



CONTINUOUS INTERSTITIAL GLUCOSE MONITORING

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Overview

The goal of diabetes management is the prevention of acute and chronic complications. For patients with insulin-dependent diabetes, self-monitoring of blood glucose (SMBG) has been proven to improve overall health and reduce the long-term complications of the disease.¹ Achieving good glucose control is especially demanding for patients who are on insulin therapy. Due to a variety of physiological factors, these patients' blood glucose levels fluctuate constantly throughout the day. A reading from blood glucose monitor only provides patients with information on their glucose level at a single point in time. The reading does not indicate if a level is dropping or rising, information that could make a critical difference in the outcome of a therapy decision. This lack of information on trending means that patients may not be aware of impending hypoglycemia, a potentially life-threatening complication that occurs more frequently as patients attempt tighter blood glucose control.

Continuous glucose monitoring has emerged as promising new technology in the field of diabetes management. The term continuous glucose monitoring refers to both: (1) the short-term professional use of a continuous glucose monitoring device as a diagnostic tool, and (2) the long-term personal use of a patient-owned continuous monitoring device. Unlike self-monitoring devices that measure glucose levels in capillary blood, continuous glucose monitoring devices measure glucose levels in interstitial fluid.² Many experts believe that with the commercial availability of continuous glucose monitoring devices we are entering a new era in the management of diabetes. However, definitive criteria for continuous glucose monitoring systems have not been established. Data suggests that patient selection is the key to improved outcomes.

Continuous glucose monitoring devices that are FDA-approved for professional use store and provide data retrospectively (the glucose readings are not displayed). The patient wears the device during daily activities like work, sleep, eating, and exercise. This enables the physician to view a comprehensive pattern of glucose values around the clock for determining therapy adjustments with the goal of improving glycemic control and reducing complications of chronic diabetes. There are two devices that are

¹ It remains unclear whether non-insulin dependent type 2 diabetics benefit from self-monitoring of blood glucose.

² Circulating blood glucose is distributed into the interstitial fluid where it is absorbed by cells. Interstitial glucose levels, therefore, lag behind blood glucose by the amount of time that is required for glucose to diffuse from the circulatory system into the interstitial fluid, on the order of 3 to 10 minutes or more. Interstitial glucose levels may be more reflective of the amount of glucose available for cellular metabolism.

FDA-approved for professional use: the CGMS® iPro™ (Medtronic Diabetes, Northridge, CA), and the Dexcom™ Seven Plus™ Continuous Glucose Monitoring System (Dexcom, San Diego, CA).

Continuous glucose monitoring devices that are FDA-approved for personal use display interstitial glucose readings approximately every 5 minutes. In addition to displaying individual glucose values, these personal use devices display directional trends and alert patients to high or low glucose values. Continuous glucose monitors thus have the potential to predict hyperglycemic and hypoglycemic events before they occur, and monitor for glucose variations that may not be detectable with SMBG. Currently there are three continuous glucose monitoring devices that are FDA-approved for personal use, these include: the Medtronic Guardian® RT (Medtronic Diabetes, Northridge, CA), the FreeStyle Navigator (Abbott Diabetes, Alameda, CA), and the Dexcom™ Seven Plus™ Continuous Glucose Monitoring System (Dexcom, San Diego, CA).

The components of a continuous glucose monitoring device include a receiver and a transmitter. A disposable interstitial glucose sensor is inserted into the subcutaneous tissue of the abdomen and attached to the transmitter. The sensor measures interstitial glucose continuously and converts individual glucose measurements to an average value which is sent to the transmitter approximately every 5 minutes. The transmitter sends data wirelessly to the receiver. Continuous interstitial glucose monitoring does not eliminate or decrease the number of required daily fingersticks. The continuous glucose monitor must be calibrated with a capillary blood glucose value at least four times a day, and according to the FDA labeling, glucose values provided by the system are not intended to be used for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on blood glucose measurements obtained using a blood glucose monitor and not on interstitial glucose readings provided by the continuous glucose monitoring system.

There is evidence to support the long-term personal use of continuous glucose monitoring in adults age 25 years of age and older with type 1 diabetes mellitus (T1DM). Studies have shown that continuous interstitial glucose monitoring may produce a sustained lowering of glycated hemoglobin (also known as hemoglobin A1c) without associated increases in the frequency or severity or hypoglycemic excursions in adult patients with T1DM. Bode et al (2004) evaluated the accuracy and effectiveness of alarms in alerting users of hypoglycemic and hyperglycemic excursions. The subjects' responses to hypoglycemic alarms resulted in a significant reduction in the duration of hypoglycemic excursions; however, over-treating hypoglycemia may have resulted in a marginally significant increase in the frequency of hyperglycemic excursions. In a randomized controlled trial of 128 patients, Tanenberg et al. (2004) found no significant differences in glycated hemoglobin at week 12 of the study, however the continuous glucose monitor group had significantly shorter duration of hypoglycemia compared to the control group (49.4 +/- 40.8 versus 81.0 +/- 61.1 minutes per event). Garg et al. (2006) conducted a randomized trial of the safety and efficacy of the DexCom SEVEN continuous glucose monitoring system in 91 insulin-treated diabetics. When compared to the control group, subjects in the continuous glucose monitor group had significantly fewer glycemic excursions. However, results in children and adolescents were not as favorable. In another small (N = 47) controlled

study, Garg et al. (2007) demonstrated that continuous glucose monitoring can further improve glycemic control in subjects with relatively well-controlled T1DM with no increase in hypoglycemic excursions. Hemoglobin A1c values at baseline were 7.43 +/- 1.0% and 7.39 +/- 1.0 % for the continuous glucose monitor group and the control groups respectively. At 12 weeks, there was a significant decrease in A1c in the continuous glucose monitor group (0.4 +/- 0.5%) and an insignificant decrease in the A1c in the control group (0.3 +/- 1.1%). Bode et al. (2008) evaluated the safety and efficacy of the FreeStyle Navigator continuous glucose monitoring system in an uncontrolled study. Subjects participated in a masked period without access to continuous glucose monitor readings followed by an unmasked period with access to continuous glucose monitor readings and alarms. Subjects with T1DM demonstrated a 55% reduction in time spent with significant hypoglycemia from masked to unmasked periods and the average number of hypoglycemic episodes fell from 1.1 per day to 0.8 per day.

In a recent and well-designed randomized controlled clinical trial, Tamborlane et al. (2008) found significantly improved glycemic control (determined by glycosylated hemoglobin level) in adults age 25 and older using a continuous glucose monitor compared to a control group without a significant increase in biochemical hypoglycemia (≤ 70 mg/dl).³The mean difference in change in glycosylated hemoglobin levels from baseline to 26 weeks was -0.53% in favor of the continuous glucose monitoring group. The observed age effect may be related to substantially greater use of sensors in the adult group. Imperfect adherence with many aspects of diabetes management has long been recognized as an obstacle to successful treatment in adolescents and young adults with T1DM. With respect to the generalizability of these results, it is important to recognize that at the start of the trial, all patients were receiving intensive insulin therapy with either an insulin pump or multiple daily injections, performed frequent home blood glucose monitoring (6.5 +/- 2.3 times per day) and most had better than average glycosylated hemoglobin levels (83% of the

³ Glycosylated hemoglobin, also known as HbA1c, is used primarily to measure the average interstitial glucose concentration over prolonged periods of time. Glycation of hemoglobin has been associated with cardiovascular disease, nephropathy and retinopathy in diabetes mellitus. While diabetic patient treatment goals vary, many include a target range of HbA1c values. The American Diabetes Association recommends that the HbA1c be below 7.0% for most patients. Recent results from large trials suggest that a target below 7% may be excessive: Below 7% the health benefits of reduced A1C become smaller, and the intensive glycemic control required to reach this level leads to an increased rate of dangerous hypoglycemic episodes. A retrospective study of 47,970 diabetes patients found that patients with an A1C greater than 6.5% had an increased mortality rate. Practitioners need to consider an individual patient's health, their risk of hypoglycemia, and their specific health risks when setting a target A1C level. For example, patients at high risk of microvascular complications may gain further benefits from reducing A1C below 7%. Lower than expected levels of HbA1c can be seen in people with shortened red blood cell life span, such as with glucose-6-phosphate dehydrogenase deficiency, sickle-cell disease, or any other condition causing premature red blood cell death. Conversely, higher than expected levels can be seen in people with a longer red blood cell life span, such as with Vitamin B12 or folate deficiency. Because patients are responsible for averting or responding to their own hypoglycemic episodes, the patient's commitment and the practitioner's assessment of the patient's self-care skills are critical.

continuous glucose monitoring group had a glycated hemoglobin level of 7.0-8.0%). Recently, Bode et al. (2009) published results of a subsequent 6-month extension study which demonstrate that the benefit of continuous glucose monitoring in this group of adults 25 years of age and older with T1DM is sustained for 12 months.

Results of these studies indicate that continuous glucose monitoring improves glycated hemoglobin levels in adults 25 years of age and older who are motivated and capable of using this technology in the management of T1DM however these results cannot be applied to other populations of patients. Whether continuous glucose monitoring succeeds in improving glycemic control in the majority of diabetic patients remains to be proven. The great potential of continuous glucose monitoring will be developed when randomized clinical trials clarify optimal clinical use and the most beneficial indications for this technology.

It is anticipated that eventually closed-loop continuous interstitial glucose monitoring systems will revolutionize diabetes management. This technology combines continuous monitoring of interstitial glucose levels, adjustment of insulin dosage and automatic controlled insulin delivery. Early studies of closed-loop continuous glucose monitoring systems have been conducted in inpatient settings for short periods of time on small numbers of patients (Chee et al., 2002; Steil et al., 2006; Weinzimer et al., 2008). At this time, closed-loop continuous glucose monitoring systems are considered experimental and investigational because there is insufficient peer-reviewed published literature to make determination of safety and efficacy. Clinical trials of closed-loop systems are underway in the U.S. and in Europe.

Definitions

Glycated hemoglobin – also known as HbA1c, is a form of hemoglobin. (Hemoglobin is the iron-rich protein in red blood cells that gives blood its red color.) In the normal 120-day life span of a red blood cell, glucose molecules react with hemoglobin forming glycated hemoglobin. Individuals with diabetes have higher quantities of glucose in their capillary blood and as a result they also have increased numbers of glycated hemoglobin molecules. The 2010 American Diabetes Association Standards of Medical Care include an HbA1c level $\geq 6.5\%$ as one of the criteria for diagnosing diabetes. Once a hemoglobin molecule is glycated, it remains that way. A build-up of glycated hemoglobin within the red blood cells therefore reflects the average level of glucose to which the cell has been exposed during its life cycle. Measuring glycated hemoglobin assesses the effectiveness of therapy for the treatment of diabetes.

Hypoglycemia – The definition of hypoglycemia has been the subject of controversy; activation of glucose counterregulatory systems occurs when blood glucose levels reach the 65–70 mg/dL range; symptoms of hypoglycemia present at the 50–55 mg/dL range, and cognitive dysfunction occurs when blood glucose levels are in the 45–50 mg/dL range.

Interstitial fluid – a fluid that is found in the interstitial spaces of the body. Interstitial fluid provides the cells of the body with nutrients and a means of waste removal. Hydrostatic pressure generated by the pumping force of the heart pushes fluid out of the capillaries and into the interstitial spaces. Not all of the contents of the blood pass into the tissue, which means that tissue fluid and blood are not the same. (Red blood cells, platelets, and plasma proteins cannot pass through the walls of the capillaries.) The composition of interstitial fluid depends upon the exchanges between the cells in

the tissue and the blood. Interstitial fluid has a different composition in different tissues and in different areas of the body. Tissue fluid passes into the surrounding lymph vessels, and eventually ends up rejoining the blood. On average, a person has about 11 liters of interstitial fluid.

Policy

Continuous glucose monitoring devices (i.e., receiver and/or transmitter) for personal use require prior authorization by FCHP.⁴

Glucose sensors also require prior authorization by FCHP.

Short-term professional use as a diagnostic tool

Effective September 1, 2010, FCHP will cover short-term (a minimum of 72 consecutive hours) continuous glucose monitoring for diagnostic purposes when medically necessary to determine optimum therapeutic regimens for plan members with insulin-dependent diabetes.

Short-term continuous glucose monitoring is considered medically necessary when all of the following medical criteria are met:

1. The plan member has insulin-dependent type 1 or type 2 diabetes.
2. There is inadequate glycemic control⁵ despite compliance with frequent self-monitoring of blood glucose (at least 4 times per day).
3. The results of continuous glucose monitoring are reviewed, interpreted, and reported by a healthcare professional.

Note: Short-term continuous glucose monitoring is used episodically to direct changes in management. Given the several month timeframe necessary to determine the efficacy of treatment modifications, short-term continuous interstitial glucose monitoring is not medically necessary more than twice in a 12-month period.

Long-term personal use of a patient-owned device

Effective November 1, 2010, FCHP will cover continuous glucose monitoring devices for personal use as an adjunct to standard medical care with the goal of achieving or maintaining optimal glycemic control, i.e., HbA1c level⁶, for plan members with T1DM when all of the following medical necessity criteria are met:

1. The plan member is 25 years of age or older.
2. The plan member is motivated to achieve and/or maintain optimal HbA1c.⁷

⁴ Plan members with a MiniMed Paradigm® insulin pump 522/722 or 523/723 (marketed as MiniMed Paradigm Insulin Pump) do not require a receiver/monitor (HCPCS code A9278). These insulin pumps are equipped with an integrated receiver.

⁵ HbA1c has become the “gold standard” for assessing and monitoring glycemic control in patients with type 1 and type 2 diabetes. HbA1c has been the independent variable against which rates of complications in all major trials have been assessed. Glycemic goals should be modified for patients in whom the risk of an adverse event exceeds the benefit of tight glycemic control.

⁶ HbA1c values represent an average over several months and may be reflective of an averaging out high blood glucose (hyperglycemia) with low blood glucose (hypoglycemia), rather than well-controlled diabetes with an HbA1c that does not vary much throughout the day or over time.

⁷ In the Standards of Medical Care in Diabetes—2010, the ADA recommends that HbA1c testing be performed at least twice per year in patients meeting treatment goals and quarterly for those who either have not meet their glycemic control goals or have recently changed therapy.

3. The plan member is capable of using of the technology.
4. The plan member receives intensive insulin therapy with either an insulin pump or multiple (3 or more) daily injections.
5. The plan member performs frequent home blood glucose monitoring (4 or more times per day).
6. The plan member's current (baseline) HbA1c level is $\geq 7.0\%$.
7. Training and education and ongoing support services are available to ensure optimal chances of success for patients transitioning onto continuous glucose monitoring.
8. Data is downloaded reviewed, interpreted and reported by a healthcare professional at least twice per year for plan members meeting treatment goals and quarterly for those who either have not met their glycemic control goals or have recently changed therapy. The written report includes an assessment of the therapeutic regimen and identification of any modifications in patient management that are needed.
9. HbA1c is performed at least twice per year for plan members meeting treatment goals and quarterly for those who either have not met their glycemic control goals or have recently changed therapy.

Continuous glucose monitoring devices (i.e., receiver and/or transmitter) and/or glucose sensors will be authorized initially for 12 months for plan members who meet all of the medical necessity criteria listed above.

After the initial 12-month period, FCHP will authorize continued coverage of a continuous glucose monitoring device and/or glucose sensors when there is evidence that the plan member is benefiting from the use of this technology. Benefit will be demonstrated by HbA1c level at or below baseline. Optimal HbA1c level may vary for some plan members depending on individual considerations.⁸

Glucose sensors:

Glucose sensors will be authorized initially for a maximum of 12 months with the initial authorization of a continuous glucose monitoring device.

When a newly enrolled plan member, age 25 years or older, already owns a continuous glucose monitoring device, FCHP will authorize glucose sensors for up to 12 months.

FCHP does not cover glucose sensors for plan members less than 25 years of age.

Following the initial 12-month authorization of glucose sensors, all subsequent authorizations of glucose sensors will require evidence that the plan member is

⁸ The ADA recommends that HbA1c goals should be individualized:

1. Certain populations such as the elderly, young children and pregnant women require special considerations.
2. Less intensive goals may be appropriate in those with a history of significant hypoglycemia or hypoglycemia unawareness.
3. More stringent goals (i.e., a normal A1C of $<6\%$) may further reduce the risk of microvascular complications at the cost of increased risk of hypoglycemia.

benefiting from the use of the continuous glucose monitoring device. Benefit is demonstrated by HbA1c level at or below baseline. Optimal HbA1c level may vary for some plan members depending on individual considerations. Glucose sensors (A9276) are covered under the medical supplies benefit, subject to the terms and conditions of the plan member's Evidence of Coverage. The following quantity limits apply to glucose sensors:

Glucose Sensors		
Model	Sensor wear/life	Quantity Limits
DexCom™ Seven Plus™ (Dexcom, San Diego, CA)	7 days	12 per 3 months
MiniMed Paradigm® or Guardian (Medtronic Diabetes, Northridge, CA)	3 days	30 per 3 months
Abbott FreeStyle Navigator (Abbott Diabetes, Alameda, CA)	5 days	18 per 3 months

Replacement of continuous glucose monitoring devices

The components of most continuous glucose monitoring devices (i.e., receiver and/or transmitter) have a limited useful life. Replacement of the receiver and/or transmitter requires prior authorization. Authorization for replacement of a receiver and/or transmitter requires evidence that the plan member is benefiting from the use of the continuous glucose monitoring device. Benefit is demonstrated by HbA1c level at or below baseline. Optimal HbA1c level may vary for some plan members depending on individual considerations. Replacement components are considered durable medical equipment (DME), subject to the terms and conditions of the plan member's Evidence of Coverage.

Exclusions

1. Closed-loop subcutaneous insulin infusion and continuous interstitial glucose monitoring systems are not covered because they are considered experimental/investigational or unproven.
2. Supplies or accessories not required for the functioning of the continuous glucose monitor such as alcohol, alcohol wipes (e.g., IV Prep), adhesives (e.g., Mastisol®), adhesive remover (e.g., Detachol®), carrying cases, clips, pouches, shower packs, etc.
3. Gluowatch G2 Biographer® (S1030, S1031) is considered experimental/investigational as it does not meet FCHP's Technology Assessment Criteria. NOTE: The Gluowatch G2 Biographer® glucose monitoring system is no longer available in the United States as of July 31, 2007.

Codes

Codes	Number	Description
CPT	95250	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

Codes	Number	Description
	95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician interpretation and report
	A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit
	A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
	A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system

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Note: CPT codes 95250 and 95251 were revised in 2009 to reflect ambulatory continuous glucose monitoring of interstitial tissue fluid for a minimum of 72 hours. Technology for continuous glucose monitoring has evolved. While some sensors continue to be placed for 72 hours, others may now be placed for 5 days or longer. Code 95251 has been revised by removing the specification of interpretation and report performed by a physician, because the interpretation and report may be performed by a health care professional other than a physician which includes an NP, PA, or CNS.

Related Policies

Diabetic Services and Supplies

Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Commonwealth Care
- ⊕ Companion Care
- ⊕ Fallon Senior Plan™
- ⊕ NaviCare

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Committee Review Dates:

Technology Assessment Subcommittee: 05/25/10

Technology Assessment Committee: 12/07/04, 06/02/10

IMPORTANT NOTE

Not all services are covered for all commercial products or employer groups. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy & Criteria Statement.

