HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Continuous Glucose Monitor (CGM)

Policy MP-008

Origination Date: 06/21/2018

Reviewed/Revised Date: 08/28/2024

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Current Effective Date: 10/28/2024

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

The American Diabetes Association (ADA) defines the continuous glucose monitoring system as "a method of continuously following glucose levels in the interstitial fluid as a base for improving metabolic control. This includes increasing time in the target glucose range by reducing hyperglycemia and minimizing the occurrence of low glucose values (including symptomatic hypoglycemia)."

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans may cover non-implantable continuous glucose monitors (CGM) in limited circumstances when coverage standards met.

Coverage Requirements:

A. **Members with Diabetes mellitus, Type 1**

i. Member at least 2 years old;

ii. Documentation of at least 1 visit with a provider treating their diabetes during the six months prior to initiation;

iii. Meets one or more of the following criteria while on a multiple daily injection insulin:

a) Glycosylated hemoglobin levels (HbA1c) greater than 8%;

b) Recent history (within the last six months) of significant, recurring hypoglycemia (less than 60mg per deciliter or requiring assistance);

c) Wide fluctuations (well above and below set glycemic targets) in blood glucose before and after meal times, despite appropriate adjustment of doses;

d) At least one documented incidence of hyperglycemic hyperosmotic syndrome or diabetic ketoacidosis within the previous six months;

B. **Members with Diabetes mellitus, Type 2:**

i. Documentation of at least 1 visit with a provider managing their diabetes during the six months prior to initiation;

ii. Meets one or more of the following criteria while on a multiple daily injection insulin:

a) Glycosylated hemoglobin levels (HbA1c) greater than 8%;

b) Recent history (within the last six months) of significant, recurring hypoglycemia (less than 60mg per deciliter or requiring assistance);

c) Wide fluctuations (well above and below set glycemic targets) in blood glucose before and after meal times, despite appropriate adjustment of doses;

d) At least one documented incidence of hyperglycemic hyperosmotic syndrome or diabetic ketoacidosis within the previous six months.

C. **Gestational Diabetes**

i. Patients with gestational diabetes or diabetes during pregnancy are exempted from previous management provisions of this policy and are eligible for CGM coverage during the pregnancy.

D. <u>Covered Preferred Products (on pharmacy benefit only, not covered as medical benefits):</u>

i. Dexcom G6, Dexcom 7

ii. Freestyle Libre1, 2 and 3 systems

E. <u>Covered Nonpreferred Products Covered (only on medical benefit):</u>

i. Medtronic Enlite

ii. Medtronic Guardian

F. Noncovered Products:
    i. Dexcom G4
    ii. Dexcom G5
    iii. Eversense implantable CGMS

G. Renewals:
    i. Patients must have had at least 1 visit with a provider managing their diabetes within the previous 12 months;
    ii. Hemoglobin A1c levels must have been within the previous year;
    iii. Documentation must show that the member is adhering to the treatment plan outlined by a diabetes specialist.

H. Exclusions:
    i. Member younger than age 2 years;
    ii. Members who require exceeding 4 grams of acetaminophen per day routinely
        a) Prior use of samples will not be considered in the determination of a member's eligibility for coverage for this medication.

Reauthorization Criteria:

For individuals previously using or authorized for CGMS, ongoing authorization will be considered when the following criteria must be met (All):

A. Documentation supports active and routine use of device
B. Documentation supports use of device has resulted in improved diabetic management manifested by any one of the following:
    i. Hemoglobin A1c within target range
    ii. Improvement and maintenance of improvement in HgbA1c since onset in use of CGM
    iii. Reduction in hypoglycemic episodes requiring intervention
    iv. Reduction in hospitalization or ER usage due to consequences of high or low blood sugars
    v. Meaningful improvement of time in a normal glycemic range

U of U Health Plans does NOT cover implantable continuous glucose monitors (CGM) systems (e.g. Eversense® CGM System) as they are considered investigational.

2. **Medicaid Plans**
   Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

   CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

A review of literature performed in January 2012 identified 2 systematic reviews and 17 peer-reviewed articles since the last review performed in 2004. After review of the supportive articles, especially the Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring Study (Beck et al), the following is a summation of specific patient groups who may benefit from a CGM.

It would seem clinically apparent that glucose measurement every 5 minutes in patients with type 1 diabetes would enhance glucose control and avoid potentially life threatening hypoglycemic events. The evidence in multiple randomized studies demonstrates limited clinical improvement except in adult type 1 patients over the age of 25. This age group demonstrated a decline of A1C by 0.53%. Unfortunately, children and adolescents did not have improvement A1C levels. Hypoglycemia in most of the studies did not show changes in frequency. In the STAR-1 trial severe hypoglycemic rates were higher in the CGM group.

As CGM relates to improvement in hypoglycemic awareness, supporters of CGM report that hypoglycemia with the use of CGM in compliant patients was 11.2 events per 100 patient years over the 12 months of the JDRF CGM study compared with 86 per 100 patient-years in the Diabetic Control and Complication Trail (DCCT). Surprisingly most CGM studies were not powered to demonstrate a lowering of hypoglycemic rates. Most focused on A1C reduction as the target for efficacy. It appears, as illustrated in the article by Battelino et al., that hypoglycemia in type1 diabetic patients with A1C <7.5 may attain enhanced diabetic control without an increase in hypoglycemic events by using a CGM.

The key article which highlights the discrepancy in results from CGM in the medical literature is the sub-analysis of the JDRF study by Beck et al. This article demonstrated that success with CGM in A1C reduction was determined by the duration the CGM was worn. The goal is >6 days /week use. All patients who succeeded in this goal achieved improvement in the A1C.

From Beck et al.'s analysis, 2 factors seemed to determine the frequency of success for the duration of CGM use; 1) the age of the patient and 2) the frequency of SMBG testing prior to initiation of the CGM. In subjects with baseline A1C >7.0% "Daily use after 6 months was strongly associated with age, with 83% of subjects >25 years sustaining CGM use >6 days /week compared with 30% of subjects 15-24 years and 50% of subjects 8-14 years. After adjustment for age, the only other baseline factor associated with successful use after 6 months was the frequency of self-reported pre-study daily blood glucose meter measurements. Subjects in all age groups who performed >6 meter measurements/day were

more likely to use the CGM on a near-daily basis than those who were monitoring fewer times per day". The outcome ratio was 1.0 for testing 3-5 times per day, 3.64 for 6-8 times per day and 4.16 for testing >9 times per day.

This Beck et al. article further goes on to summarize the potential gains and risks associated with CGM, noting CGM may be a powerful tool if used consistently. The age of the patient and frequency of pre-monitor SMBG appear predict those patients who have the most to gain from this technology.

With regard to the question of the clinical utility of CGM in patients with type 2 diabetes as discussed in the systematic reviews, A1C reductions may occur in type 2 diabetic patients who use CGM. The articles supporting CGM use have different goals and the types of enrollees are not consistent within the type 2 diabetic studies. Some of the studies include patients who are not on insulin. The studies were also typically of short duration. The American Association of Clinical Endocrinologists (AACE) and the American Diabetes Association (ADA) recommended further studies to predict success and compliance with the device to determine what patients have the most to gain clinically.

Another frequent use promoted for CGM is during pregnancy. Continuous glucose monitoring (CGM) personal systems during pregnancy has limited literature to support its use. Articles by Hawkins and Murphy et al., acknowledged CGM was useful in reducing the rates of fetal overgrowth and gestational weight gain. However, determining the optimal frequency and timing of CGM was not established. Professional (office-based or ambulatory) CGM has identified previously unknown hyperglycemia in pregnant women who have both gestational and type 1 diabetes. The AACE recommends that all pregnant women with type 1 diabetes to receive professional CGM. Women with type 2 diabetes are typically able to maintain adequate glucose control if they are adherent to a monitoring schedule requiring 6 SMBG readings per day. For these patients, CGM may facilitate treatment adherence, but its use is not absolutely indicated.

On March 27, 2018 the FDA created a new category of class II integrated CGM (iCGM) devices for 510(k) approval. The G6 CGM has been approved as the first 10-day non-adjunctive factory-calibrated system for ages 2 and older.

In June of 2018, the Eversense Continuous Glucose Monitoring system, a new prescribed CGM system, received FDA approval. This system is indicated for 90 day continuous use for adults (18 and up) and is intended to compliment, not replace finger stick blood glucose monitoring. The sensor is inserted and removed by a physician. The intentions are to provide real-time glucose readings, glucose trend information, and alerts for the detection and prediction of low and high blood glucose.

In summary, the current literature related to the impact CGM is expansive but diffuse. It identifies subpopulations of diabetics such as type 1 diabetics of certain ages which seem to obtain benefit and others who seemingly do not, e.g. gestational diabetes for personal CGM monitors. Many questions remain unanswered.

Applicable Coding

CPT Codes

95249 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

95250 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor

95251 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report

Not Covered-Investigational

0446T Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training

0447T Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision

0448T Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

HCPCS Codes

A4239 Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service

A9276 Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply

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

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

S1035 Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system

S1036 Transmitter; external, for use with artificial pancreas device system

S1037 Receiver (monitor); external, for use with artificial pancreas device system

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