Insulin Delivery Devices and Continuous Glucose Monitoring Systems

Last Review Date: February 9, 2018
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Definitions

Continuous glucose monitoring (CGM) — CGM systems are minimally invasive or noninvasive devices that measure glucose levels in interstitial fluid at frequent intervals over a period of several days. CGM systems are designed to obtain information regarding diurnal patterns in glucose levels that, when evaluated in real time or reviewed retrospectively by a physician, can guide adjustments to therapy.

Combination CGM devices — comprised of a monitoring and insulin delivery (pump) component. A transmitter connected to a sensor sends data wirelessly to the pump and display unit, which can automatically adjust insulin levels.

Guideline

Members are eligible for a single external insulin infusion delivery system, an interstitial CGM, or a combined CGM and insulin-delivery device for either short-term (72-hour) blood glucose level evaluation or long-term insulin-dosing management (on-going) (as appropriate) when criteria 1, 2 or 3 are met.

Note: The device must be prescribed by an endocrinologist or maternal fetal medicine specialist for adults < 25 and children. Long-term criteria is restricted to either severe recurrent hypoglycemia (< 50) or evidence of hypoglycemia unawareness)

1. 72-hour (preauthorization not required) — considered appropriate for Types 1 or 2 diabetes for either:
   a. Repeated hypoglycemia (< 50 mg/dl) or hyperglycemia (> 150 mg/dl)
   b. Episodic hypoglycemic unawareness or nocturnal hypoglycemia

2. Long-term — combined CGM/Insulin-delivery device — Type 1 diabetes or pregnant members who are on insulin and all of the following:
   a. ≥ 4 finger sticks required per day
   b. Insulin injections required ≥ 3 times per day or member utilizes an insulin pump
   c. Despite aggressive therapy and compliance documented in physician progress notes and member daily logs; i or ii must be met:

      Hemoglobin A1C — 2 measurements > 7.0 separated by 3 months or more over a 6-month period; and, inadequate glycemic control despite consistent SMBG — ≥ 4 times daily over a 3-
month period, which can include fasting hyperglycemia (> 150 mg/dl) or episodic recurrence of severe hypoglycemia (< 50 mg/dl) or fluctuations of > 200 mg/dl per day

OR

i. Episodic hypoglycemic unawareness or nocturnal hypoglycemia (if demonstrated > 1 time during the 3 months of data), as presented in a and b above.

3. Long-term — single external insulin delivery infusion pump

a. The member has completed a comprehensive diabetes education program; has been on a program of multiple daily injections of insulin (i.e., ≥ 3 injections per day) with frequent self-adjustments of insulin dose for ≥ 6 months prior to initiation of the insulin pump; has documented frequency of glucose self-testing an average of ≥ 4 times per day during the 2 months prior to initiation of the insulin pump and meets ≥ 1 of the following criteria while on the multiple injection regimen:

   i. Glycosylated hemoglobin level (HbA1C) > 7 %
   ii. History of recurring hypoglycemia
   iii. Wide fluctuations in blood glucose before mealtime
   iv. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
   v. History of severe glycemic excursions

OR

b. The member has been on an external insulin infusion pump prior to enrollment with the plan and has documented frequency of glucose self-testing an average of ≥ 4 times per day during the month prior to enrollment

Limitations/Exclusions

1. Only FDA-approved devices will be covered.

2. The Freestyle Libre Flash Glucose Monitoring System is covered for members ≥ 18 years of age when the long-term single external insulin delivery infusion pump criteria listed above are met.

3. Members must meet eligibility criteria for a combined monitoring insulin delivery device in order to qualify for systems with a low glucose auto-suspend feature such as the MiniMed® 530G and 630 systems.

4. Requests for upgrades to the MiniMed 670G hybrid closed looped system (a closer approximation to an artificial pancreas device system [APDS] due to the additional features of automated basal delivery and predictive suspend technologies) will be reviewed on a case by case basis.

5. Effective 1/12/2017, Medicare members are covered for the Dexcom G5® Mobile System

   The Medicare DME Benefit excludes coverage for non-medical items, even when the items may be used to serve a medical purpose. As a result, smart devices (smart phones, tablets, personal computers, etc.) are non-covered by Medicare under this exclusion. In addition to the DME receiver included in the Dexcom G5® Mobile CGM System, an alternative option for displaying the received data is with a smart device using the Dexcom G5® app and a beneficiary-owned smart device such as a smart phone or tablet. Medicare does not cover a beneficiary-owned smart device. (See also Noridian Coding and Coverage — Therapeutic Continuous Glucose Monitors [CGM]).

6. Use of a programmable disposable external insulin pump with wireless communication capability to a hand-held control unit (e.g., OmniPod®) is an acceptable alternative to a standard pump when the medical necessity criteria above are met. (OmniPod is covered for Commercial and Medicare members only)

7. Use of an attachment (e.g., MiniMed Connect) to allow wireless transmission from a continuous glucose monitor to a smart phone or computer is not considered medically necessary, as it is regarded as a convenience feature.

8. No additional reimbursement will be provided for a wireless transmission feature that is integrated into a continuous glucose monitor (e.g., Dexcom SHARE), as it is regarded as a convenience feature.
9. The following devices are not considered medically necessary, and are therefore not covered, due to insufficient evidence of therapeutic value:
   a. Implantable insulin pumps
   b. Nonprogrammable disposable insulin delivery systems without wireless communication capability (e.g., V-Go® Disposable Insulin Delivery Device)
   c. Remote wireless glucose monitoring devices for real-time monitoring, as a technique of diabetic monitoring (e.g., Dexcom C5®)

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>2/9/2018</td>
<td>Added coverage of the Freestyle Libre Flash Glucose Monitoring System</td>
</tr>
<tr>
<td>4/7/2017</td>
<td>Added coverage of the Dexcom G5 for Medicare members only (exclusions apply; listed above).</td>
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<tr>
<td>3/10/2017</td>
<td>Communicated that upgrade requests for the MiniMed 670 System will be reviewed on a case by case basis.</td>
</tr>
<tr>
<td>8/24/2016</td>
<td>Clarified that remote wireless and smartphone capabilities are not considered medically necessary.</td>
</tr>
<tr>
<td>8/5/2016</td>
<td>Added OmniPod clarification to differentiate from V-Go.</td>
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Applicable Procedure Codes

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>95249</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording (Eff. 01/01/2018)</td>
</tr>
<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>
<td>0446T</td>
<td>Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training</td>
</tr>
<tr>
<td>0447T</td>
<td>Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision</td>
</tr>
<tr>
<td>0448T</td>
<td>Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation</td>
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<tr>
<td>A4224</td>
<td>Supplies for maintenance of insulin infusion catheter, per week</td>
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<tr>
<td>A4225</td>
<td>Supplies for external insulin infusion pump, syringe type cartridge, sterile, each</td>
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<tr>
<td>A4230</td>
<td>Infusion set for external insulin pump, non-needle cannula type</td>
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<tr>
<td>A4231</td>
<td>Infusion set for external insulin pump, needle type</td>
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<tr>
<td>A4232</td>
<td>Syringe with needle for external insulin pump, sterile, 3 cc</td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories (Not covered when used to report nonprogrammable external insulin delivery systems (e.g., V-Go®))</td>
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<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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<tr>
<td>A9999</td>
<td>Miscellaneous DME supply or accessory, not otherwise specified</td>
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<tr>
<td>E0607</td>
<td>Home blood glucose monitor</td>
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### Applicable ICD-10 Codes

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<td>E0784</td>
<td>External ambulatory infusion pump, insulin (Coverage is limited to Commercial and Medicare members when code is reported specific to the OmniPod)</td>
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<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<tr>
<td>E2100</td>
<td>Blood glucose monitor with integrated voice synthesizer</td>
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<tr>
<td>E2101</td>
<td>Blood glucose monitor with integrated lancing/blood sample</td>
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<tr>
<td>K0553</td>
<td>Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit of Service (Eff. 01/01/2018)</td>
</tr>
<tr>
<td>K0554</td>
<td>Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system (Eff. 01/01/2018)</td>
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<td>Type 1 diabetes mellitus with ketoacidosis with coma</td>
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<tr>
<td>E10.21</td>
<td>Type 1 diabetes mellitus with diabetic nephropathy</td>
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<td>E10.22</td>
<td>Type 1 diabetes mellitus with diabetic chronic kidney disease</td>
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<td>E10.29</td>
<td>Type 1 diabetes mellitus with other diabetic kidney complication</td>
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<td>Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye</td>
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<td>E10.3212</td>
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<td>Pre-existing type 1 diabetes mellitus, in the puerperium</td>
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**References**


Specialty-matched clinical peer review.
