APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
BACKGROUND

Diabetes mellitus is characterized by hyperglycemia due to impaired pancreatic insulin secretion or inefficient use of insulin by the body. Members with insulin-dependent (type 1) diabetes require chronic treatment with exogenous insulin. To calculate the insulin dose needed to manage their blood glucose levels, these members perform self-monitoring of blood glucose (SMBG) using samples obtained by finger sticks; however, frequent SMBG may not detect all significant deviations in blood glucose, particularly in members with rapidly fluctuating glucose levels. As a result, some members who perform multiple daily finger sticks may fail to detect blood glucose excursions above or below the desired range, especially when glucose fluctuations occur at night.1,2

A list of continuous glucose monitoring (CGM) systems that have been approved by the Food and Drug Administration (FDA) can be located at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

These systems have all been developed to detect trends and track patterns in glucose levels over a period of several days, information that can be used to optimize insulin therapy and, thereby, potentially improve glycemic control. The MiniMed systems utilize sensors that are inserted into the subcutaneous tissues of the abdomen. These devices extract glucose from the interstitial fluid, measure and record the glucose level, and convert the measurement into an equivalent blood glucose reading.3

National Institute for Health and Clinical Excellence (NICE)

NICE recommends the use of continuous glucose monitoring systems in adults on insulin therapy who have consistent problems with controlling blood glucose levels, notably repeated hyper- or hypoglycemia at the same time of day or hypoglycemia unawareness, unresponsive to conventional insulin dose adjustment. NICE also recommends that continuous glucose monitoring systems be available to children and young adults with type 1 diabetes who have persistent problems with impaired awareness of hypoglycemia or repeated hypoglycemia and hyperglycemia.1,4

American Diabetes Association (ADA) 5,6,7

In the 2009 Standards of Medical Care in Diabetes, the ADA states that continuous glucose monitoring (CGM) may be a supplemental tool to SMBG in type 1 diabetes patients with hypoglycemia unawareness and/or frequent hypoglycemic episodes. CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age greater than or equal to 25 years) with type 1 diabetes. 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 (ADA, 2009). The ADA (2010) also found that in a randomized clinical trial, CGM did not provide significant results in lowering HbA1c; self-monitoring is recommended however continued research on the benefits of CGM among pediatric patients is needed.

The ADA 2013 statement continues to support use of CGM in adults and pediatric patients.

American Association of Clinical Endocrinologists (AACE)

The 2010 Clinical Practice Guidelines for the Management of Diabetes state that advances in blood glucose monitoring and continuous monitoring of interstitial glucose, along with the introduction of "smart" insulin pumps,
provide clinicians and patients with powerful tools to monitor and adjust treatment regimens. The guidelines recommend arranging for continuous glucose monitoring for patients with type 1 diabetes with unstable glucose control and for patients unable to achieve an acceptable HbA1c level; continuous glucose monitoring is particularly valuable in detecting both unrecognized nocturnal hypoglycemia and postprandial hyperglycemia.8

**POSITION STATEMENT**

**Applicable To:**
- Medicare – All Markets

Extended monitoring of glucose levels in interstitial fluid is considered medically necessary if ALL of the following criteria are met:
- Member has used best practices and was compliant with 4 or more finger sticks per day; **AND,**
- Member has previous 30 day short-term use of monitor to guide alterations in insulin administration, behavioral modifications, and hypoglycemic awareness; **AND,**
- Continuous glucose monitoring has led to a beneficial series of behavioral modifications resulting in a reduction of hypoglycemic events; **AND,**
- Insulin injections are required 3 or more times per day or a medically necessary insulin pump is used for maintenance of blood sugar control; **AND,**
- A comprehensive glucose level log is maintained, documenting significant changes in diabetic management as a result of the continuous monitoring.

Intermittent (up to 72 hour) monitoring of glucose levels in interstitial fluid is considered medically necessary in members with type I diabetes prior to insulin pump initiation and calibration to determine basal insulin levels. Continuous (long term) monitoring of glucose levels in interstitial fluid in pregnant members DURING PREGNANCY is considered medically necessary if ALL of the above criteria are met.

* Poorly controlled type I diabetes includes the following circumstances:
- Unexplained hypoglycemic episodes; **OR,**
- Nocturnal hypoglycemic episode(s); **OR,**
- Hypoglycemic unawareness leading to impairments in activities of daily living; **OR,**
- Suspected postprandial hyperglycemia; **OR,**
- Recurrent diabetic ketoacidosis

**CODING**

**Covered CPT© Codes and Reporting Limitations**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<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 (Do not report more than once per month.)</td>
</tr>
<tr>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician interpretation and report (Do not report more than once per month.)</td>
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</tbody>
</table>

**Covered HCPCS Level II © Codes**

<table>
<thead>
<tr>
<th>Code</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 (NOTE: Limited to authorization of 3 months at a time).</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 (for physician interpretation of data, use CPT code)</td>
</tr>
<tr>
<td>S1031+</td>
<td>Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)</td>
</tr>
</tbody>
</table>
Note: A and S-Codes are NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes
For Medicare, bill the appropriate CPT code listed above.

Covered ICD-9-CM Diagnosis Codes
250.03 Diabetes Mellitus, Type I, uncontrolled, without mention of complications
250.13 Diabetes Mellitus, Type I, uncontrolled, with ketoacidosis, without mention of coma
250.43 Diabetes Mellitus, Type I, uncontrolled, with renal manifestations
250.53 Diabetes Mellitus, Type I, uncontrolled, with ophthalmic manifestations
250.63 Diabetes Mellitus, Type I, uncontrolled, with neurological manifestations
250.73 Diabetes Mellitus, Type I, uncontrolled, with peripheral circulatory disorders
250.83 Diabetes Mellitus, Type I, uncontrolled, with other specified manifestations
648.00 - 648.04 Maternal diabetes mellitus (Type I), complicating pregnancy, childbirth, or the puerperium

Covered Draft ICD-10-CM Diagnosis Codes
E10.65 Type 1 diabetes mellitus with hyperglycemia

GEM Combination 1
E10.10 Type 1 diabetes mellitus with ketoacidosis without coma
E10.65 Type 1 diabetes mellitus with hyperglycemia

GEM Combination 1
E10.21 Type 1 diabetes mellitus with diabetic nephropathy
E10.65 Type 1 diabetes mellitus with hyperglycemia

GEM Combination 1
E10.311 Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.65 Type 1 diabetes mellitus with hyperglycemia

GEM Combination 2
E10.319 Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.65 Type 1 diabetes mellitus with hyperglycemia

GEM Combination 3
E10.36 Type 1 diabetes mellitus with diabetic cataract
E10.65 Type 1 diabetes mellitus with hyperglycemia

GEM Combination 4
E10.39 Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.65 Type 1 diabetes mellitus with hyperglycemia

GEM Combination 1
E10.40 Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.65 Type 1 diabetes mellitus with hyperglycemia

GEM Combination 1
E10.51 Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E10.65 Type 1 diabetes mellitus with hyperglycemia

GEM Combination 1
E10.69 Type 1 diabetes mellitus with other specified complication
E10.65 Type 1 diabetes mellitus with hyperglycemia

O24.019 Pre-existing diabetes mellitus, type 1, in pregnancy, unspecified trimester
O24.119 Pre-existing diabetes mellitus, type 2, in pregnancy, unspecified trimester
O24.319 Unspecified pre-existing diabetes mellitus in pregnancy, unspecified trimester
O24.819 Other pre-existing diabetes mellitus in pregnancy, unspecified trimester
O24.919 Unspecified diabetes mellitus in pregnancy, unspecified trimester
O24.011 Pre-existing diabetes mellitus, type 1, in pregnancy, first trimester
O24.012 Pre-existing diabetes mellitus, type 1, in pregnancy, second trimester
O24.013 Pre-existing diabetes mellitus, type 1, in pregnancy, third trimester
O24.02 Pre-existing diabetes mellitus, type 1, in childbirth
O24.111 Pre-existing diabetes mellitus, type 2, in pregnancy, first trimester
O24.112 Pre-existing diabetes mellitus, type 2, in pregnancy, second trimester
O24.113 Pre-existing diabetes mellitus, type 2, in pregnancy, third trimester
O24.12 Pre-existing diabetes mellitus, type 2, in childbirth
O24.311 Unspecified pre-existing diabetes mellitus in pregnancy, first trimester
O24.312 Unspecified pre-existing diabetes mellitus in pregnancy, second trimester
O24.313 Unspecified pre-existing diabetes mellitus in pregnancy, third trimester
O24.32 Unspecified pre-existing diabetes mellitus in childbirth
O24.811 Other pre-existing diabetes mellitus in pregnancy, first trimester
O24.812 Other pre-existing diabetes mellitus in pregnancy, second trimester
O24.813 Other pre-existing diabetes mellitus in pregnancy, third trimester
O24.82 Other pre-existing diabetes mellitus in childbirth
O24.911 Unspecified diabetes mellitus in pregnancy, first trimester
O24.912 Unspecified diabetes mellitus in pregnancy, second trimester
O24.913 Unspecified diabetes mellitus in pregnancy, third trimester
O24.92 Unspecified diabetes mellitus in childbirth
O24.93 Unspecified diabetes mellitus in the puerperium
O24.01 Pre-existing diabetes mellitus, type 1, in pregnancy
O24.02 Pre-existing diabetes mellitus, type 1, in childbirth
O24.31 Unspecified pre-existing diabetes mellitus in pregnancy
O24.81 Other pre-existing diabetes mellitus in pregnancy
O24.91 Unspecified diabetes mellitus in pregnancy
O24.92 Unspecified diabetes mellitus in childbirth
O24.93 Unspecified diabetes mellitus in the puerperium


REFERENCES


CONTINUOUS GLUCOSE MONITORING
HS-138


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>8/6/2015</td>
<td>• Approved by MPC. Removal of requirement for 30 day trial.</td>
</tr>
<tr>
<td>10/4/2014</td>
<td>• Approved by MPC. Implemented supply limit for A9276; updated coding – no changes to Position Statement.</td>
</tr>
<tr>
<td>10/3/2013, 10/4/2012</td>
<td>• Approved by MPC. No changes.</td>
</tr>
<tr>
<td>12/1/2011</td>
<td>• New template design approved by MPC.</td>
</tr>
<tr>
<td>9/15/2011</td>
<td>• Approved by MPC. Added Hayes rating and 2010 statement by the American Diabetes Association.</td>
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