MEDICAL POLICY

Excellus

SUBJECT: CONTINUOUS GLUCOSE MONITORING SYSTEMS	EFFECTIVE DATE: 07/20/00 REVISED DATE: 07/02/01, 06/20/02, 07/24/03, 10/23/03, 05/27/04, 06/23/05, 06/22/06, 08/23/07, 12/11/08, 12/10/09, 10/28/10, 12/09/10, 02/27/12, 08/22/13
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- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of **continuous** use of the Continuous Glucose Monitoring System (CGMS) devices (e.g., MiniMed Guardian® Real-Time, MiniMed Paradigm® Real-Time system) has been medically proven to be effective and therefore **medically appropriate** for patients who are 7 years or older and are currently using an external insulin pump and for the following indications:
   A. when their diabetes is poorly controlled as evidenced by unexplained severe hypoglycemic episodes defined as an episode of low blood sugar resulting in a profound degree of cognitive dysfunction (e.g., stupor, seizure or unconsciousness) which requires external assistance for recovery; and
   B. The patient is participating in or has completed a comprehensive diabetic education program; and
   C. There is documented self-monitoring of blood glucose at least 4 times per day by the patient; and
   D. The patient is compliant with recommended medical regimens; and
   E. The patient must have used an external insulin pump for 6 months.

II. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of **continuous** use of the Continuous Glucose Monitoring System (CGMS) devices (e.g., MiniMed Guardian® Real-Time, MiniMed Paradigm® Real-Time system) has been medically proven to be effective and therefore **medically appropriate** for women with type I diabetes who are pregnant or about to become pregnant who cannot meet recommended targets for control of diabetes in pregnancy and when:
   A. The patient is participating in or has completed a comprehensive diabetic education program; and
   B. There is documented self-monitoring of blood glucose at least 4 times per day by the patient; and
   C. The patient is compliant with recommended medical regimens.

III. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of **intermittent** use of the Continuous Glucose Monitoring System (CGMS) devices (e.g., MiniMed CGMS® System Gold™ or MiniMed iPro™ CGM), has been medically proven to be effective and therefore **medically appropriate** for the following indications:
   A. Patients whose diabetes is poorly controlled despite current evidence of best practices as indicated by the following clinical situations:
      1. unexplained hypoglycemic episodes for whom hypoglycemia puts the patients or others at risk; or
      2. hypoglycemic unawareness; or
      3. unexplained large fluctuations in the daily preprandial blood glucose levels; or
      4. recurrent ketoacidosis;

   OR

   B. Women with type I diabetes who are pregnant or about to become pregnant who cannot meet recommended targets for control of diabetes in pregnancy.

   AND

   C. The patient is participating in or has completed a comprehensive diabetic education program; and
   D. There is documented self-monitoring of blood glucose at least 4 times per day by the patient; and
   E. The patient is compliant with recommended medical regimens.

IV. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of **continuous** use of the Continuous Glucose Monitoring System (CGMS) devices (e.g., MiniMed Guardian® Real-Time, MiniMed Paradigm® Real-Time system) has not been shown to provide a benefit to patients younger than 7 years and is considered **investigational** *(Refer to Rationale Section)*.

V. For *New York State Managed Medicaid members*, continuous glucose monitors (A9276-A9278) are considered to have no long term positive medical outcome associated with their use and therefore, are non-covered under the DME benefit.

VI. Other uses of continuous monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique of diabetic monitoring, is considered **investigational**.

VII. Replacement of a CGMS is considered **medically necessary** when:
- A. The transmitter is out of warranty; and
- B. The transmitter is malfunctioning; and
- C. There is documented evidence the member is compliant with their current CGMS device. Compliance is defined as at least 70% use rate of the device (e.g., 5 out of 7 days) based on the log data, and
- D. There is documented evidence of improvement in control of the disease.

VIII. Continuation of sensor use after one year is considered **medically necessary** when:
- A. The CGMS has been previously approved by the Health Plan or the CGMS is in use prior to the user enrolling in the Health Plan; and
- B. There is documented evidence the member is compliant with their current CGMS device. Compliance is defined as at least 70% use rate of the device (e.g., 5out of 7 days) based on the log data, and
- C. There is documented evidence of improvement in control of the disease.

POLICY GUIDELINES:

I. Replacement of purchased equipment which is damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

II. Intermittent monitoring is generally conducted in 72 hours intervals. It may be repeated at a subsequent time depending on the patients level of diabetic control.

Refer to Corporate Medical Policy#1.01.00 regarding Durable Medical Equipment (DME) – Standard and Non-Standard.

Refer to Corporate Medical Policy #10.01.04 regarding External Insulin Pumps for Diabetes.

DESCRIPTION:

Current best practices for treatment of diabetes may include multiple (4 or more) daily checks of blood glucose and multiple (3 or more) insulin injections or use of an insulin pump. Sometimes despite use of best practices diabetes may remain poorly controlled which may result in adverse events. Some patients are able to recognize symptoms of hypoglycemia, but many are unaware of their lowered blood sugar which can lead to a severe hypoglycemic episode.

CGMS devices are used by diabetic patients to supplement, not replace, blood glucose information obtained using standard fingerstick glucose meters and test strips. These devices automatically measure, track interstitial glucose, and produce trends in glucose measurements throughout the day which may allow for tighter glucose control and a subsequent decrease in complications from diabetes. The CGMS device consists of a sensor, transmitter and receiver. The sensors are usually changed every 3-7 days. The warranty for the transmitters range from 6 months to 1 year depending on the type of pump. Examples of FDA approved CGMS devices include but is not limited to the MiniMed CGMS® System Gold™ device, MiniMed Guardian® Real-Time CGMS device, MiniMed Paradigm® Real-Time system, DexCom STS-7 System, and the FreeStyle Navigator™. The MiniMed Paradigm® Real-Time system and

MiniMed Guardian® Real-Time CGMS device are recommended for adults, age 18 years and over, children and adolescents with diabetes, age 7 to 17 years. The DexCom STS-7 System and FreeStyle Navigator™ are not recommended for children under 18 years.

RATIONALE:

A 2008 study funded by the Juvenile Diabetes Research Foundation enrolled 322 children, teenagers, and adults with Type 1 diabetes, randomly assigned half the participants to use CGM devices. At the end of six months, the adults (ages 25 to 72 years old) who were assigned to use continuous glucose monitors had a reduction of about half a percentage point in their HbA1c levels compared to the control group, which saw a slight increase in HbA1c levels. This improvement was achieved without a difference in hypoglycemia, or low blood glucose levels, between the two groups. Statistically significant reductions in HbA1c were not seen in the two groups of younger people (ages 8 to 14 years old and 15 to 24 years old) who participated in the study. However, the people in these age groups used their CGM devices only 50% of the time or less. The adult group, which did see a drop in HbA1c levels, used the device more than 85% of the time. In all age groups, people who used the CGM device at least six days a week lowered their HbA1c levels. The researchers concluded that continuous glucose monitoring improves HbA1c levels and may enhance the management of Type 1 diabetes in adults who have the motivation to use this technology and the capability to incorporate it into their own daily diabetes management.

Raccah et al., performed a randomized two arm open-label study of 115 patients who used an insulin pump with CGMS or without. The authors observed improvement in A1c, a decrease in mean glucose concentration, and less glycemic variation in both groups, especially in the insulin pump + sensor group when the sensor was worn at least 70% of the time. The authors support use of insulin pumps capable of incorporating CGMS for improvement in glycemic control in previously poorly-controlled diabetes. However the compliance rate of the CGMS must be at least 70% to realize the greatest improvement. Kamble et al., compared the cost-effectiveness of using either an insulin pump with CGMS (Sensor Augmented Pump therapy -SAPT) or multiple daily injections (MDI) and self-monitoring blood glucose (SMBG) in patients that were part of the Sensor-Augmented Pump therapy for A1c Reduction (STAR 3) trial. The costs were the same for both groups for glucose meters, test strips, lancets, insulin and provider time but the costs associated with the insulin pump and CGMS also included the insulin pumps, transmitters sensors, insertion devices and other pump supplies. The authors found that the HbA1c values decreased more (0.6 % points) in the SAPT group when used at least 65% of the time but hospital admission, hospital inpatient days, and ED visits were similar for both groups. The SAPT group utilized more provider time, possibly related to device use. The lifetime estimate of direct medical costs was $253,493 for the SAPT group and $167,170 for the MDI group. The SAPT group had an assigned QALY of 10.794 while the MDI group's QALY was 10.418. The fear of hypoglycemia was less for the SAPT group which had an effect on the ICERS and showed a reduction. The authors concluded SAPT reduces HbA1c but when considering cost associated with SAPT compared to MDI, SAPT is not economically attractive in a number of situations. Differences in fear of hypoglycemia impacts cost effective ratios. The authors note that participants in the trials are highly motivated and received a high level of care which may bias results.

Continuous glucose monitors (CGMs) provide continuous "real-time" readings and data about trends in glucose levels. This can allow people with diabetes to understand the level of their glucose, maintain tighter control of their glucose levels which can lead to improved diabetes management and decrease risk of complications from diabetes.

The American Diabetes Association Standards in Medical Practice (2011) states that "continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age greater than 25 years) with type 1 diabetes. (Level of evidence: A). 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. (Level of evidence: C).

The Endocrine Society Clinical Practice Guideline (2011) recommend CGM be used by children and adolescents with T1DM who have achieved HbA1c levels below 7.0% because it will assist in maintaining target HbA1c levels while limiting the risk of hypoglycemia. CGM are also recommended to be used with children and adolescents with T1DM

who have HbA1c levels less than 7.0% who are able to use these devices on a nearly daily basis. No recommendations were made for or against the use of CGM by children withT1DM who are less than 8 years of age.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
	95251	physician interpretation and report

HCPCS:	S1030	Continuous noninvasive glucose monitoring device, purchase
	S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor
	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
ICD9:	250-250.92	Diabetes mellitus (code range)
	648-648.84	Gestational diabetes (code range)
	775.1	Neonatal diabetes mellitus
	790.2	Nonclinical diabetes
	790.6	Hyperglycemia NOS
ICD10:	E10.10-E10.9	Type 1 diabetes mellitus (code range)
	E11.00-E11.9	Type 2 diabetes mellitus (code range)
	E13.00-E13.9	Other specified diabetes mellitus (code range)
	E79.0	Hyperuricemia without signs of inflammatory arthritis and tophaceous disease
	O24.410-O24.439	Gestational diabetes mellitus (code range)
	O99.810-O99.815	Abnormal glucose complicating pregnancy, childbirth and the puerperium (code range)
	P70.2	Neonatal diabetes mellitus
	R73.01-R73.9	Elevated blood glucose level (code range)

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KEY WORDS:

CGMS, Continuous glucose monitor, DexCom STS, Freestyle Navigator, Interstitial glucose monitoring, MiniMed CGMS® System Gold™, MiniMed Guardian® Real-Time, MiniMed Paradigm® Real-Time system, Wrist glucose monitor.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Glucose Monitors. Please refer to the following LCD website for Medicare Members:
http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L11530_2012-11-01_rev_2012-12_PA_2011-07.pdf

There is currently a Local Coverage Article for Glucose Monitors (A33614). Please refer to the following LCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=33614&ver=24&ContrId=137&ContrVer=1&CntrctrSelected=137*1&Date=01%2f01%2f2011&DocID=A33614+&bc=hAAAAAgAQAAA&