The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required for continuous, long-term monitoring.* 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.

Description

Tight glucose control in patients with diabetes has been associated with improved 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.

Background

The advent of blood glucose monitors for use by patients in the home over 20 years ago revolutionized the management of diabetes. Using fingersticks, patients could monitor their blood glucose level both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. The importance of tight diabetic control has been validated over the past 10 years by several published randomized clinical trials (RCTs), which have demonstrated that decreasing diabetic complications is associated with tight glucose control, defined as a hemoglobin A1c measurement of less than 7%.

However, tight glucose control may require multiple measurements of blood glucose each day (i.e., before meals and at bedtime), a commitment that some patients may be unwilling or unable to meet. In addition, the goal of tight glucose control has to be balanced with an associated risk of hypoglycemia. An additional limitation of periodic self-measurements of blood glucose is that glucose values 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 hemoglobin A1c values.

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.

Several devices have received U.S. Food and Drug Administration (FDA) approval. The first two approved devices were the Continuous Glucose Monitoring System (CGMS) (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 with an electric current (referred to as reverse iontophoresis). While the time intervals at which interstitial glucose is measured range from every five minutes (CGMS) to every 10 minutes (GlucoWatch), both types of monitoring have been referred to as continuous glucose monitoring (CGM). While both devices potentially eliminate or decrease the number of required daily fingersticks, it should be noted that, according to the FDA labeling, neither is intended to be an alternative to traditional self-monitoring of blood glucose levels but rather serve as an adjunct, supplying additional information on glucose trends that are not available from self-monitoring. Additional devices have been...
approved in recent years. These include devices for pediatric use and devices with more advanced software, more frequent measurements of glucose levels, more sophisticated alarm systems, etc.

In evaluating the continuous glucose monitoring systems, it is important to recognize that they may be used intermittently, e.g., time periods of 72 hours, or continuously. In addition, it is important to note that all FDA-approved CGM systems are indicated as adjuncts to traditional self-monitoring of blood glucose and should not be used instead of self-monitoring.

**Regulatory Status**

Several continuous glucose monitoring systems have been approved by the FDA through the premarket approval process:

- The Continuous Glucose Monitoring System (CGMS) (MiniMed) in 1999 (approved for three-day use in a physician's office).
- The GlucoWatch G2 Biographer in 2001. Of note, neither the GlucoWatch nor the autosensors have been available after July 31, 2008.
- The Guardian-RT (Real-Time) CGMS (Medtronic, MiniMed) in July 2005. (MiniMed was purchased by Medtronic).
- The DexCom STS CGMS system (DexCom) was approved by the FDA in March 2006.
- The Paradigm REAL-Time System (Medtronic, MiniMed) was approved by the FDA in 2006. This system integrates a continuous glucose monitor with a Paradigm insulin pump. The second generation integrated system is called the MiniMed Paradigm Revel System.
- The FreeStyle Navigator CGM System (Abbott) was approved in March 2008.

**Corporate Medical Guideline**

Intermittent monitoring, i.e., 72 hours, of glucose levels in interstitial fluid may be considered **medically necessary** in patients with type I diabetes whose diabetes is poorly controlled despite current use of best practices (see Policy Guidelines). Poorly controlled type I diabetes 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 prior to insulin pump initiation to determine basal insulin levels.

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 I diabetes who have recurrent, unexplained, severe, symptomatic (generally blood glucose levels less than 50 mg/dl) hypoglycemia for whom hypoglycemia puts the patient or others at risk; or
- Patients with type I diabetes who are pregnant whose diabetes is poorly controlled. Poorly controlled type I diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

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

Best practices in diabetes control for patients with type I diabetes include compliance with a regimen of four or more fingersticks each day and use of 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. Prior use of an intermittent (72-hour) glucose monitor would be considered a part of best practices for those considering use of a continuous glucose monitor.

Women with type I diabetes 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 at a subsequent time depending on the patient’s level of diabetes control.

Medicare Advantage

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 precautionary and therefore not medically necessary for Medicare Advantage.

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.

References

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


