KAISER PERMANENTE®

Review Criteria
Georgia Region

Title:	Continuous Glucose Monitors- Pediatrics		
Department:	QUALITY RESOURCE MANAGEMENT	**Page:**	1 of 4
Section:	UTILIZATION MANAGEMENT	**Policy Number:**	03-36
Type:	() New	**Effective Date:**	7/10/2009
	(X) Reviewed / Revised	**Date:**	1/29/2018 1/15/2019 1/2/2020 1/11/2021 1/10/2022 1/17/2023

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.

DIAGNOSIS/CONDITION: Diabetes Mellitus
ICD-10 E10
CPT-4/ HCPCS CODE AND DESCRIPTION: INDICATORS A9276; A9277; A9278

1.0 INDICATIONS
Pt should have been followed by pediatric endocrinologist

2.0 Member is less than 18 years of age and has all of the following:
1. Diagnosis of type I diabetes
2. Using insulin pump or multiple daily shot schedule - three or more shots daily
3. Currently checks blood glucose as instructed by provider to adjust insulin regimen (Frequency of testing should not be considered as a reason not to approve)
4. Have 2 in person or virtual visits with an endocrinologist over last 6 - 12 months and in between phone contact with diabetes educator.
5. Request for CGM from Pediatric Endocrinologist.
6. For Type I DM and Complicated Diabetes, managed by Endocrinologist - CGM may be requested after 1st visit **(must meet insulin requirements above)**

And at least one of the following:
1. Children with hypoglycemia unawareness - hypoglycemia requiring assistance from an adult and/or Inj Glucagon or visit to ER within the last three months.
2. Nocturnal hypoglycemia refractory to insulin dose changes.
3. Seizure associated with Hypoglycemia - one or more episode in last 6 months.
4. Difficulty in accomplishing the target A1C, in a setting of motivated family and child in spite of working closely with endocrinologist and diabetes educator over the last 6 months.
5. Use of the CGM is needed to maintain at or below the goal for glucose control.

Clinical Review:

2.0 CONTRAINDICATIONS
- Patients only on oral diabetes medication

- Inability, unwillingness to use sensor CGM as demonstrated from trial
- 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.

3.0 VIEWS OF THE SOUTHEAST PERMANENTE MEDICAL GROUP

- The Southeast Permanente Medical Group considers the use of CGM medically necessary for pediatric patients with type I diabetes on insulin pump or with multiple injections and documented hypoglycemia unawareness, seizures, or poor control of diabetes despite multiple insulin adjustments by endocrinology. Pt will need to have trial

4.0 CLINICAL SUMMARY:

Diabetes mellitus is characterized by hyperglycemia due to impaired pancreatic insulin secretion or inefficient use of insulin by the body. Patients with insulin-dependent (type 1) diabetes or insulin-requiring non-insulin-dependent (type 2) diabetes require chronic treatment with exogenous insulin. To calculate the insulin dose needed to manage their blood glucose levels, these patients perform self-monitoring of blood glucose (SMBG) using samples obtained by fingersticks; however, frequent SMBG may not detect all significant deviations in blood glucose, particularly in patients with rapidly fluctuating glucose levels. As a result, some patients who perform multiple daily fingersticks may fail to detect glucose excursions above or below the desired range, especially when glucose fluctuations occur at night. The continuous glucose monitoring (CGM) systems currently approved by the Food and Drug administration (FDA), the MiniMed® Continuous Glucose Monitoring System (CGMS), the MiniMed Guardian® REAL-Time System, the MiniMed Paradigm® REAL-Time System, the GlucoWatch® Automated Biographer, and DexCom™ STS® have 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 and DexCom 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

Real time – Dexcom G6 : Real-time CGM devices measure and transmit glucose values every five minutes. All of the real-time CGM devices alert (alarm) for hypoglycemia or hyperglycemia. The immediate feedback of glucose results allows timely intervention for rising or low/decreasing glucose levels to aid management and avert serious hypoglycemic events. Glucose values can be automatically and securely shared with a clinician via mobile medical glucose-monitoring applications downloaded on to a mobile device, such as a smartphone and web-based diabetes-management software [41]. Many CGM devices also allow individuals to share their glucose data in real time with friends, relatives, or caregivers using a smartphone app. This feature may be particularly important to alert caregivers and friends when an individual has hypoglycemia.

Requirements for confirmatory fingerstick glucose measurements (for calibration and/or prior to making treatment decisions) vary with the CGM device. Some devices are factory calibrated, but other real-time CGM devices still require some blood glucose monitoring (BGM) testing for calibration. Several devices do not require fingerstick glucose determinations for confirmatory measurements prior to making insulin dosing decisions , whereas others do.

BGM may also be needed during sensor warm-up periods, when glucose levels are rapidly changing, as well as when the patient suspects hypoglycemia or sensor inaccuracies. In one study, using an older CGM device with an enhanced algorithm, CGM without confirmatory BGM was as safe and effective as using it with BGM

●**Intermittently scanned flash CGM** – Intermittently scanning CGM devices freestyle Libra measure glucose every minute and record measurements every 15 minutes. They can be worn for up to 14 days. To view recent glucose readings and trend arrows, the user swipes a reader over the sensor/transmitter, which is worn on the arm. Only the last eight hours of glucose readings are reported on the device or smartphone graph (ambulatory glucose profile). If the sensor is not scanned at least every eight hours, data are lost. The early model has no alarms for hyper- or hypoglycemia, and the person can use their smartphone as the "reader." In a later model, optional real-time glucose alarms are available. Fingerstick glucose determinations are not needed for calibration or confirmation of routine blood glucose values In the United States, the flash CGM is less expensive than real-time CGM devices

5.0 REVIEW OF THE LITERATURE:

INTC: June 2009: The Georgia Region has determined that in select patients with severe hypoglycemic unawareness, severe nocturnal hypoglycemia that is refractive to insulin dose changes or hypoglycemic seizures, coverage for CGM will be provided under the member's DME benefit. Requests for this device should be forwarded to QRM for review.

One Transmitter/ Receiver per member with 6 months of sensors.

Sensors are supplied monthly for 6 months. A review of usage is encouraged at month 5 prior to submitting for reauthorization at 6 months. Additional sensors to be reauthorized every 6 months at the discretion of the ordering endocrinologist.
Note: Medtronic MiniMed is FDA approved for ages 7 and above; DexCom is FDA approved for ages 18 and above.

6.0 REFERENCES:

Ncal and Scal Pediatric CGM Criteria

Member is less than 18 years of age and has all of the following:
1. Diagnosis of type I diabetes
2. Using insulin pump or multiple daily shot schedule - three or more shots daily
3. Currently self monitoring blood glucose testing at least 4 times daily
4. Have documented consistent visits with an endocrinologist every 3 months, over last 6 - 12 months and in between phone contact with diabetes educator.

And at least one of the following:
1. Children with hypoglycemia unawareness - hypoglycemia requiring assistance from an adult and/or Inj Glucagon or visit to ER within the last three months.

2. Nocturnal hypoglycemia refractory to insulin dose changes.
3. Seizure associated with Hypoglycemia - one or more episode in last 6 months.
4. Difficulty in accomplishing the target A1C, in a setting of motivated family and child in spite of working closely with endocrinologist and diabetes educator over the last 6 months.

Clinical Review:
Requires order by a pediatric endocrinologist.
Usage Guidelines:
One Transmitter/ Receiver per member with 6 months of sensors.
Sensors are supplied monthly for 6 months. A review of usage is encouraged at month 5 prior to submitting for reauthorization at 6 months. Additional sensors to be reauthorized every 6 months

American Diabetes Association

Children and Adolescents: *Standards of Medical Care in Diabetes—2019*

1. American Diabetes Association
Diabetes Care 2019 Jan; 42(Supplement 1): S148-S164. https://doi.org/10.2337/dc19-S013

- **13.19** Continuous glucose monitoring should be considered in all children and adolescents with type 1 diabetes, whether using injections or continuous subcutaneous insulin infusion, as an additional tool to help improve glucose control. Benefits of continuous glucose monitoring correlate with adherence to ongoing use of the device. **B**
- **13.20** Automated insulin delivery systems appear to improve glycemic control and reduce hypoglycemia in children and should be considered in children with type 1 diabetes. **B**
- **13.21** An A1C target of <7.5% (58 mmol/mol) should be considered in children and adolescents with type 1 diabetes but should be individualized based on the needs and situation of the patient and family. **E**

Approval

Luke Beno, MD
Physician Program Director, Quality Resource Management

Date

Date