

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline

WellCare Prescription Insurance, Inc.



*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*



WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

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WellCare of New York, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

Continuous Glucose Monitoring

Guideline Number: HS-138

Original Effective Date: 10/15/2009

Revision Date: n/a

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Intermittent (up to 72 hours) monitoring of glucose levels in interstitial fluid is considered medically necessary if ALL of the following criteria are met:

- Member has poorly controlled type I diabetes*; **AND**,
- Member used best practices and was compliant with 4 or more finger sticks per day and there were multiple alterations in self-monitoring and insulin administration regimens to optimize care; **AND**,
- Insulin injections are required 3 or more times per day or an insulin pump is used for maintenance of blood sugar control; **AND**,
- Monitoring is for the purpose of identifying glucose excursions and facilitating adjustments in therapy.

*** Poorly controlled type I diabetes may include the following circumstances:**

- Unexplained hypoglycemic episodes; **OR**,
- Hypoglycemic unawareness; **OR**,
- Suspected postprandial hyperglycemia; **OR**,
- Recurrent diabetic ketoacidosis.

Intermittent (up to 72 hours) monitoring of glucose levels in interstitial fluid is considered medically necessary in members with type I diabetes prior to insulin pump initiation to determine basal insulin levels.

Continuous (long term) monitoring of glucose levels in interstitial fluid is considered medically necessary if ALL of the following criteria are met:

- Member has used best practices and was compliant with 4 or more finger sticks per day, but still exhibited failure to control type I diabetes; **AND**,
- Member has previous use of a 72-hour monitor to guide alterations in insulin administration; **AND**,

- Member with type I diabetes has recurrent, unexplained, severe, symptomatic hypoglycemia (blood glucose levels less than 50 mg/dl), putting the member and others at risk; **AND**,
- Insulin injections are required 3 or more times per day or a medically necessary insulin pump is used for maintenance of blood sugar control

Continuous (long term) monitoring of glucose levels in interstitial fluid in pregnant members DURING PREGNANCY is considered medically necessary if ALL of the above criteria are met.

BACKGROUND

Diabetes mellitus is characterized by hyperglycemia due to impaired pancreatic insulin secretion or inefficient use of insulin by the body. Members with insulin-dependent (type 1) diabetes require chronic treatment with exogenous insulin. To calculate the insulin dose needed to manage their blood glucose levels, these members perform self-monitoring of blood glucose (SMBG) using samples obtained by finger sticks; however, frequent SMBG may not detect all significant deviations in blood glucose, particularly in members with rapidly fluctuating glucose levels. As a result, some members who perform multiple daily finger sticks may fail to detect blood glucose excursions above or below the desired range, especially when glucose fluctuations occur at night.

The following continuous glucose monitoring (CGM) systems have been approved by the Food and Drug Administration (FDA):

- MiniMed Continuous Glucose Monitoring System (CGMS) (Medtronic MiniMed Inc.)
- MiniMed Guardian® REAL-Time System (Medtronic MiniMed Inc.)
- MiniMed Paradigm® REAL-Time System (Medtronic MiniMed Inc.)
- DexCom STS® and DexCom STS®-7; currently marketed as DexCom SEVEN® System (DexCom Inc.)
- FreeStyle Navigator® Continuous Glucose Monitoring System (Abbott Diabetes Care)

These systems have all been developed to detect trends and track patterns in glucose levels over a period of several days, information that can be used to optimize insulin therapy and, thereby, potentially improve glycemic control. The MiniMed systems utilize sensors that are inserted into the subcutaneous tissues of the abdomen. These devices extract glucose from the interstitial fluid, measure and record the glucose level, and convert the measurement into an equivalent blood glucose reading (from Hayes, 2008).

National Institute for Health and Clinical Excellence (NICE)

NICE recommends the use of continuous glucose monitoring systems in adults on insulin therapy who have consistent problems with controlling blood glucose levels, notably repeated hyper- or hypoglycemia at the same time of day or hypoglycemia unawareness, unresponsive to conventional insulin dose adjustment. (NICE, 2008)

NICE also recommends that continuous glucose monitoring systems be available to children and young adults with type 1 diabetes who have persistent problems with impaired awareness of hypoglycemia or repeated hypoglycemia and hyperglycemia (NICE, 2004).

American Diabetes Association (ADA)

In the 2009 Standards of Medical Care in Diabetes, the ADA states that continuous glucose monitoring (CGM) may be a supplemental tool to SMBG in type 1 diabetes patients with hypoglycemia unawareness and/or frequent hypoglycemic episodes. CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age greater than or equal to 25 years) with type 1 diabetes. Although the evidence for A1C lowering is less strong in children, teens and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device (ADA, 2009).

American Association of Clinical Endocrinologists (AACE)

The 2007 Clinical Practice Guidelines for the Management of Diabetes state that advances in blood glucose monitoring

and continuous monitoring of interstitial glucose, along with the introduction of "smart" insulin pumps, provide clinicians and patients with powerful tools to monitor and adjust treatment regimens. The guidelines recommend arranging for continuous glucose monitoring for patients with type 1 diabetes with unstable glucose control and for patients unable to achieve an acceptable HbA1c level; continuous glucose monitoring is particularly valuable in detecting both unrecognized nocturnal hypoglycemia and postprandial hyperglycemia (AAACE, 2007).

CODING

CPT® Codes

- 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 (Do not report more than once per month.)
- 95251 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician interpretation and report (Do not report more than once per month.)

HCPCS Codes

- 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 continuous glucose monitoring system
- S1030*+ Continuous noninvasive glucose monitoring device, purchase
+for physician interpretation of data, use CPT code
- S1031*+ Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor
+for physician interpretation of data, use CPT code

* **Note:** S-Codes are NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes For Medicare, bill the appropriate CPT code listed above.

ICD-9-CM Diagnosis Codes

- 250.00 - 250.93 Diabetes mellitus
- 648.00 - 648.04 Maternal diabetes mellitus, complicating pregnancy, childbirth, or the puerperium
- 648.80 - 648.84 Gestational diabetes

*Current Procedural Terminology (CPT®) ©2009 American Medical Association: Chicago, IL.

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