Protocol

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

(10120)

Medical Benefit		**Effective Date**: 01/01/14	**Next Review Date**: 05/15
Preauthorization	Yes	**Review Dates**: 07/07, 07/08, 07/09, 01/10, 01/11, 01/12, 01/13, 05/13, 01/14, 05/14	

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. Tight diabetic control, defined as a strategy involving frequent glucose checks and a target hemoglobin A_{1c} (HgA_{1c}) in the range of 7%, is now considered standard of care for diabetic patients. Randomized controlled trials (RCTs) of tight control have demonstrated benefits for type I diabetics in decreasing microvascular complications. The impact of tight control on type II diabetic patients and on macrovascular complications such as stroke or myocardial infarction is less certain.

However, tight glucose control requires 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 HgA_{1c} 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. Although devices measure glucose in 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 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).

Additional devices that have subsequently been approved include those for pediatric use and those with more advanced software, more frequent measurements of glucose levels, more sophisticated alarm systems, etc. Devices initially measured interstitial glucose every five to 10 minutes and, with currently available devices the time intervals at which interstitial glucose is measured ranges from every one to two minutes to five minutes. While CGMs potentially eliminate or decrease the number of required daily fingersticks, it should be noted that, according to the FDA labeling, monitors are not intended to be an alternative to traditional self-monitoring of blood glucose levels but rather provide adjunct monitoring, supplying additional information on glucose trends that are not available from self-monitoring. In addition, it is important to note that devices may be used intermittently, e.g., time periods of 72 hours, or on a long-term basis.

In addition to stand-alone CGMs, several insulin pump systems have included a built-in CGM. This Protocol addresses continuous glucose monitoring devices, not the insulin pump portion of these systems. Also, under development is what is known as an artificial pancreas or artificial pancreas device system (APDS). The proposed artificial pancreas is a series of devices, e.g., a CGM, blood glucose device and an insulin pump, plus a computer algorithm that communicates with all of the devices. The goal of the APDS is to automatically monitor glucose levels and adjust insulin levels. These systems are also called closed-loop systems or autonomous systems for glucose control. One technology associated with artificial pancreas development is a "low glucose suspend (LGS)" feature included with an insulin pump. The LGS feature is designed to suspend insulin delivery when plasma glucose levels fall below a prespecified threshold.

Regulatory Status

Several continuous glucose monitoring systems have been approved by 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 FDA in March 2006.
- The Paradigm® REAL-Time System (Medtronic, MiniMed) was approved by FDA in 2006. This system integrates a CGM 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.
- The OmniPod® Insulin Management System (Insulet Corporation), integrating the Freestyle Navigator CGM system with the Pod insulin pump, was approved in December 2011.
- The DexCom G4 Platinum (DexCom) CGM was approved for use in adults 18 years and older in October 2012. The device can be worn for up to seven days. In February 2014, FDA expanded use of the Dexcom Platinum CGM to include patients with diabetes, age two to 17 years-old.

Artificial pancreas device systems:

- The Minimed 530G System (Medtronic) integrating an insulin pump and glucose meter, and including a low glucose suspend feature, was cleared for marketing in September 2013. The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is equal to or lower than a preset threshold within the 60 mg/dL to 90 mg/dL range. When the glucose value reaches this threshold, an alarm sounds. If patients respond to the alarm, they can choose to continue or cancel the insulin suspend feature.

If patients fail to respond to the alarm, the pump automatically suspends action for two hours, and then insulin therapy resumes. The device is approved only for use in patients 16 years and older.

Policy (Formerly 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, (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**.

Use of an artificial pancreas system, including but not limited to closed-loop monitoring devices with low-glucose suspend (LGS) features, are considered **investigational**.

Policy Guideline

Several insulin pump systems (e.g., Omnipod Insulin Management System, Paradigm REAL-Time System) have a built-in continuous glucose monitor (CGM). This Protocol is evaluating the CGM-device only; the Protocol does not evaluate insulin pumps. In the case of insulin pumps systems with a built-in CGM and a low glucose suspend (LGS) feature, the CGM device and the low glucose suspend feature are evaluated in the policy, not the insulin pump.

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 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 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, is 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.

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Use of Intermittent or Continuous Interstitial Fluid Glucose Monitoring in Patients with Diabetes Mellitus. TEC Assessments 2003; Volume 18, Tab 16.
2. Gandhi GY, Kovalaske M, Kudva Y et al. Efficacy of continuous glucose monitoring in improved glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. J Diabetes Sci Technol 2011; 5(4):952-65.
3. Wojciechowski P, Rys P, Lipowska A et al. Efficacy and safety comparison of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes. Pol Arch Med Wewn 2011; 121(10):333-43.
4. Langendam M, Luijf YM, Hooft L et al. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database Syst Rev 2012; 1:CD008101.
5. Floyd B, Chandra P, Hall S et al. Comparative analysis of the efficacy of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes mellitus. J Diabetes Sci Technol 2012; 6(5):1094-102.
6. Poolsup N, Suksomboon N, Kyaw AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. Diabetol Metab Syndr 2013; 5(1):39.
7. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med 2008; 359(14):1469-76.
8. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Effectiveness of continuous glucose monitoring in a clinical care environment. Diabetes Care 2010; 33(1):17-22.
9. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. The effect of continuous glucose monitoring in well-controlled type 1 diabetes. Diabetes Care 2009; 32(8):1378-83.
10. Newman SP, Cooke D, Casbard A et al. A randomised controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE). Health Technol Assess 2009; 13(28):iii-iv, 1-194.

11. Mauras N, Beck R, Xing D et al. A randomized clinical trial to assess the efficacy and safety of real-time continuous glucose monitoring in the management of type 1 diabetes in young children aged 4 to < 10 years. Diabetes Care 2012; 35(2):204-10.
12. Ehrhardt NM, Chellappa M, Walker MS et al. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. J Diabetes Sci Technol 2011; 5(3):668-75.
13. Vigersky RA, Fonda SJ, Chellappa M et al. Short- and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. Diabetes Care 2012; 35(1):32-8.
14. Voormolen DN, Devries JH, Evers IM et al. The efficacy and effectiveness of continuous glucose monitoring during pregnancy: a systematic review. Obstet Gynecol Surv 2013; 68(11):753-63.
15. Secher AL, Ringholm L, Andersen HU et al. The Effect of Real-Time Continuous Glucose Monitoring in Pregnant Women With Diabetes: A randomized controlled trial. Diabetes Care 2013.
16. Murphy HR, Rayman G, Lewis K et al. Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. BMJ 2008; 337:a1680.
17. Raccah D, Sulmont V, Reznik Y et al. Incremental value of continuous glucose monitoring when starting pump therapy in patients with poorly controlled type 1 diabetes: the RealTrend study. Diabetes Care 2009; 32(12):2245-50.
18. Battelino T, Conget I, Olsen B et al. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: a randomised controlled trial. Diabetologia 2012; 55(12):3155-62.
19. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Artificial Pancreas Device Systems. TEC Assessments 2013; Volume 28.
20. Bergenstal RM, Klonoff DC, Garg SK et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. N Engl J Med 2013; 369(3):224-32.
21. Garg S, Brazg RL, Bailey TS et al. Reduction in duration of hypoglycemia by automatic suspension of insulin delivery: the in-clinic ASPIRE study. Diabetes Technol Ther 2012; 14(3):205-9.
22. Phillip M, Battelino T, Atlas E et al. Nocturnal glucose control with an artificial pancreas at a diabetes camp. N Engl J Med 2013; 368(9):824-33.
23. Nimri R, Danne T, Kordonouri O et al. The “Glucositter” overnight automated closed loop system for type 1 diabetes: a randomized crossover trial. Pediatr Diabetes 2013; 14(3):159-67.
24. Melbourne SVH. The Performance of an Artificial Pancreas at Home in People With Type 1 Diabetes (NCT02040571). Available online at: www.clinicaltrials.gov. Last accessed February, 2014.
25. Sponsored by Rabin Medical Center (Israel). Overnight Type 1 Diabetes Control Under MD-Logic Closed Loop System at the Patient’s Home (NCT01726829). Available online at: www.clinicaltrials.gov. Last accessed February, 2014.
26. Nimri R, Muller I, Atlas E et al. Night glucose control with MD-Logic artificial pancreas in home setting: a single blind, randomized crossover trial-interim analysis. Pediatr Diabetes 2013.
27. American Diabetes A. Standards of medical care in diabetes--2013. Diabetes Care 2013; 36 Suppl 1:S11-66.
28. Klonoff DC, Buckingham B, Christiansen JS et al. Continuous glucose monitoring: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2011; 96(10):2968-79.
29. National Government Services Local Coverage Article: Glucose Monitors - Policy Article - Effective January 2014 (A33614), Revision Effective Date 01/01/2014.