

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

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Date: 04/02/09

**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: MiniMed® Continuous Glucose Monitoring System (CGMS), Guardian Real Time Glucose Monitor (MiniMed), and the STS Monitoring System (DexCom).

**Criteria:**

- I. ODS will cover 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 fluctuation of blood glucose levels despite documentation of blood glucose testing (≥4x/day) and insulin administration (≥3x/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

**NOTE:** When continuous glucose monitors are for short-term (up to 72 hours) diagnostic use, no more than two glucose monitoring periods are considered medically necessary within a 12-month period.

- II. Requests for long-term use of a continuous glucose monitor beyond 72 hours will be reviewed by the ODS Medical Director. 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 **OR** has a history of hypoglycemic unawareness; **and**
  - E. 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**
  - F. An ODS nurse will contact the member to obtain verbal consent from the member to participate in the ODS Disease Management Program. **Authorization for the long-term CGM is contingent upon the member agreeing to participate in the ODS Disease Management Program. This consent must be obtained prior to authorization being given.** When the member agrees to enroll in the ODS Disease Management program, they will receive periodic telephone follow-up from a Disease Management Health Coach.

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**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**

<b>95250</b>	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
<b>A9276</b>	Sensor; invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
<b>A9277</b>	Transmitter; external, for use with interstitial continuous glucose monitoring system
<b>A9278</b>	Receiver (monitor); external, for use with interstitial glucose monitoring system
<b>S1030</b>	Continuous noninvasive glucose monitoring device, purchase
<b>S1031</b>	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor

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