor placements and removals.

According to Hayes (2018), “although the evidence suggests moderate accuracy of the Eversense CGM, the body of evidence is limited by an evidence base of fair- to poor-quality studies, small number of patients, limited data assessing the accuracy of the CGM across different glucose parameters, and inconsistencies between studies. Assessments of clinical utility were insufficient to allow for definitive conclusions to be drawn due to a limited number of studies, of poor individual study quality.”

Based on the available evidence the Eversense Implantable CGM System is considered not medically necessary. The implantation of the Eversense device should be reported with Category III CPT® codes.

A search of the peer reviewed literature was performed from August 2016 through September 2018. Findings in the current literature do not change the medically necessary indications for subcutaneous continuous glucose monitoring for diabetic patients. For all other indications, the clinical evidence does not support the medical necessity of the use of CGM.

Update 2016:
A search of the peer reviewed literature was performed from July 2014 through July 2016. Findings in the current literature do not change the medically necessary indications for continuous glucose monitoring for diabetic patients. For all other indications, the clinical evidence does not support the use of CGM.

Update 2015:
Guidelines published in September 2014 from the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) Consensus Conference on Glucose Monitoring now support the use of CGM in certain type II patients as well as certain type I patients. A body of evidence shows that patients with type II diabetes whose disease has progressed have similar needs for glucose control as type I patients and may experience similar complications. Studies have shown that these type II patients can benefit from diagnostic CGM, and carefully selected patients may obtain a benefit from long-term use. Although the evidence is not as robust as for type I patients, there is ample evidence to conclude that CGM can be used in type II patients who exhibit similar characteristics as the

difficult-to-control type I patients. Therefore, the medically necessary indication has been expanded to include type II patients.

Update 2014:
A search of the peer reviewed literature was performed from July 2012 through July 2014. Findings in the current literature do not change the medically necessary indications for continuous glucose monitoring for diabetic patients. For all other indications, the clinical evidence does not support the use of CGM.

Update 2012:
Continuous glucose monitoring has clinical value in improved outcomes and disease management proven in randomized controlled trials in type 1 diabetic patients who meet certain characteristics. The American Association of Clinical Endocrinologists (AACE) recommends a personal CGM for type 1 diabetics with the following characteristics:

- hypoglycemic unawareness or frequent hypoglycemia
- HbA1c over target or with excess glycemic variability
- requiring HbA1c lowering without increased hypoglycemia
- during preconception and pregnancy

No AACE recommendation has been made for type 2 diabetics who have progressed to requiring insulin or experience poor diabetic control. However, there are reviewers who do recommend CGM for type 2 patients who require better glucose control (Harrell and Orzeck, 2010). The studies overall are limited, but positive for the use of CGM in certain type 2 patients. One large randomized controlled trial (n=404) by Cooke and colleagues (2009) reported that the use of CGM did not improve HbA1c levels; however, one of the devices was the Glucowatch, which has been off the market since 2007. Vigersky and colleagues (2012) conducted a randomized study of the effect of CGM versus SMBG on a population of non-insulin dependent diabetics. The CGM group used the device on an intermittent basis for 12 weeks. The improvement in HbA1c was significantly greater in the CGM group at the end of the 12-week period over the control group. At one-year follow-up measurement the improvement was sustained even though CGM was not used after the first 12 weeks. The authors suggested that use of the CGM taught the patients how their glucose was affected by lifestyle, activities, and food choices, and enabled them to better care for themselves. This was the first study on the use of CGM in non-insulin dependent diabetics.

Based on this evidence, the policy statements are unchanged.

Update 2010:
A search of the peer reviewed literature was performed from December 2008 through April 2010. Findings in the current literature do not change the medically necessary indications for continuous glucose monitoring for diabetic patients. For all other indications, there is a lack of evidence regarding use of CGM in these diabetic populations.

Benefit Applications

Separate benefits are not provided for the time spent downloading data, as this is considered ***included in*** the technical component of the continuous glucose monitoring procedure.

Separate benefits are not provided for rental of the monitor or transmitter, or for single use sensors (A9276, A9277, A9278) when the monitoring is used intermittently as a diagnostic test, as these are included in the technical component of the test.

NOTE: For FEP members, check member's contract for benefits.

NOTE [2]: The District of Columbia Insulin and Diabetes Device Affordability Amendment Act of 2020, DC Law 23-252, applicable to certain DC-situsedplans, dictates coverage and benefit guidelines for prescription insulin drugs, diabetes devices, and diabetic ketoacidosis devices. The Act became effective January 1, 2022, and benefits are described in applicable member contracts.

NOTE [3]: The State of Maryland Insulin Cost Reduction Act, Md. Ins. 15-822.1, applicable to certain Maryland-situsedplans, provides coverage and benefit guidelines for prescription insulin drugs. The Act becomes effective on applicable policies issued, delivered, or renewed January 1, 2023 or later, and benefits are described in applicable member contracts.

Provider Guidelines

Continuous glucose monitoring of interstitial tissue fluid should be reported with the appropriate Category I CPT® code. These codes should not be reported more than once per month.

The GlucoWatch G2 Biographer® glucose monitoring system is no longer available in the United States as of July 31, 2007. Neither the GlucoWatch nor the autosensors are available after July 31, 2008.

Cross References to Related Policies and Procedures

1.01.001	Durable Medical Equipment, Attached Table, Policy
1.01.004	Archived Blood Glucose Monitors (Glucometer), Policy

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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