

Continuous Glucose Monitoring Systems and Insulin Pumps



Medical Coverage Policy

Original Effective Date: 08/23/2007

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Change Summary: Updated Coverage Determination

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Disclaimer

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Description

Continuous Glucose Monitoring Systems

Continuous glucose monitoring systems (CGMS) are devices that measure glucose levels in interstitial fluid at programmable intervals. These readings, used along with fingerstick results, help detect any patterns or trends with a patient's glucose levels and are intended to assist in calculating the insulin dosage needed to manage glycemic control. CGMS readings are intended to supplement, not replace, fingersticks.¹

CGMS use sensors that are inserted under the skin in the abdomen and work by extracting glucose from the interstitial fluid, measure and record the glucose level and convert these measurements into equivalent blood glucose readings. Sensors are designed to be worn three to seven days, depending on the product. Calibration is required whenever a new glucose sensor is inserted, which requires obtaining blood glucose from a traditional fingerstick sample.

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Examples of Food and Drug Administration (FDA) approved invasive CGMS include, but may not be limited to:

Diagnostic/Short term CGMS:

- **Minimed[®] Continuous Subcutaneous Glucose Monitoring System:** CGMS that uses a recorder and glucose sensor to store data to be downloaded to a personal computer. The system provides continuous measurements of the interstitial glucose levels that range from 40 to 400 mg/dl. The glucose sensor signal is acquired every ten seconds. An average of the acquired signals is saved in memory every five minutes. The system is used as a diagnostic tool to evaluate and potentially modify diabetes treatment regimens and is intended for occasional rather than every day use.

Personal/Long-Term CGMS:

- **DexCom[™] STS[™]:** CGMS that incorporates a sensor, transmitter and receiver and allows glucose to be monitored every five minutes. The sensor reports glucose for three days before a new sensor replacement is necessary. A built in alarm system can be programmed by the user when glucose falls below a pre-set low and a pre-set high level.
- **DexCom[™] STS-7[™]:** CGMS that mirrors the Dexcom STS, with the exception that the sensor reports glucose for seven days before replacement is necessary.
- **FreeStyle Navigator[®]:** CGMS that uses a sensor, transmitter and a receiver. The sensor can be worn for up to five days, then is disposed of and replaced. Glucose levels are continuously measured once per minute to a pager-sized receiver. Early warning alarms can indicate high/low glucose 10, 20 or 30 minutes in advance. Glucose information can be stored for up to 60 days for the user or a health care provider to analyze.
- **Guardian[®] REAL-Time Continuous Glucose Monitoring System:** CGMS device that uses a glucose sensor connected to a transmitter that sends glucose readings every five minutes to a monitor. The glucose sensor is typically discarded and replaced after three days. Unique features include predictive and rate of change alarms and expanded trend graphs. Graphs

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can show the effect of exercise, diet, lifestyle as well as medication on glucose values using three, six, 12 and 24 hour increments. Alarms that signal high and low glucose alerts warn patients of any significant glucose changes. Data is downloaded using the Medtronic Carelink[®] Therapy Management Software.

Insulin Pumps

Insulin pumps are devices used to deliver insulin in a programmed and controlled manner to diabetic patients. The goals of insulin pump therapy are to achieve near-normal control of blood glucose levels. Insulin pumps are categorized as follows:

- **Combined External Insulin Pumps with CGMS**

Also referred to as an open loop monitoring device. These systems combine continuous blood glucose sensing and insulin delivery and are not intended to replace finger sticks. Examples of FDA approved combined external insulin pumps with CGMS include, but may not be limited to:

- **MiniMed Paradigm[®] REAL-Time Revel[™] System:** Second generation device that integrates an insulin pump with real-time continuous glucose monitoring. It is the only FDA-approved integrated system: insulin pump, continuous glucose monitoring (CGM) and therapy management software. The system incorporates new CGM features including predictive alerts that give early warnings so action can be taken to prevent dangerous high or low glucose events.
- **External insulin pumps:** Deliver insulin via subcutaneous or intraperitoneal routes.
 - **Disposable external insulin pumps (e.g., OmniPod Management System):** Consolidates the pump, tubing and subcutaneous needle into one compact unit. The unit is worn up to three days before requiring replacement.
- **Implantable insulin pumps:** Deliver insulin via intraperitoneal or intravenous routes. **(See Coverage Limitations Section)**

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Coverage Determination

Humana members **MAY** be eligible for FDA approved **diagnostic/short term CGMS (Minimed[®])** for persons with type 1 or type 2 diabetes with an insulin requirement on a **periodic** basis when **ALL** the following are met:

- Inadequate glycemic control as noted with frequent self-monitoring and recurring episodes of severe hypoglycemia (<50 mg/dl) and fasting hyperglycemia (>150 mg/dl); **AND**
- Monitoring sessions must be between three consecutive days (72 hours) to one week: **AND**
- No more than two monitoring sessions within a twelve month period.

Humana members **MAY** be eligible for **personal/long-term use of CGMS** as an adjunct to fingerstick testing of blood glucose in persons with type 1 diabetes who have had:

- Inadequate glycemic control (**despite compliance**) as noted with frequent self-monitoring (at least four fingersticks per day); **OR**
- Recurrent episodes of severe hypoglycemia (blood glucose less than 50mg/dl) despite appropriate modifications in insulin regimen; **OR**
- Hypoglycemic unawareness.

Humana members may be eligible under the Plan for the use of a **CGMS (sensor/transmitter) with wireless communication to a compatible external insulin pump (e.g., Paradigm[®] REAL-Time Revel[™] System)** for the following indications:

- The criteria for an **external** insulin pump has been met as noted below; **AND**
- The criteria for a **long term** continuous glucose monitoring system has been met as noted above: **AND**

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- Member does **NOT** have existing devices that are fully functional and duplicate the same purpose that is served by a CGMS with wireless communication capability to an external insulin pump.

Humana members may be eligible under the Plan for the use of a FDA approved **external insulin pump (including the disposable Omni Pod Management System)** and related drugs/supplies as medically necessary for patients who meet **ALL** of the following criteria:

- The patient has completed a comprehensive diabetes education program within the past 12 months (If the request is for a replacement insulin pump and the member's contract allows for replacement, then the member must have completed a comprehensive diabetes education program prior to receiving the initial insulin pump. If the member has never completed a comprehensive diabetes education program, then the member must complete a comprehensive diabetes education program prior to receiving the replacement pump).; **AND**
- The patient has been on a program of multiple injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustment of insulin doses for at least 6 months prior to initiation of the insulin pump; **AND**
- The patient has documented frequency of glucose self-testing an average of at least 4 times a day during the 2 months prior to initiation of the insulin pump; **AND**
- The patient meets at least one of the following criteria while on multiple daily injections of insulin:
 - Glycosylated hemoglobin level (HbA1c) >7.0; **OR**
 - History of recurring hypoglycemia; **OR**
 - Wide fluctuations in blood glucose before mealtime; **OR**
 - History of severe glycemic excursions; **OR**
 - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl.

Note: This criteria for **external** insulin pumps is **NOT** consistent with the Medicare National Coverage Policy, and therefore may not be applicable to Medicare members. Refer to the CMS web site at <http://www.cms.hhs.gov> for additional information.

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Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **CGMS or external insulin pumps (including the disposable Omni Pod Management System)** for any other indications other than those listed above.

Humana members may **NOT** be eligible under the Plan for **implantable insulin pumps**.

Humana members may **NOT** be eligible under the Plan for a **CGMS (sensor/transmitter) with wireless communication to a compatible external insulin pump (e.g., Paradigm[®] REAL-Time Revel[™] System)** for the following:

- Any indications not listed above; **OR**
- Member has existing devices that are fully functional and duplicate the same purpose that is served by a CGMS with wireless communication capability to an external insulin pump.

This technology is considered experimental/investigational or **NOT** medically necessary if it is not utilized in accordance with nationally recognized standards of medical practice and/or identified as safe, widely used and generally accepted as effective for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

For requests including repairs and maintenance, add-ons/upgrades, duplicative or replacement equipment for CGMS or insulin pumps: [See Durable Medical Equipment \(DME\)](#).

Note: This criteria for **implantable** insulin pumps is consistent with the Medicare National Coverage Policy, and therefore may be applicable to Medicare members. Refer to the CMS web site at <http://www.cms.hhs.gov> for additional information.

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Background

Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar, starches and other food into energy needed for daily life. The cause of diabetes continues to be a mystery, although both genetics and environmental factors such as obesity and lack of exercise appear to play roles.

The major types of diabetes are:

- Type 1 Diabetes: Results from the body's failure to produce insulin, the hormone that "unlocks" the cells of the body, allowing glucose to enter and fuel them. It is estimated that five to ten percent of Americans who are diagnosed with diabetes have type 1 diabetes.
- Type 2 Diabetes: Results from insulin resistance (a condition in which the body fails to properly use insulin), combined with relative insulin deficiency. Most Americans who are diagnosed with diabetes have type 2 diabetes.
- Gestational Diabetes: A form of glucose intolerance diagnosed during pregnancy. Immediately after pregnancy, five to ten percent of women with gestational diabetes are found to have diabetes, usually, type 2.

There are 23.6 million people in the United States, or 8% of the population, who have diabetes. While an estimated 17.9 million have been diagnosed with diabetes, unfortunately, 5.7 million people (or nearly one quarter) are unaware that they have the disease.²

Medical Alternatives

Alternatives to **CGMS** include, but may not be limited to:

- Self monitoring glucose with fingerstick testing.

Alternatives to **insulin pumps** include, but may not be limited to:

- Multiple daily insulin injections.

To make the best health decision for your individual needs, consult your physician.

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Humana may offer a disease management program for this disease. **Call the number on your member identification card to ask about our programs to help you manage your care.**

Provider Claims Codes

All provider claims codes surrounding this topic may not be included in the following table:

| CPT© Codes | Description | Comments |
|--------------|--|--|
| 49324 | Laparoscopy, surgical; with insertion of intraperitoneal cannula or catheter, permanent | |
| 49325 | Laparoscopy, surgical; with revision of previously placed intraperitoneal cannula or catheter, with removal of intraluminal obstructive material if performed | |
| 49419 | Insertion of intraperitoneal cannula or catheter, with subcutaneous reservoir, permanent (i.e., totally implantable) | Not Covered for Implantable Insulin Pumps |
| 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 | |
| 95251 | Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report | |
| | | |
| HCPCS© Codes | Description | Comments |
| A4230 | Infusion set for external insulin pump, nonneedle cannula type | |
| A4231 | Infusion set for external insulin pump, needle type | |
| A4232 | Syringe with needle for external insulin pump, sterile, 3cc | |
| A9274 | External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories | |

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| | | |
|-------|--|--|
| 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 | |
| A9279 | Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified | |
| E0782 | Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc) | Not Covered for Implantable Insulin Pumps |
| E0783 | Infusion pump, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.) | Not Covered for Implantable Insulin Pumps |
| E0784 | External ambulatory infusion pump, insulin | |
| E1340 | Repair or nonroutine service for durable medical equipment requiring the skill of a technician, labor component, per 15 minutes | Not Covered Code Deleted 12/31/2009 |
| G0108 | Diabetes outpatient self-management training services, individual, per 30 minutes | |
| G0109 | Diabetes self-management training service, group session (2 or more), per 30 minutes | |
| J1817 | Insulin for administration through DME (i.e., insulin pump) per 50 units | |
| K0601 | Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each | |
| K0602 | Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each | |
| K0603 | Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each | |

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| | | |
|---------------------------------------|--|-----------------|
| K0604 | Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each | |
| K0605 | Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each | |
| 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) | |
| S9145 | Insulin pump initiation, instruction in initial use of pump (pump not included) | |
| S9353 | Home infusion therapy, continuous insulin infusion therapy; administrative service, professional pharmacy service, care coordination, and all necessary supplies and equipment (drugs and nursing visits codes separately), per diem | |
| | | |
| ICD-9© Procedure Codes | Description | Comments |
| | No specific code identified | |

Medical Terms

Adjunct - Addition to the principal procedure or course of therapy.

Calibration - Process of adjusting an instrument so that its reading can be correlated to the actual value being measured.

Compliance - Adherence to a drug regimen as in taking medications correctly and on time.

Continuous - Continuing in time without interruption.

Dawn Phenomenon - Refers to the early-morning (4 am to 8 am) rise in blood glucose levels.

Equivalent - Two or more expressions that have the same value.

Fingerstick - Blood tests that are conducted on venous blood obtained by fingerprick.

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Genetics - Study of genes and heredity.

Glucose - Simple sugar found in the blood. It is the body's main source of energy; also known as dextrose.

Glycemic Control - Medical term referring to the typical levels of blood sugar (glucose) in a person with diabetes mellitus. Good glycemic control, in the sense of a "target" for treatment, has become an important goal of diabetes care.

Glycemic Excursions - Fluctuation in which a person's blood glucose levels go up and down during the course of a day.

Glycosylated Hemoglobin Level - A molecule in red blood cells that attaches to glucose (blood sugar). You have more glycosylated hemoglobin if you have more glucose in your blood.

Hyperglycemia - Abnormally high level of glucose in the blood.

Hypoglycemia - Low levels of glucose in blood.

Insulin - Hormone released by the pancreas in response to increased levels of sugar in the blood.

Interstitial Fluid - Liquid found between the cells of the body that provides much of the liquid environment of the body.

Intraperitoneal - Within or administered through the peritoneum. The peritoneum is a thin, transparent membrane that lines the walls of the abdominal (peritoneal) cavity and contains/encloses the abdominal organs such as the stomach and intestines.

Invasive - Medical procedure which penetrates or breaks the skin or body cavity.

Periodic - Recurring or reappearing from time to time.

Real Time - The process of producing information without any latency.

Serum - Watery fluid from animal tissue, such as that found in edema.

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Subcutaneous - Refers to administration by injection under the skin.

Type1 Diabetes - Previously known as "insulin-dependent diabetes mellitus," (IDDM) or "juvenile diabetes." Type 1 diabetes is a life-long condition in which the pancreas stops making insulin.

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¹ Hayes, Winifred S. Directory. Continuous glucose monitoring systems. June 23, 2009.

² American Diabetes Association Website. All about diabetes. Available at: <http://www.diabetes.org>. Accessed August 13, 2009.