MEDICAL POLICY

SUBJECT: CONTINUOUS GLUCOSE MONITORING SYSTEMS

POLICY NUMBER: 1.01.30
CATEGORY: Equipment/Supplies

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, 10/23/14, 10/28/15 12/8/16

PAGE: 1 OF 8

• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.
• If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.
• If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT:

I. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of continuous use of Continuous Glucose Monitoring System (CGMS) devices (e.g., MiniMed Guardian® Real-Time, MiniMed Paradigm Revel® Real-Time system, DexCom G5® (DexCom, Inc), FreeStyle Navigator® Continuous Glucose Monitoring System (Abbott)) has been medically proven to be effective and therefore medically appropriate for patients with Type 1 diabetes who are 7 years or older and are currently using an external insulin pump and meet all of the following indications:

A. Their diabetes is poorly controlled as evidenced by recurrent, unexplained severe hypoglycemic episodes defined as blood glucose levels less than 50 mg/dL that puts the patient or others at risk; or hypoglycemic unawareness; 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 3 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), DexCom G5® (DexCom, Inc), has been medically proven to be effective and therefore medically appropriate for patients with Type 1 diabetes who are 2 years or older and are currently using an external insulin pump and meet all of the criteria in Policy Statement I.

III. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of continuous use of Continuous Glucose Monitoring System (CGMS) devices 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 and who cannot meet recommended targets for control of diabetes in pregnancy 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.

IV. Based upon our criteria and review of the peer-reviewed literature, the artificial pancreas system, which consists of sensor-augmented insulin pump therapy with the low glucose threshold suspend feature (e.g. Minimed® 530G system or 630G with SmartGuard™, Medtronic, Inc) and a continuous glucose monitor (e.g., Enlite®, Medtronic, Inc), is considered medically necessary for individuals 16 years and older when the criteria for both the external insulin pump and continuous glucose monitor has been met.

V. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of intermittent use of 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

Proprietary Information of Excellus Health Plan, Inc.
A nonprofit independent licensee of the BlueCross BlueShield Association
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 and 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.

VI. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of continuous use of Continuous Glucose Monitoring System (CGMS) devices has not been shown to provide a benefit to patients younger than 7 years and is considered investigational (Refer to Description Section).

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

VIII. 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.

IX. 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., 5 out 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 patient’s 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 warranties for the transmitters range from 6 months to 1 year
depending on the type of device. Examples of FDA approved CGMS devices include but are not limited to the
MiniMed CGMS® System Gold™ device, MiniMed Guardian® Real-Time CGMS device, MiniMed Paradigm Revel®
system and MiniMed Guardian® Real-Time CGMS device are recommended for adults, age 18 years and over and,
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. The Dexcom G5® Mobile is the only CGM approved for adults and pediatric
patients two years of age and older.

New York State Law mandates coverage for continuous glucose monitoring systems under health care contracts that
provide major medical or similar comprehensive-type coverage for the treatment of diabetes, if recommended or
prescribed by a physician or other licensed health care provider legally authorized to prescribe such devices under the
New York State Education Law.

RATIONAL:
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 with T1DM who are less than 8 years of age.

The National Institute for Health and Care Excellence (NICE) guidelines on diagnosis and management of type 1 diabetes in adults (2015) state the following:

Do not offer real-time continuous glucose monitoring routinely to adults with type 1 diabetes. Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:

- Complete loss of awareness of hypoglycaemia.
- More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
- Extreme fear of hypoglycaemia.
- Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day.

Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.

The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Outpatient Glucose Monitoring Consensus Statement states that glucose monitoring is an essential component of care in all patients with diabetes. Blood glucose monitors (BGM) and CGMS are intended to empower patients to manage glucose levels and reduce the risk of hypoglycemia. Clinical practice guidelines from all major diabetes organizations recommend routine BGM for patients with Type 1 diabetes. Most of the guidelines recommend CGMS for patients with a history of severe hypoglycemia, or hypoglycemia unawareness as well as, for patients not at goal based on A1c. Many pediatric patients with diabetes are candidates for CGMS, especially if they or their family caregivers have the appropriate training to use the information effectively. There have been some studies of CGMS in Type 2 diabetes, but more studies are needed to identify the setting in which it can be more beneficial and cost-effective.

**CODES:**

<table>
<thead>
<tr>
<th>Number</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>
**SUBJECT:** CONTINUOUS GLUCOSE MONITORING SYSTEMS

**POLICY NUMBER:** 1.01.30

**CATEGORY:** Equipment/Supplies

**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, 10/23/14, 10/28/15

<table>
<thead>
<tr>
<th>HCPCS</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, 1 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 noninvasive glucose monitoring device, purchase</td>
</tr>
<tr>
<td>S1031</td>
<td>Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor</td>
</tr>
<tr>
<td>S1034</td>
<td>Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices</td>
</tr>
<tr>
<td>S1035</td>
<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system</td>
</tr>
<tr>
<td>S1036</td>
<td>Transmitter; external, for use with artificial pancreas device system</td>
</tr>
<tr>
<td>S1037</td>
<td>Receiver (monitor); external, for use with artificial pancreas device system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD9</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>250-250.92</td>
<td>Diabetes mellitus (code range)</td>
</tr>
<tr>
<td>648-648.84</td>
<td>Gestational diabetes (code range)</td>
</tr>
<tr>
<td>775.1</td>
<td>Neonatal diabetes mellitus</td>
</tr>
<tr>
<td>790.2</td>
<td>Nonclinical diabetes</td>
</tr>
<tr>
<td>790.6</td>
<td>Hyperglycemia NOS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD10</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E10.10-E10.9</td>
<td>Type 1 diabetes mellitus (code range)</td>
</tr>
<tr>
<td>E11.00-E11.9</td>
<td>Type 2 diabetes mellitus (code range)</td>
</tr>
<tr>
<td>E13.00-E13.9</td>
<td>Other specified diabetes mellitus (code range)</td>
</tr>
<tr>
<td>E79.0</td>
<td>Hyperuricemia without signs of inflammatory arthritis and tophaceous disease</td>
</tr>
<tr>
<td>O24.410-O24.439</td>
<td>Gestational diabetes mellitus (code range)</td>
</tr>
<tr>
<td>O99.810-O99.815</td>
<td>Abnormal glucose complicating pregnancy, childbirth and the puerperium (code range)</td>
</tr>
</tbody>
</table>

*Proprietary Information of Excellus Health Plan, Inc.*
Proprietary Information of Excellus Health Plan, Inc.
<table>
<thead>
<tr>
<th>Subject: Continuous Glucose Monitoring Systems</th>
<th>Effective Date: 07/20/00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number: 1.01.30</td>
<td>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, 10/23/14, 10/28/15</td>
</tr>
<tr>
<td>Category: Equipment/Supplies</td>
<td>Page: 7 of 8</td>
</tr>
</tbody>
</table>


New York State Consolidated Insurance Law. Article 43. S 4303.


**Key Words:**

There is currently a Local Coverage Article for Glucose Monitors (A52464). Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52464&ver=4&Contrctr=389&ContrVer=1&ContrctrSelected=389*1&DocStatus=Active&s=41&bc=AhAAAAIAAAAAA%3d%3d&

There is currently a Local Coverage Determination (LCD) for Glucose Monitors. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33822&ContrId=389&ver=6&ContrVer=1&ContrctrSelected=389*1&Contrctr=389&s=41&DocType=Active&bc=AggAAQAIAAAAA%3d%3d&