Class: Continuous Glucose Monitoring Devices
Line of Business: Non-Medicare
Effective date: November 16, 2016
Revision date: November 16, 2016

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutic Subcommittee.

Policy/Criteria:

1. Continuous glucose monitoring (CGM) devices are considered medically necessary for members with Type I Diabetes Mellitus, when all of the following are met:
   a. Must be prescribed by endocrinologist;
   b. Adhere to a multiple daily injections of insulin regimen (at least 3 injections per day) or an insulin pump regimen;
   c. Adhere to frequent glucose self-monitoring (at least 4 fingersticks per day);
   d. Members received diabetes education, training and support on CGM devices (e.g. sensor insertion, calibration, real-time data interpretation, etc.).
   e. Documented presence of any of the following conditions while on insulin therapy:
      i. Inadequate glycemic control, demonstrated by documented HbA1c >7% despite adherence with insulin therapy;
      ii. Recurrent episodes of diabetic ketoacidosis;
      iii. Recurrent episodes of hypoglycemia (blood glucose less than 50mg/dL);
      iv. Hypoglycemia unawareness: patient is not aware of symptom and requires assistance from another person to administer oral carbohydrate, glucagon or other resuscitative actions.
      v. Recurrent postprandial hyperglycemia;
      vi. Dawn phenomenon: frequent fasting blood glucose exceeding 200mg/dL;
      vii. Wide fluctuation in blood glucose before mealtime.

2. Short term use of continuous glucose monitoring (CGM) device is considered medically necessary for members with Type 2 Diabetes Mellitus, when all of the following are met:
   a. Must be prescribed by endocrinologist;
   b. Adhere to a multiple daily injections of insulin regimen (at least 3 injections per day) or an insulin pump regimen;
   c. Adhere to frequent glucose self-monitoring (at least 4 fingersticks per day);
d. Members received diabetes education, training and support on CGM devices (e.g. sensor insertion, calibration, real-time data interpretation, etc.).

e. Documented presence of any of the following conditions while on insulin therapy:
   i. Inadequate glycemic control, demonstrated by documented HbA1c >7% despite adherence with insulin therapy;
   ii. Recurrent episodes of diabetic ketoacidosis;
   iii. Recurrent episodes of hypoglycemia (blood glucose less than 50mg/dL);
   iv. Hypoglycemia unawareness: patient is not aware of symptom and requires assistance from another person to administer oral carbohydrate, glucagon or other resuscitative actions.
   v. Recurrent postprandial hyperglycemia;
   vi. Dawn phenomenon: frequent fasting blood glucose exceeding 200mg/dL;
   vii. Wide fluctuation in blood glucose before mealtime.

3. Request for gestational diabetes will be reviewed on a case-by-case basis.

4. Long term use of continuous glucose monitors should not be used for other investigational indications that lack established clinical benefits including, but not limited to: nesidioblastosis (primary islet cell hypertrophy) and for blood glucose monitoring in nondiabetic patients following gastric bypass.

Applicable Codes:

The Current Procedural Terminology (CPT) codes and/or Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive. Below codes are current as of October 2016, for more details, please refer to the Medicare Coverage Database.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>95250</td>
<td>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</td>
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<tr>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report</td>
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<tr>
<th>HCPCS Code</th>
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<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>
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<tr>
<td>A9277</td>
<td>Transmitter; external, for use with interstitial continuous glucose monitoring system</td>
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<tr>
<td>A9278</td>
<td>Receiver (monitor); external, for use with interstitial continuous glucose monitoring system</td>
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</table>
All components of the CGM require prior approval. The reasonable useful lifetime of the monitor and transmitter is two years. Request for replacement prior to this time will be reviewed on a case-by-case basis. The sensors are designed to be replaced every 5-7 days and will be covered at a standard maximum allowed quantity of four units per month. Requests for overutilization are reviewed on a case by case basis when medical necessity is justified and prescribed by the endocrinologist.

Clinical Justification:

Background:
- Managing optimal glycemic control while avoiding hypoglycemic and hyperglycemic excursions have been daily challenges for diabetic patients. Episodes of severe hypoglycemia and hyperglycemia can cause a tremendous, immediate impact mentally and physically.
- Maintenance of glycemic control near-normal limit has been shown to significantly decrease the development of long-term diabetic complications.
- CGM technology can provide guidance to treatment adjustments in order to optimize overall glycemic control by capturing continuous glucose fluctuation measurements that is not otherwise recorded by intermittent finger stick testing.

American Diabetes Association- Standards of Medical Care in Diabetes 2016
- When used properly, continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens is a useful tool to lower A1C in selected adults (aged ≥25 years) with type 1 diabetes.
- Real-time CGM measures interstitial glucose (which correlates well with plasma glucose) and includes sophisticated alarms for hypo- and hyperglycemic excursions, but the U.S. Food and Drug administration (FDA) has not approved these devices as a sole agent to monitor glucose. CGMs require calibration with SMBG, with the latter still required for making acute treatment decisions.
- A 26-week randomized trial of 322 patients with type 1 diabetes showed that adults aged ≥25 years using intensive insulin therapy and CGM experienced a 0.5% reduction in A1C (from ~7.6% to 7.1%), compared with those suing intensive insulin therapy with SMBG.
- A registry study of 17,317 participants confirmed that more frequent CGM use is associated with lower A1c, whereas another study showed that children with >70% sensor use missed fewer school days.
- A meta-analysis suggests that, compared with SMBG, CGM is associated with short-term A1C lowering of ~0.26%. 

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| S1030 | Continuous noninvasive glucose monitoring device, purchase |
| S1031 | Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor |
| A9279 | Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified |
• This technology may be particularly useful in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes, although studies have not shown consistent reductions in severe hypoglycemia.

**American Association of Clinical Endocrinologists and American College of Endocrinology-2016 Outpatient Glucose Monitoring Consensus Statement**

**Adult Patients with T1DM**

• People with T1DM experience much greater glycemic variability than those with T2DM. This variability is associated with a higher risk of hypoglycemic. GM has a role in the early detection of hypoglycemia prior to overt symptoms.

• These guidelines also recommend the use of CGM, particularly for patients with a history of severe hypoglycemia or hypoglycemia unawareness. Once again, the timing and frequency of monitoring must be individualized to meet specific patient needs.

**Pediatric Patients with T1DM**

• As in the case of BGM, CGM is only as beneficial as the patient’s desire and ability to use it. It is essential that all CGM users know the basic of sensor insertion, calibration, and real-time data interpretation. To maintain a high frequency of use, patients and their parents require in-depth training with reinforcement, including periodic follow-up with clinicians and diabetes educators.

• An international group of leading pediatric diabetologist issued a 2012 consensus statement regarding the use of CGM in children. They recommended that CGM be considered for regularly daily use in children and adolescents with T1DM who:
  o Are performing frequent BGM;
  o Have experienced severe hypoglycemic episodes;
  o Have hypoglycemic unawareness, especially in young children;
  o Have nocturnal hypoglycemia;
  o Have wide glucose excursions, regardless of A1C;
  o Having suboptimal glycemic control, with A1C exceeding the target range;
  o Have A1C levels <7% and wish to maintain target glycemic control while limiting hypoglycemia risk.

• Accordingly, CGM is potentially applicable and desirable in most children with diabetes. Recent enhancement has made it possible for parents and others to monitor glucose levels continuously via smartphones, wrist watches and computers.

**Use of CGM in patients with T2DM**

• There are limited data on the use of real-time CGM in patients with T2DM, either masked for retrospective analysis or unmasked for real-time use.

• Additional randomized trials of CGM will be helpful in the evaluation of the benefits of CGM in T2DM.
<table>
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<tr>
<th>Diabetes type</th>
<th>BGM recommendations</th>
<th>CGM recommendations</th>
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<tbody>
<tr>
<td>Type 1 – Adult</td>
<td>At least twice per day to 6-10 times per day, including before meals, occasionally postprandially, before exercise or critical tasks (e.g., driving), and at bedtime.</td>
<td>CGM recommended, particularly for patients with history of severe hypoglycemia, hypoglycemia unawareness and to assist in the correction of hyperglycemia in patients not at goal. CGM users must know basics of sensor insertion, calibration, and real-time data interpretation.</td>
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<tr>
<td>Type 1 – Pediatric</td>
<td>At least 4 times per day, including before eating and at bedtime. A more accurate picture of daily glucose trends may be gained with additional testing, including 1-2 hours after meals, overnight, and before/after exercise. Insulin requirements for pediatric patients change frequently. Physicians, patients, and caregivers should learn to recognize glucose trends that indicate that the insulin regimen requires adjustment. This requires maintaining and periodically reviewing electronic or written logs of BG levels.</td>
<td>Same as Adult Type 1. Both prevalence and persistent use of CGM is lower in children than adults. More in-depth training as well as more frequent follow-up is recommended to enable children to adopt the technology more successfully.</td>
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<tr>
<td>Type 2 – Receiving insulin/sulfonylureas, glinides</td>
<td>Structured BGM is recommended. BGM in patients on intensive insulin: fasting, premeal, bedtime, and periodically in the middle of the night. BGM in patients on insulin ± other diabetes medication: at minimum, when fasting and at bedtime. BGM in patients on basal insulin + 1 daily prandial or premixed insulin injection: at minimum when fasting and before the prandial or premixed insulin, and periodically at other times (i.e., premeal, bedtime. Additional testing before exercise or critical tasks (e.g., driving) as needed.</td>
<td>Data on CGM in T2DM are limited at this time. Trials assessing the use of CGM in T2DM patients are ongoing.</td>
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<tr>
<td>Type 2 – Low risk of hypoglycemia</td>
<td>Daily BGM not recommended. Initial periodic structured BGM (e.g., at meals and bedtime) may be useful in helping patients understand effectiveness of MNT/lifestyle therapy. Once at A1C goal, less frequent monitoring is acceptable.</td>
<td>No recommendation.</td>
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<tr>
<td>Gestational</td>
<td>Patients not receiving insulin: fasting and 1 hour postprandial. Patients receiving insulin: fasting, prandial, and 1 hour postprandial.</td>
<td>Benefits of CGM in pregnant females with pre-existing diabetes are unclear based on current data; additional studies are ongoing. CGM during pregnancy can be used as a teaching tool, to evaluate glucose patterns, and to fine-tune insulin dosing. CGM in pregnancy can supplement BGM, in particular for monitoring nocturnal hypoglycemia or hyperglycemia and postprandial hyperglycemia.</td>
</tr>
</tbody>
</table>

**Abbreviations:** A1C = glycated hemoglobin, BG = blood glucose, BGM = blood glucose monitoring, CGM = continuous glucose monitoring, MNT = medical nutrition therapy, T2DM = type 2 diabetes mellitus.
We recommend real-time continuous glucose monitoring (RT-CGM) devices for adult patients with T1DM who have A1C levels above target and who are willing and able to use these devices on a nearly daily basis.

We recommend RT-CGM devices for adult patients with well-controlled T1DM who are willing and able to use these devices on a nearly daily basis.

We suggest short-term, intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A1C ≥7% and are willing and able to use the device.

References:
8. National Coverage Determination (NCD) for Home Blood Glucose Monitors (40.2)