**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.

**DICLAIMER**

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines.”

**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](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.\(^3\)

DexCom G5 Mobile is indicated for pediatric and adult patients with type 1 DM and type 2 DM and requires at least twice daily fingerstick blood glucose measurements for calibration.

Freestyle Libre Flash Glucose Monitoring System does not require blood sugar testing for calibration and indicated only for adults patients with diabetes on insulin.

**National Institute for Health and Clinical Excellence (NICE).** NICE recommends that real-time continuous glucose monitoring be considered 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 optimized use of insulin therapy and conventional blood glucose monitoring:

- More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycaemia.
- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
- Extreme fear of hypoglycaemia.

**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 HbA1c 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 useful 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 2015 Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan state that continuous glucose monitoring should be considered for patients with type 1 diabetes and type 2 diabetes on basal-bolus therapy to improve A1C levels and reduce hypoglycemia. It also states that early reports suggest that even patients not taking insulin may benefit from CGM. The AACE says CGM may be useful in patients with recurrent asymptomatic hypoglycemia. In pediatric patients CGM was beneficial only when used on a virtually daily basis. When CGM was used ≥6 days per week, decreases in both A1C and the frequency and severity of hypoglycemia were been reported.\(^8\)

AACE states that despite improvements, more research is needed before recommendations can be made regarding CGM use in patients with type 2 diabetes. Patient adherence to monitoring and treatment is the greatest predictor of glycemic control. When used appropriately, CGM can lead to decreased A1C and reduced hypoglycemic exposure.\(^8\)

**Centers for Medicare and Medicaid Services (CMS)**\(^9\) On January 12, 2017 CMS issued Ruling No. [CMS-1682-R] to classify continuous glucose monitorings as durable medical equipment (DME). Below the conclusion of the ruling.
For CGM products that are used in the home and approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions, these therapeutic CGMs are primarily and customarily used to serve a medical purpose because they are used by Medicare beneficiaries with diabetes who must measure their glucose level frequently and check trends in their glucose measurements for the purpose of adjusting their diet and insulin in the treatment of their diabetes. Because they are used directly in making diabetes treatment decisions, as opposed to alerting the patient to use a blood glucose monitor to make those decisions, they are not precautionary in nature.

A receiver (or type of monitor) for a therapeutic CGM that has an expected life of at least 3 years and is the component performing the medically necessary function of accurately monitoring the trends of the patients' blood glucose levels so that he or she can make necessary diabetes treatment decisions meets the 3-year MLR.

The system as a whole replaces the blood glucose monitor for glucose monitoring purposes. As a result, the durable receiver for a therapeutic CGM is considered DME. For therapeutic CGMs, the glucose sensors and transmitters are considered essential accessories necessary for the effective use of the therapeutic CGM and replacement of the glucose sensors and transmitters are considered replacements of essential accessories necessary for the effective use of DME.

Although this ruling is to classify these items as DME items, specifically glucose testing equipment, and related accessories essential for the effective use of glucose testing equipment, section 1862(a)(1)(A) of the Act would still prohibit Medicare payment for these items if they are not determined to be reasonable and necessary for the treatment of the diabetes illness.

Continuous glucose monitoring systems are considered therapeutic CGMs that meet the definition of durable medical equipment at section 1861(n) of the Act and 42 CFR 414.202 if the equipment—

- Is approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions (for example, changes in diet and insulin dosage);
- Generally is not useful to the individual in the absence of an illness or injury;
- Is appropriate for use in the home; and
- Includes a durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements.

In all other cases in which a CGM does not replace a blood glucose monitor for making diabetes treatment decisions, a CGM is not considered DME and is not covered. This Ruling does not apply to items and services furnished prior to the effective date of the Ruling.

**POSITION STATEMENT**

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

**Exclusions**

1. **Medicare Only:** Non-Therapeutic Extended Continuous Glucose Monitors are not covered as they are not considered to be DME and cannot replace a glucometer.

**Coverage**

Intermittent (up to 72 hour) monitoring of glucose levels in interstitial fluid is considered medically necessary when all of the following criteria are met:

1. The member has type 1 diabetes; AND,
2. Monitoring is being done prior to insulin pump initiation and calibration to determine basal insulin levels.
Therapeutic Continuous Glucose Monitors are considered medically necessary when all of the following criteria are met:

1. The member has diabetes mellitus (type 1DM and type 2DM); AND,
2. The member requires twice day BGM (for device calibration for DexCom G5 mobile); AND,
3. The member is insulin-treated with multiple daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; AND,
4. The member's insulin treatment regimen requires frequent adjustment by the member on the basis of therapeutic continuous glucose monitoring (CGM) testing results; AND,
5. The member requires insulin injections 3 or more times per day or a medically necessary insulin pump is used for maintenance of blood sugar control.
6. A comprehensive glucose level log is maintained, documenting significant changes in diabetic management as a result of the continuous monitoring.

Pregnant Members

Continuous (long term) monitoring of glucose levels in interstitial fluid in during pregnancy is considered medically necessary if ALL of the below criteria are met.

1. The member has diabetes mellitus; AND,
2. The member has been using a home blood glucose monitor (BGM) and performing frequent (four or more times a day) BGM testing; AND,
3. The member is insulin-treated with multiple daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; AND,
4. The member's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of therapeutic CGM testing results; AND,
5. The member has used best practices and was compliant with 4 or more finger sticks per day; AND,
6. Continuous glucose monitoring has led to a beneficial series of behavioral modifications resulting in a reduction of hypoglycemic events; AND,
7. 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,
8. A comprehensive glucose level log is maintained, documenting significant changes in diabetic management as a result of the continuous monitoring.

CODING

Code K0553 describes a supply allowance used with a therapeutic CGM device. The supply allowance includes all items necessary for the use of the device and includes, but is not limited to: CGM sensor, CGM transmitter, home BGM and related BGM supplies (test strips, lancets, lancing device, calibration solutions) and batteries. K0553 must not be used for supplies used with CGM coded as A9278.

A supplier does not have to deliver supplies used with a therapeutic CGM every month in order to bill code K0553 every month. In order to bill code K0553, the supplier must have previously delivered quantities of supplies that are sufficient to last for one (1) full month following the DOS on the claim. Suppliers must monitor usage of supplies. Billing for code K0553 may continue on a monthly basis as long as sufficient supplies remain to last for one (1) full month as previously described. If there are insufficient supplies to be able to last for one (1) full month, additional supplies must be provided before the supply allowance is billed. No more than 1 unit of service (UOS) for code K0553 per month is billable at a time.

Code K0554 describes a continuous glucose monitor that meets the requirements of the DME benefit as described in CMS Ruling 1682R. CGM devices that meet these requirements are termed "Therapeutic CGM".

Codes A9276 (SENSOR; INVASIVE (E.G., SUBCUTANEOUS), DISPOSABLE, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY) and A9277 (TRANSMITTER;
EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM) describe the supplies used with a non-therapeutic CGM. Codes A9276 and A9277 are not used to bill for supplies used with code K0554.

Code A9278 (RECEIVER (MONITOR); EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM) describes any CGM system that fails to meet the DME Benefit requirements as described in CMS Ruling 1682R.

Covered CPT®* Codes and Reporting Limitations

95250  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.)

95251  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.)

Covered HCPCS Level II © Codes

A9276+  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).

A9277+  Transmitter; external, for use with interstitial continuous glucose monitoring system

A9278+  Receiver (monitor); external, for use with interstitial continuous glucose monitoring system

K0553  Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit of Service

K0554  Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system

S1030+  Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)

S1031+  Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)

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-10-CM Diagnosis Codes

NOTE: Refer to the ICD10 manual for specific sub-term codes that meet the patients’ diagnosis.

E10.1  Type 1 diabetes mellitus with ketoacidosis
E10.2  Type 1 diabetes mellitus with kidney complications
E10.3  Type 1 diabetes mellitus with ophthalmic complications
E10.321  Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.329  Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E10.331  Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.339  Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E10.341  Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.351  Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.352  Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula
E10.353  Type 1 diabetes mellitus w/ proliferative diabetic retinopathy with traction retinal detachment not involving the macula
E10.354  Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment
E10.355  Type 1 diabetes mellitus with stable proliferative diabetic retinopathy
E10.36  Type 1 diabetes mellitus with diabetic cataract
E10.37  Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment
E10.39  Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.4  Type 1 diabetes mellitus with neurological complications
E10.5  Type 1 diabetes mellitus with circulatory complications
E10.61  Type 1 diabetes mellitus with diabetic arthropathy
E10.62  Type 1 diabetes mellitus with skin complications
E10.63  Type 1 diabetes mellitus with oral complications
E10.64 Type 1 diabetes mellitus with hypoglycemia
E10.65 Type 1 diabetes mellitus with hyperglycemia
E10.69 Type 1 diabetes mellitus with other specified complication
E10.8 Type 1 diabetes mellitus with unspecified complications
E10.9 Type 1 diabetes mellitus without complications
E11.0 Type 2 diabetes mellitus with hyperosmolality
E11.1 Type 2 diabetes mellitus with ketoacidosis
E11.2 Type 2 diabetes mellitus with kidney complications
E11.3 Type 2 diabetes mellitus with ophthalmic complications
E11.321 Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.329 Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E11.331 Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.339 Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E11.341 Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.349 Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E11.351 Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E11.352 Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula
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E11.39 Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11.4 Type 2 diabetes mellitus with neurological complications
E11.5 Type 2 diabetes mellitus with circulatory complications
E11.6 Type 2 diabetes mellitus with other specified complications
E11.62 Type 2 diabetes mellitus with skin complications
E11.63 Type 2 diabetes mellitus with oral complications
E11.64 Type 2 diabetes mellitus with hypoglycemia
E11.65 Type 2 diabetes mellitus with hyperglycemia
E11.69 Type 2 diabetes mellitus with other specified complication
E11.8 Type 2 diabetes mellitus with unspecified complications
E11.9 Type 2 diabetes mellitus without complications
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
O24.911 Other pre-existing diabetes mellitus in childhod
O24.912 Unspecified diabetes mellitus in pregnancy, second trimester
O24.913 Unspecified diabetes mellitus in pregnancy, third trimester
O24.92 Unspecified diabetes mellitus in childhod
O24.93 Unspecified diabetes mellitus in the puerperium
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
O24.111 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
O24.311 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
O24.811 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
O24.911 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
O24.03 Pre-existing diabetes mellitus, type 1, in the puerperium
O24.13 Pre-existing diabetes mellitus, type 2, in the puerperium
O24.33 Unspecified pre-existing diabetes mellitus in the puerperium
O24.83 Other pre-existing diabetes mellitus in the puerperium
O24.93 Unspecified diabetes mellitus in the puerperium

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

11. DME and medical supply services coverage and limitations handbook. Agency for Health Care Administration Web site.


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>7/12/2018</td>
<td>• Approved by MPC. Updated exclusion for Medicare only.</td>
</tr>
<tr>
<td>11/2/2017</td>
<td>• Approved by MPC. New CMS coverage changes added.</td>
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<tr>
<td>2/2/2017</td>
<td>• Approved by MPC. No changes</td>
</tr>
<tr>
<td>8/6/2015</td>
<td>• Approved by MPC. Removal of requirement for 30 day trial.</td>
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<tr>
<td>10/4/2014</td>
<td>• Approved by MPC. Implemented supply limit for A9276; updated coding – no changes to Position Statement.</td>
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<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>
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<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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