Continuous Glucose Monitoring (CGM): Professional Services & Durable Medical Equipment (DME i.e. Personal Device)

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr. Go to “Comunicados a Proveedores”, and click “Cartas Circulares”.]

Medical Policy: MP-DME-01-13
Original Effective Date: December 1, 2013
Reviewed:
Revised:
Related Policies:
☐ MP-DME-01-10 External Insulin Infusion Pumps for Diabetes (EIP).
☐ This medical policy replaces and unifies previous medical policies MP-ME-01-10 & MP-DME-03-10.

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider’s contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

Continuous Glucose Monitoring is intended to continuously measure glucose levels in the interstitial fluid of the subcutaneous layer of the skin and to provide real-time results for patients with type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) (ECRI, 1/20/10).

A Continuous Glucose Monitoring System (CGMS) is an FDA-approved device that records blood sugar levels throughout the day and night. There are several approved devices: Medtronic’s MiniMed device, DexCom, and the Navigator, for example, that can provide up to 288 blood sugar measurements every 24 hours. The system is used to measure an average blood sugar for three to seven days (depending on the model), while the person with diabetes continues daily activities at home (WebMD, 2012).

The systems consist of three parts: a disposable, short-term sensor to measure glucose in interstitial fluid; a transmitter attached to the sensor; and a receiver that displays and stores glucose-value information.

Continuous Glucose Monitoring (CGM) equipment can be divided into 2 categories: professional and personal devices. Professional CGM equipment (also sometimes referred to as retrospective CGM) is owned by the health care professional, clinic, or hospital, and is generally used for masked data collection. Patients remain unaware of monitoring results until they are downloaded and analyzed by the health care professional; this allows for an unbiased assessment of patients’ glucose control. Patients are typically asked to attend an office visit, receive instruction, wear a sensor for 3 to 5 days, keep a food and activity logbook, and then return to the office for interpretation (AACE, 2010). This information is used by the physician for the treatment plan.

In contrast, personal CGM devices are owned by patients. With personal real-time CGM, glucose values are visible continuously; this allows for immediate therapeutic adjustments by the patient based on “real-time” glucose results (AACE, 2010).
An **Insulin Pump with Continuous Glucose Monitoring System (CGMS)** (i.e. Medtronic, Inc.’s MiniMed 530G System) combines a continuous glucose monitoring system with an insulin pump. A glucose sensor is inserted under the patient’s skin and is calibrated against standard fingerstick glucose testing. After calibration, the system automatically transmits information about glucose levels from the sensor to the glucose monitor every five minutes. The insulin pump is programmed to deliver appropriate amounts of insulin based on data from the glucose monitor and information from the user about meals. The glucose monitor data can also be stored for later analysis, and the system can be set to generate alerts (tone or vibration) if glucose levels do not fall within a preprogrammed target zone (ECRI, 4/9/12).

**COVERAGE**

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits and coverage.

**Note 1:** Professional CGM (also referred to as retrospective or intermittent CGM), is usually provided with devices owned and operated by health care professionals. Personal CGM, sometimes called “real-time monitoring” are patient owned devices in a home setting. This medical policy addresses the specific coverage for both devices.

**Note 2:** Professional CGM services will be covered for **BOTH** the Commercial & Classicare Line of Business (LOB). Personal CGM (DME) will be covered **ONLY** for the Commercial LOB (CMS LCA A33745, 2011).

**Note 3:** Before using the Continuous Glucose Monitor Systems, healthcare providers and patients must be trained to insert and replace sensors; calibrate, program, and operate the device; and respond to alarm conditions (TES & JOCEM, 2011).

**INDICATIONS**

I. **Medical Card System, Inc., (MCS)** considers the use of the **Professional Services** (also referred to a retrospective or intermittent) for Continuous Glucose Monitoring [CGM] as reasonable and **medically necessary** for adult and pediatric patients with Diabetes that meet **ALL** requirements from Criteria A, and meet **ONE or MORE** requirements from Criteria B:

   A. Type 1 (DM-1), or Type 2 (DM-2) diabetics who have:

      1. Been instructed by a health care professional in the management of diabetes, and

      2. Documented frequency of glucose self-testing an average of at least 4 times per day during the previous month, and

      3. Been on a program of Multiple Daily Injections (MDI) of insulin (at least 2 injections per day) with self-adjustment of their insulin dose based on self-testing results.
B. Patients meet **ONE or MORE** of the following criteria, while on the Multiple Daily Injection (MDI) regimen:

1. Glycated hemoglobin (Hgb A1C) values <4 or > 9; or
2. Unexplained large fluctuations in daily glucose values before meals; or
3. Unexplained frequent hypoglycemic attacks; or
4. Episodes of ketoacidosis or hospitalizations for uncontrolled glucose levels; or
5. Type 1 diabetics (DM-1) with an implanted insulin pump; or
6. Type 1 (DM-1) or Type 2 (DM-2) diabetic women, who are newly pregnant or, women who have developed gestational diabetes that require insulin therapy; or
7. Patients experimenting with important changes to their diabetes regimen (such as switching from Multiple Daily Injections (MDI) to pump therapy) (TES & JOCEM, 2011); or
8. Patients experiencing problems with **ANY** of the following (AACE, 2010):
   a. Nocturnal hypoglycemia; or
   b. The dawn phenomenon; or
   c. Hypoglycemia unawareness; or
   d. Postprandial hyperglycemia.
II. Medical Card System, Inc., (MCS) considers the approval of the Personal Device (DME) for Continuous Glucose Monitoring (CGM) (also “Real-time” / RT-CGM) as reasonable and medically necessary (ONLY for the Commercial LOB) for patients that meet ALL requirements from criteria A below, and ANY criterion under criteria B, C, or D, also below:

A. Type 1 (DM-1), or Type 2 (DM-2) diabetics who have:

1. Been instructed by a health care professional in the management of diabetes, and

2. Documented frequency of glucose self-testing an average of at least 4 times per day during the previous month, and

3. Been on a program of Multiple Daily Injections (MDI) of insulin (at least 2 injections per day) with self-adjustment of their insulin dose based on self-testing results.

B. Adult patients with Diabetes Type 1 (DM-1):

1. To assist Self-Monitoring Blood Glucose (SMBG) in those with hypoglycemia unawareness, or frequent hypoglycemic episodes, either potentially disabling or life threatening; or

2. For patients who have HbA1c levels of at least 7.0% and, who have demonstrated that they can use these devices on a nearly daily basis (TES & JOCEM, 2011); or

3. For patients who have HbA1c levels less than 7.0% and who have demonstrated that they can use these devices on a nearly daily basis (TES & JOCEM, 2011).

OR

C. Pediatric Patients with Diabetes Type 1 (DM-1):

1. For patients 8 years or older who have already achieved excellent glycosylated hemoglobin (A1C or HbA1c) control (A1C <7%) because it will assist in maintaining target HbA1c levels while limiting the risk of hypoglycemia; or

2. For pediatric patients that are younger than 8 years of age: a trial period of 2 to 4 weeks if patients (AACE, 2010):

   a. frequently monitor their blood glucose levels; and

   b. Have committed families, especially if the patient is having problems with hypoglycemia.
Note 4: Treatment guidelines should be provided to both adult & pediatric patients in order to allow them to safely and effectively take advantage of the information provided to them by the RT-CGM (TES & JOCEM, 2011).

OR

D. **Pregnant Women** with Diabetes Type 1 (DM-1), or with Diabetes Type 2 (DM-2), or with Gestational Diabetes (GD) (AACE, 2010):

1. During preconception and pregnancy.

Note 5: During pregnancy, to allow immediate response to eating and glucose level patterns that can vary on a day-to-day basis.

III. **Medical Card System, Inc., (MCS)** will consider the use of a Continuous Glucose Monitoring Device sensor/transmitter with wireless communication to a compatible external insulin pump (e.g., MiniMed® 530G System) as medically necessary when **ALL** the following criteria are met:

1. The patient meets the criteria for an External Portable Continuous Insulin Infusion Pump (Please see medical policy MP-DME-01-10 External Insulin Infusion Pumps for Diabetes [EIP]); and

2. The patient meets the criteria for Continuous Glucose Monitoring contained within this medical policy.

3. The patient must be sixteen years of age and older (FDA, 9/26/13).

**CONTRAINDICATIONS**


2. Contraindicated in patients taking acetaminophen containing medications when the sensor is inserted (ECRI, 1/20/10).

3. For patients with visual or auditory limitations that do not allow full recognition of the systems signals and alarms/alerts (ECRI, 1/20/10).

4. Use of the MiniMed® 530G is contraindicated in patients who are unwilling or unable to perform a minimum of four blood glucose tests per day, who are unwilling or unable to maintain contact with their healthcare professional, and whose vision or hearing does not allow recognition of pump signals and alarm (ECRI, 10/28/13).

5. The MiniMed® 530G labeling indicates the Enlite Serter component should not be used on products other than the Enlite sensor. The manufacturer (Medtronic) cannot guarantee this product’s safety or efficacy if used in other products (FDA, 9/26/13).
LIMITATIONS

1. Professional CGM Coverage will apply to both the Classicare and Commercial Line of Business (LOB).

2. Personal CGM Coverage only applies to the Commercial LOB.

3. According to FDA labeling continuous glucose monitoring devices are to be used only as a supplement to, and not a replacement for, standard self-monitoring of blood glucose via fingerstick. The intent is to guide future management of the patient based on noted trends, and includes the determination of appropriate timing and frequency of fingerstick samples (CMS LCD L31165, 2013).

4. Unless being used concurrently with an insulin pump, or in the setting of gestational diabetes, it is anticipated that the Professional CGM modality will be utilized no more than once every six months to improve diabetic control (CMS LCD L31165, 2013).

5. Device must be prescribed by an endocrinologist.

6. The expected life of a glucose sensor inserted into the body is from 3 to 5 days, depending on the product being used (Diabetes Services, 2012).

7. The recommended monitoring period is at least 72 hours. Monitoring for less than 24 hours is not considered medically reasonable or necessary (CMS LCD L6179, 2009).

8. The MiniMed® 530G System is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the MiniMed 530G System (FDA, 9/26/13).

9. The MiniMed® 530G System is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the Threshold Suspend alarm to take measures to prevent or treat hypoglycemia himself (FDA, 9/26/13).

10. The MiniMed® 530G System is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide (FDA, 2012).

CODING INFORMATION
CPT® Codes (List may not be all inclusive)

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>95250</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a</td>
</tr>
</tbody>
</table>
subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording

<table>
<thead>
<tr>
<th>HCPCS® CODES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9276</td>
<td>Sensor; Invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply</td>
</tr>
<tr>
<td>A9277</td>
<td>Transmitter; external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td>A9278</td>
<td>Receiver (Monitor); external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td>S1030</td>
<td>Continuous non invasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)</td>
</tr>
<tr>
<td>S1031</td>
<td>Continuous non invasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)</td>
</tr>
</tbody>
</table>


**HCPCS Codes for Commercial LOB Only (List may not be all inclusive)**

<table>
<thead>
<tr>
<th>HCPCS® CODES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9276</td>
<td>Sensor; Invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply</td>
</tr>
<tr>
<td>A9277</td>
<td>Transmitter; external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td>A9278</td>
<td>Receiver (Monitor); external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td>S1030</td>
<td>Continuous non invasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)</td>
</tr>
<tr>
<td>S1031</td>
<td>Continuous non invasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)</td>
</tr>
</tbody>
</table>


**ICD-9 CM® Diagnosis Codes (List may not be all inclusive)**

<table>
<thead>
<tr>
<th>ICD-9 CM® CODES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>250.01</td>
<td>Diabetes Mellitus without mention of complications, type I (Juvenile Type), not stated as uncontrolled</td>
</tr>
<tr>
<td>250.02</td>
<td>Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Uncontrolled</td>
</tr>
<tr>
<td>250.03</td>
<td>Diabetes Mellitus without mentions of complications, type I (Juvenile Type), uncontrolled</td>
</tr>
<tr>
<td>250.11</td>
<td>Diabetes with Ketoacidosis, type I (Juvenile Type), not stated as uncontrolled</td>
</tr>
<tr>
<td>250.13</td>
<td>Diabetes with Ketoacidosis, type I (Juvenile type), uncontrolled</td>
</tr>
<tr>
<td>250.21</td>
<td>Diabetes with Hyperosmolarity, type I (Juvenile type), Not stated as uncontrolled</td>
</tr>
<tr>
<td>250.23</td>
<td>Diabetes with Hyperosmolarity, type I (Juvenile type), uncontrolled</td>
</tr>
<tr>
<td>250.31</td>
<td>Diabetes with other Coma, Type I (Juvenile type), not stated as uncontrolled</td>
</tr>
<tr>
<td>250.33</td>
<td>Diabetes with other Coma, Type I, (Juvenile type), uncontrolled</td>
</tr>
<tr>
<td>250.41</td>
<td>Diabetes with renal manifestations, Type I (Juvenile Type), not stated uncontrolled</td>
</tr>
<tr>
<td>250.43</td>
<td>Diabetes with renal manifestations, type I (Juvenile type), uncontrolled</td>
</tr>
<tr>
<td>250.51</td>
<td>Diabetes with Ophthalmic manifestations, type I (Juvenile type), not stated as uncontrolled</td>
</tr>
<tr>
<td>250.53</td>
<td>Diabetes with Ophthalmic manifestations, type I (Juvenile type), uncontrolled</td>
</tr>
<tr>
<td>250.61</td>
<td>Diabetes with neurological manifestations, type I (Juvenile Type), not stated as uncontrolled</td>
</tr>
<tr>
<td>250.63</td>
<td>Diabetes with neurological manifestations, type I (Juvenile type), Uncontrolled</td>
</tr>
<tr>
<td>250.73</td>
<td>Diabetes with peripheral circulatory disorders, type I (Juvenile type), uncontrolled</td>
</tr>
</tbody>
</table>
### REFERENCES


---

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>250.81</td>
<td>Diabetes with other specified manifestations, type I (Juvenile Type), not stated as uncontrolled</td>
</tr>
<tr>
<td>250.82</td>
<td>Diabetes With Other Specified Manifestations, Type II or Unspecified Type, Uncontrolled</td>
</tr>
<tr>
<td>250.83</td>
<td>Diabetes with other specified manifestations, type I (Juvenile type ), uncontrolled</td>
</tr>
<tr>
<td>250.91</td>
<td>Diabetes with unspecified complication, type I (Juvenile type), not stated as uncontrolled</td>
</tr>
<tr>
<td>251.1</td>
<td>Other Specified Hypoglycemia</td>
</tr>
<tr>
<td>648.80</td>
<td>Abnormal Glucose Tolerance, Unspecified as to Episode of Care or Not Applicable</td>
</tr>
<tr>
<td>648.81</td>
<td>Abnormal Glucose Tolerance, Delivered, With or Without Mention of Antepartum Condition</td>
</tr>
<tr>
<td>648.82</td>
<td>Abnormal Glucose Tolerance, Delivered, With Mention of Postpartum Complication</td>
</tr>
<tr>
<td>648.83</td>
<td>Abnormal Glucose Tolerance, Antepartum Condition or Complication</td>
</tr>
<tr>
<td>648.84</td>
<td>Abnormal Glucose Tolerance, Postpartum Condition or Complication</td>
</tr>
<tr>
<td>V45.85</td>
<td>Insulin Pump Status</td>
</tr>
</tbody>
</table>

*2013 ICD-9-CM® For Physicians, VOLUMES I & II, Professional Edition (American Medical Association).*


17. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) for Glucose Monitors (L11520). Contractor Name: CGS Administrators, LLC. Original Determination Effective Date: For services performed on or after 10/01/1993. Revision Effective Date: For services performed on or after 08/01/2013. Accessed December 10, 2013. Available at URL address: http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11520&ContrId=140&ver=48&ContrVer=2&CntrctrSelected=140*2&Cntrctr=140&name=CGS+Administrators%2c+LLC+(18003%2c+DME+MAC)&s=46&DocType=Active&bc=AggAAAAIAAAAAA%3d%3d&


http://www.ncbi.nlm.nih.gov/books/NBK16671/

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2769770/

http://www.integrateddiabetes.com/Articles/hcare/cgm%20chapter.pdf

http://jcem.endojournals.org/content/96/10/2968.full.pdf+html

http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050020c.pdf


Accessed December 10, 2013. Available at URL address:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078281.htm

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm074293.htm

http://www.fda.gov/medicaldevices/safety/listofrecalls/ucm360618.htm

http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/recently-approveddevices/ucm372176.htm

56. U.S. Food & Drug Administration (FDA). Medtronic’s Urgent Medical Device Safety Notification. Potential for Over or Under Delivery of Insulin if Insulin or Other Fluids Contact the Inside of Medtronic Paradigm Infusion Set Connectors. Published: June 10, 2013. Accessed December 10, 2013. Available at URL address:


http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=25075


**POLICY HISTORY**

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 4, 2013</td>
<td>Origination of Policy</td>
<td>This medical policy was reviewed, approved and made effective by the MCS Medical Advisory Committee on December 10, 2013.</td>
</tr>
</tbody>
</table>
\[\text{Nocturnal Hypoglycemia} = \text{occurs during sleep and is particularly dangerous because patients are unlikely to recognize symptoms or awaken during an episode} (\text{Brunton, 2007}).\]

\[\text{Dawn Phenomenon} = \text{term used to describe hyperglycemia or an increase in the amount of insulin needed to maintain normoglycemia, occurring in the absence of antecedent hypoglycemia or waning insulin levels, during the early morning hours} (\text{Carroll & Schade, 2005}).\]

\[\text{Postprandial Hyperglycemia} = \text{after-meal hyperglycemia, which is defined as a blood sugar usually greater than 180 mg/dL. In patients without diabetes, postprandial or post-meal sugars rarely go over 140 mg/dL} (\text{WebMD, 2013}).\]