KAISER PERMANENTE®

# Review Criteria

Georgia Region

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| DEPARTMENT: | Quality Resource Management | CRITERIA NUMBER: | No. 3-35 |
| SECTION: | Utilization Management | EFFECTIVE DATE: | 5/27/2009 |
| TITLE: | Continuous Glucose Monitors: Adults | LAST REVISION DATE: | 8/28/2023 |
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| APPROVAL BODY/ COMMITTEE: | Utilization Management Committee | | |

## 1.0 PURPOSE

This policy provides the indications and contraindications necessary for the Quality Resource Management staff to make the most appropriate decision related to the medical necessity of the procedure listed.

## 2.0 DIAGNOSIS/CONDITION

2.1 Diabetes Mellitus ICD-10- E10

## 3.0 CPT/HCPCS CODES AND DESCRIPTIONS

3.1 A9278; A9279; A9276; A9277

## 4.0 INDICATIONS

4.1 Criteria for CGM (must meet one of the following categories (must have type 1 or 2 diabetes mellitus):

4.1.1 Type I DM (must meet all the following):

- On insulin pump or using 3 or more insulin injections a day.
- Currently checks blood glucose as instructed by provider to adjust insulin regimen.
- Two in-person or Video visit with provider within 6 months of request for CGM.
- Not meeting glycemic targets OR the patient is experiencing hypoglycemia (including hypoglycemia unawareness).

4.1.2 Type I DM and Complicated Diabetes, managed by Endocrinologist - CGM may be requested after 1st visit (must meet insulin requirements above).

4.1.3 Type I DM pre-conception, and during pregnancy to reduce the incidence of fetal mortality and anomalies. May be initiated after 1st visit (must meet insulin requirements above).

4.1.4 Type 2 DM (must meet insulin requirement above) must meet all the following:

- Two in-person or Video visit with provider within 6 months of request for CGM with any of the following:
- Primary care physician
- Clinical Pharmacist
- Diabetes nurse
- Endocrinologist
- Not meeting glycemic targets OR the patient is experiencing hypoglycemia (including hypoglycemia unawareness)

4.1.5 For Type 2 DM HbA1c > 9 mg/dl - CGM may be requested after 1st visit if resulted within 2 months of the visit (must meet insulin requirements above).

4.1.5.1 Type 2 DM on chronic insulin treatment (any dose) and has one of the following:

4.1.5.2 Severe Dexterity impairment (inability to use standard blood glucose monitor)

OR

4.1.5.3 Severe vision impairment (severe, uncorrectable vision impairment, resulting in inability to read standard blood glucose meter)

OR

4.1.5.4 HbA1c > 9 mg/dl (must be on insulin at least BID)—result must be within 2 months of a clinical visit.

OR

4.1.5.5 History of severe hypoglycemia not responsive to changes in the insulin regimen by the treating provider as defined by one of the following:

- Hypoglycemia requiring assistance and/or glucagon injection or visit to the Emergency Department within the past three months.
- Hypoglycemia associated seizures within the last 6 months.
- Nocturnal hypoglycemia (blood glucose < 50 at least three times per week over the past month while asleep, which is refractory to insulin dose changes.

- Individuals of all ages with diabetes mellitus successfully using a continuous glucose meter during the month prior to enrollment with KPGA. They must meet the medical necessity criteria or have prior insurance authorization for coverage. Proof of prior insurance authorization will be required if they do not meet the medical necessity criteria.

4.2 The supply allowance (code K0553) is billed as 1 Unit of Service (UOS) per thirty (30) days. Only one (1) UOS of code K0553 may be billed to the DME MACs at a time. Billing more than 1 UOS per 30 days of code K0553 will be denied as not reasonable and necessary.

4.2.1 The preferred CGM's for KPGA are the Freestyle Libre 2 and the Dexcom G7. Members may be changed to these devices (from the Dexcom G6) by target review if the member is not on an insulin pump. Once these devices are compatible with the Omnipod and T slim insulin pumps, members may be changed to either the Freestyle Libre 2 (or 3 if available) or Dexcom G7 by target review. This is an exception to DME policy for duplicate devices.

4.2.2 Recommendation from Dr. Hendee TSPMG Endocrinology: Members not meeting criteria for CGM but wanting to monitor blood sugar may be written prescriptions for Free style libre reader and sensors and obtain at an internal or external pharmacy as "self-pay" without a referral.

4.2.3 Usage Guidelines: Initial approval includes 1 reader/ 2 transistor along with sensors for supplies.
Recertification for additional sensors required Annually.
Note: Some transmitters need to be replaced every 3 months due to battery loss.

## 5.0 CONTRAINDICATIONS

5.1 Patients ONLY on oral diabetes medication.

5.2 Inability, unwillingness to use sensor CGM.

5.3 Cognitive impairment (without a care giver).

## 6.0 VIEWS OF THE SOUTHEAST PERMANENTE MEDICAL GROUP

6.1 The Southeast Permanente Medical Group considers the use of CGM medically necessary for long term use in patients meeting the above criteria which includes type I or type II diabetes, on 3 our more insulin injections or insulin pump. Patient must also be compliant with instructions.

## 7.0 REFERENCES


7.1 NCAL and SCAL Kaiser Criteria 1/2019 for Therapeutic CGM (see indications).

7.2 Diabetes Technology: Standards of Medical Care in Diabetes—2019

7.3 American Diabetes Association

7.3.1 Diabetes Care 2019 Jan; 42(Supplement 1): S71-S80. https://doi.org/10.2337/dc19-S007

7.3.2 Continuous Glucose Monitors

7.3.2.1 Recommendations:

7.3.2.1.1 Sensor-augmented pump therapy may be considered for children, adolescents, and adults to improve glycemic control without an increase in hypoglycemia or severe hypoglycemia. Benefits correlate with adherence to ongoing use of the device. A

7.3.2.1.2 When prescribing continuous glucose monitoring, robust diabetes education, training, and support are required for optimal continuous glucose monitor implementation and ongoing use. E

7.3.2.1.3 People who have been successfully using continuous glucose monitors should have continued access across third-party payers. E

7.3.3 Real-time Continuous Glucose Monitor Use in Adults

7.3.4 Recommendations:

7.3.4.1.1 When used properly, real-time continuous glucose monitoring in conjunction with intensive insulin regimens is a useful tool to lower A1C in adults with type 1 diabetes who are not meeting glycemic targets. A

7.3.4.1.2 Real-time continuous glucose monitoring may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. B

7.3.4.1.3 Real-time continuous glucose monitoring should be used as close to daily as possible for maximal benefit. A

7.3.4.1.4 Real-time continuous glucose monitoring may be used effectively to improve A1C levels and neonatal outcomes in pregnant women with type 1 diabetes. B

7.3.4.1.5 Sensor-augmented pump therapy with automatic low-glucose suspend may be considered for adults with type 1 diabetes at high

risk of hypoglycemia to prevent episodes of hypoglycemia and reduce their severity. B

7.4 Center for Medicare and Medicaid Services (CMS)- 2017

7.4.1 Therapeutic continuous glucose monitors (CGMs)

7.4.2 Medicare covers therapeutic continuous glucose monitors (CGMs) and related supplies instead of blood sugar monitors for making diabetes treatment decisions, like changes in diet and insulin dosage.

7.5 Continuous Glucose Monitors (CGM)

7.5.1 CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGMs. Refer to the Non-Medical Necessity Coverage and Payment Rules in the LCD-related Policy Article for additional information.

7.5.2 Therapeutic CGMs and related supplies are covered by Medicare when all the following coverage criteria (1-5) are met:

7.5.2.1 The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,

7.5.2.2 The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,

7.5.2.3 The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary based on BGM or CGM testing results; and,

7.5.2.4 Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-3) above are met; and,

7.5.2.5 Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.

7.5.3 When a therapeutic CGM (code K0554) is covered, the related supply allowance (code K0553) is also covered.

7.5.4 If any of coverage criteria (1-5) are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.

7.5.5 The supply allowance (code K0553) is billed as 1 Unit of Service (UOS) per thirty (30) days. Only one (1) UOS of code K0553 may be billed to the DME MACs at a time. Billing more than 1 UOS per 30 days of code K0553 will be denied as not reasonable and necessary.

7.5.6 Therapeutic CGM devices replace a standard home blood glucose monitor (HCPCS codes E0607, E2100, E2101) and related supplies (HCPCS codes A4233, A4234, A4235, A4236, A4244, A4245, A4246, A4247, A4250, A4253, A4255, A4256, A4257, A4258, A4259). Claims for a BGM and related supplies, billed in addition to an approved CGM device (code K0554) and associated supply allowance (code K0553), will be denied. Refer to the Coding Guidelines in the LCD-related Policy Article for additional information.

7.6 MCG 24th Edition Criteria for CGM

7.7 Continuous glucose monitoring may be indicated for 1 or more of the following (1)(2)(3)(4)(5):

7.7.1 Type 1 or type 2 diabetes mellitus, and long-term continuous glucose monitoring needed, as indicated by ALL the following (27)(28)(29)

7.7.2 Intensive insulin regimen (3 or more insulin injections per day, or use of continuous subcutaneous insulin infusion pump).. (52)(53)

7.7.3 Patient is motivated and knowledgeable about use of continuous glucose monitoring, is adherent to diabetic treatment plan, and participates in ongoing education and support. (7)(32)(58)(59)(60)

7.8 Aetna Continuous Glucose Monitor Devices: CPB July 2021- Diabetes, Supplies and Testing.

7.8.1 Aetna considers the long-term (greater than 1 week) therapeutic use of continuous glucose monitoring devices medically necessary in adults aged 18 years and older with type 1 or type 2 diabetes using intensive insulin regimens (multiple (3 or more) daily injections or insulin pump therapy) who are either not meeting glycemic targets or experiencing hypoglycemia (including hypoglycemic unawareness). CGMS are also considered medically necessary for younger persons with type 1 diabetes or type 2 diabetes using intensive insulin regimens. Continued use of CGMs is considered medically necessary in adults aged 18 years and older who are either 1) experiencing improved glycemic control or decreased hypoglycemia episodes while using a CGM, or 2) are being assessed every six months by the prescriber for adherence to their CGM regimen and diabetes treatment plan. Continued use of CGMs is also considered medically necessary for children and adolescents less than 18 years of age with type 1 or

type 2 diabetes. Long-term use of continuous glucose monitoring devices is considered experimental and investigational for all other indications.

7.9 Artificial Pancreas Device Systems

7.9.1 Aetna considers a continuous glucose monitor and insulin pump with a low glucose suspend feature (e.g., MiniMed 630G) an equally acceptable alternative to a standard insulin pump and continuous glucose monitors for medically necessary indications.

7.9.2 Aetna considers a continuous glucose monitor and insulin pump with closed loop system (programmed to automatically adjust delivery of basal insulin based on continuous glucose monitor sensor glucose values) (e.g., Medtronic MiniMed 670G, Tandem t: slim X2 insulin pump with Basal-IQ Technology) an equally acceptable alternative to a standard insulin pump and continuous glucose monitor for medically necessary indications.

## Reviewed By/Approved By

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