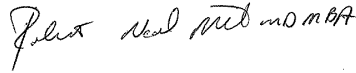


Origination Date: 2/01	Revision Date(s): 4/04, 4/05, 3/06, 11/06, 12/07, 3/08, 9/08, 4/09, 2/11, 4/11, 5/11
Developed By: Medical Criteria Committee	



Approved: Robert Mills, MD

Date: 05/26/2011

Description:

A continuous glucose monitor (CGM) is a minimally invasive device that is designed to measure and record glucose levels continuously and automatically in a patient. The device measures glucose values in the interstitial fluid of subcutaneous tissue. The goal of CGM devices is to record patterns of glucose levels and use these patterns to guide patient management and improve overall glycemic control. A continuous glucose monitoring device is an adjunct to supplement, not replace, standard home glucose monitoring. These devices are used in specific clinical situations. Examples of CGM systems are: Medtronic iPro Professional® Continuous Glucose Monitoring System (CGMS), Guardian Real Time Glucose Monitor (MiniMed), and the STS Monitoring System (DexCom).

NOTE: Short term continuous CGM does not require prior authorization. When continuous glucose monitors are for short-term (up to 72 hours) diagnostic use, no more than four glucose monitoring periods are considered medically necessary within a 12-month period. Additional short term monitoring periods will need prior authorization.

Criteria:

- I. ODS will cover short term continuous monitoring of glucose levels in the interstitial fluid via an implanted sensor for 3 days (72 hours) as medically necessary for members with type 1 diabetes when **one** of the following criteria is met:
 - A. Glycosylated hemoglobin (HbA1c) values <6.0 and >8.5; **or**
 - B. Wide fluctuations of blood glucose levels despite documentation of blood glucose testing (≥ 4 x/day) and insulin administration (≥ 3 x/day); **or**
 - C. Unexplained frequent hypoglycemic episodes in a diabetic taking insulin; **or**
 - D. Repeated hypo- or hyperglycemia at the same time each day; **or**
 - E. Episodes of ketoacidosis or hospitalizations for glucose out of control; **or**
 - F. Preconception or pregnancy with a history of suboptimal glycemic control; **or**
 - G. Starting insulin for the first time or starting an insulin pump regimen

- II. ODS may cover long-term use of a continuous glucose monitor if **all** of the following criteria are met:
 - A. Member has type 1 diabetes; **and**
 - B. Member is age 7 or older; **and**
 - C. Member is on an insulin pump or on multiple daily insulin injections (≥ 3 daily injections); **and**
 - D. Patient has wide variations in blood glucose levels requiring 4 or more fingersticks per day with frequent self-adjustments of insulin dosage **OR** has a history of hypoglycemic unawareness; **and**
 - E. Member has completed a comprehensive diabetic program **and**
 - F. Written statement from the ordering physician indicating that the patient is a good candidate for long-term use of a continuous glucose monitor based on the patient's prior compliance and understanding of their diabetic regimen; **and**
 - G. An ODS nurse will contact the member to offer ODS Diabetes Care Program services

Origination Date: 2/01	Revision Date(s): 4/04, 4/05, 3/06, 11/06, 12/07, 3/08, 9/08, 4/09, 2/11, 4/11, 5/11
Developed By: Medical Criteria Committee	

- III. ODS will cover short-term and long-term use of continuous glucose monitor for patients with Type II diabetes when the criteria below are met:
- A. With severe recurrent hypoglycemic events (<50mg/dl glucose readings) in spite of frequent self monitoring of glucose levels at least four times per day and compliance of proper insulin modifications
 - B. An ODS nurse will contact the member to offer ODS Diabetes Care Program services.

NOTE: When a long-term CGM is found to be medically necessary, authorization for the sensors will be given for 1 year. Continued authorization for the sensors is contingent upon the member meeting letter F above - the member must be enrolled in the ODS Disease Management Program. For members who have purchased their own long-term CGM, criteria A-F above must be met in order for ODS to cover the related sensors.

Excluded Devices

1. The GlucoWatch is another device that measures interstitial glucose levels beyond 3 days. The use of this device is considered experimental and investigational and is not a covered item.
2. ODS does not cover additional software that may be required for downloading data from a CGM to a computer for further management of member's diabetes. This is considered a convenience item and is not medically necessary.
3. ODS does not cover combination devices such as a blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes. These combination devices are considered convenience items and are not medically necessary.

Information to be Submitted with Pre-Authorization Request:

1. Physician progress notes for the past six months
2. Evaluations and consultations related to the diagnosis
3. Blood glucose laboratory values

Applicable CPT/HCPC:

NOTE: this list may not be all inclusive

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 recording
95251	Interpretation and report
A9276	Sensor; invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial glucose monitoring system
S1030	Continuous noninvasive glucose monitoring device, purchase
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor

Origination Date: 2/01	Revision Date(s): 4/04, 4/05, 3/06, 11/06, 12/07, 3/08, 9/08, 4/09, 2/11, 4/11, 5/11
Developed By: Medical Criteria Committee	

References:

- ADA Standards of Medical Care in Diabetes. Accessed on February 21, 2011 at: <http://care.diabetesjournals.org/content/33/Supplement-1/S11.extract>
- Alert-on the horizon. Next generation of continuous glucose monitoring systems. Hayes Alert. 2005 Jan;8(1)
- American Association of Clinical Endocrinologists (AACE). Diabetes Mellitus Clinical Practice Guidelines Task Force. Diabetes mellitus guidelines. Diabetes and pregnancy. Endocr Pract 2007b May-Jun; 13 (Suppl 1):55-59. Accessed on February 21, 2011 at <http://www.aace.com/pub/pdf/guidelines/DMGuidelines2007.pdf>
- Bailey TS, Zisser HC, Garg SK. Reduction in hemoglobin A1C with real-time continuous glucose monitoring: results from a 12-week observational study. Diabetes Technol Ther. 2007 Jun;9(3):203-10.
- Blevins, T., Bode, B., Garg, S., et al. (2010). American Association of Clinical Endocrinologists Consensus Statement on continuous glucose monitoring. Endocrine Practice 16(5); 1-14.
- Bode BW, Sabbah H, Davidson PC. What's ahead in glucose monitoring? New techniques hold promise for improved ease and accuracy. Postgrad Med. 2001 Apr;109(4):41-4, 47-9.
- Buckingham B, Beck RW, Tamborlane WV, et al. Continuous glucose monitoring in children with type 1 diabetes. J Pediatr. 2007 Oct;151(4):388-93.
- Centers for Medicare and Medicaid Services (CMS). Decision memo for insulin pump: C-peptide levels as a criterion for use (CAG-00092R. Baltimore, MD: CMS; December 17, 2004. Accessed on February 21, 2011 at: <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=109>.
- CGMS: FDA Summary of Safety and Effectiveness. Accessed on February 21, 2011 at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094134.htm>
- Diabetes Control and Complications Trial (DCCT). National Institute of Diabetes and Digestive and Kidney Diseases. NIH publication No. 97-3874. Sept 1994.
- Garg S, Jovanovic L. Relationship of fasting and hourly blood glucose levels to HbA1c values. Safety, accuracy, and improvement in glucose profiles obtained using a 7-day continuous glucose sensor. Diabetes Care. 2006 Dec;29(12):2644-2649.
- Garg S, Zisser H, Schwartz S, et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor. Diabetes Care. 2006 Jan; 29(1):44-50.
- Garg SK, Schwartz S, Edelman SV. Improved glucose excursions using an implantable real-time continuous glucose sensor in adults with type 1 diabetes. Diabetes Care. 2004 Mar;27(3):734-8.
- GlucoWatch does not improve glycemic control in children with type 1 diabetes. Hayes Alert. 2005 June;8(6).
- Hovorka R. Continuous glucose monitoring and closed-loop systems. Diabet Med. 2006 Jan;23(1):1-12.
- Jovanovic L, Zisser H, Schwartz S, et al. A randomized controlled study of a transcutaneous real-time continuous glucose sensor demonstrates improvement in glycemic control. The 65th Scientific Sessions of the American Diabetes Association. June 2005.
- Kerr D. Continuous blood glucose monitoring: detection and prevention of hypoglycemia. Int J Clin Pract Suppl. 2001 Sep;(123):43-6.
- Medtronic MiniMed. (2010) Summary of the Statement by the American Association of Clinical Endocrinologists Consensus Panel on continuous glucose monitoring. 9501340-011; 1-2. Raskin, P., Bode, B., Marks, J. et al. Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes: A randomized, parallel-group, 24-week study. Diabetes Care. 2003;26(9):2598-2603.
- Skyler J. The economic burden of diabetes and the benefits of improved glycemic control: the potential role of a continuous glucose monitor. Diabetes Technol Ther. 2000;2(supplement 1).

Origination Date: 2/01	Revision Date(s): 4/04, 4/05, 3/06, 11/06, 12/07, 3/08, 9/08, 4/09, 2/11, 4/11, 5/11
Developed By: Medical Criteria Committee	

- The Medical Letter. Continuous Glucose Monitoring. February 12, 2007; 49(1254):13-15.
- Toth-Heyn P, Korner A, Madacsy L. Continuous glucose monitoring systems, as a valuable tool in the care of children and adolescents with diabetes mellitus. Orv Hetil. 2004 Jun 13;145(24):1265-70.
- Wong LJ, Buckingham BA, Kunselman B, et al. Extended use of a new continuous glucose monitoring system with wireless data transmission in children with type 1 diabetes mellitus. Diabetes Technol Ther. 2006 Apr;8(2):139-45.
- Physician Advisors