Purpose:
To address Continuous Glucose Monitoring (CGM) systems and describe the criteria used to determine coverage decisions.

Policy Statement:
Based on [client] medical necessity criteria and review of the peer-reviewed literature, [client] has determined that CGM is medically necessary for members with diabetes who meet the selection criteria (see Medical Criteria below). [client] considers CGM a supplement to standard self-monitoring of blood glucose (SMBG) and medically necessary when identification of trends and patterns in glucose levels over time will serve to optimize glycemic control and reduce hypoglycemia in insulin-dependent diabetics.

Definitions:
Professional CGM: Professional CGM uses provider owned equipment and is considered medically necessary, as an adjunct to standard care, when a provider determines that such monitoring is necessary to establish optimal insulin regimens for members with insulin-requiring diabetes and inadequate glycemic control despite compliance with frequent self-monitoring. Results must be monitored and interpreted under the provider's supervision.

Personal CGM: Personal CGM uses equipment purchased for an individual member and is considered medically necessary for members with type 1 diabetes, including pregnant women with poorly controlled type 1 diabetes, when such monitoring is necessary to detect trends and patterns in glucose levels over time, optimize glycemic control, and reduce hypoglycemia. Personal CGM is not considered medically necessary for individuals with type 2 diabetes or pregnant women with gestational diabetes, as there is limited evidence that the use of such monitoring leads to improved glycemic control.

HbA1c: Glycosylated Hemoglobin Test. Hemoglobin, a protein within red blood cells that carries oxygen throughout your body, joins with glucose in the blood and becomes 'glycosylated'. This test is designed to identify a three-month average plasma glucose concentration.

Prerequisites:
Personal CGM systems require prior authorization. The combined use of a continuous glucose monitor and an external insulin pump require prior authorization of both devices (see Insulin Infusion Pumps Policy). Standard diabetic equipment and supplies are provided in accordance with [client] formulary and do not require prior authorization.

Professional CGM systems do not require prior authorization when ordered by the provider according to the medical necessity definition (above) for up to 72 hours as a diagnostic test. Providers who bill for professional CGM (CPT codes 95250 & 95251) are reimbursed up to a maximum of 4 times per year per member.

Special Features:
[client] will only reimburse for a basic CGM. If a member chooses to purchase a CGM with additional or special features (e.g., talking device), the member will be responsible for the cost of the additional/special features in full. [client] will authorize coverage of these additional/special features only if they are listed in the prior authorization request and [client] determines that they are reasonable and medically necessary due to a member's particular co-morbidity (e.g., vision

impairment). Specifically, there must be clear and compelling evidence that the added features are expected to directly contribute towards improvement in the member's glycemic control or reduction in the incidence of hypoglycemia.

Repair and Replacement:
For information regarding the repair and replacement of CGM, refer to the Evidence of Coverage for Durable Medical Equipment (DME). Replacement of purchased equipment is not covered when damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.).

An upgrade to a new CGM is considered medically necessary when the warranty of the old CGM expires and it is malfunctioning. Only then, when appropriately ordered by the endocrinologist, will it be covered according to the member's coverage allowance. [client] authorizes replacement of a personal CGM device with a comparable device when **all** the following are met:

1. The member continues to require insulin injections at least 3 times per day or uses an insulin pump for maintenance of blood glucose control; and
2. The endocrinologist recommends continued use of a CGM for the member with type 1 diabetes attesting to the benefit of CGM as a supplement to SMBG for the member; and

When a new CGM is requested with additional or special features (e.g., talking device) the member will be responsible for the cost of the additional/special features in full unless specific criteria are met (see Special Features above).

Medical Criteria

[client] authorizes FDA-approved personal CGM systems when medical record documentation from the practitioner managing the member's diabetes confirms that the member with type 1 diabetes is capable of using a long-term CGM system, and meets the following criteria:

I. The member requires insulin injections at least 3 times per day, or uses an insulin pump, for maintenance of blood glucose control; and
II. The member is compliant with the ordered diabetic treatment plan including regular SMBG (at least four times a day) and multiple alterations in insulin administration regimens; and
III. The member has completed a diabetes education program within the past 12 months sufficient to independently operate the CGM device; and
IV. The member has experienced ONE of the following while on multiple daily injections (minimum of 3 injections per day) of insulin:
    a. Hypoglycemic unawareness characterized by one of the following:
        - Recurrent, severe bouts of hypoglycemia defined as a disabling episode requiring assistance of another individual to manage; or
        - Neuroglycopenic symptoms (abnormal mentation, ataxia, confusion, difficulty speaking, stupor) as the first manifestation of hypoglycemia as opposed to neurogenic symptoms (shakiness, anxiety, tremulousness, palpitations, sweating, hunger);
        - Frequent nocturnal hypoglycemia; or
    b. Elevated glycosylated hemoglobin level (HbA1c greater than 7.0% for the latest two consecutive tests); or
    c. Recurring hypoglycemia (less than 50 mg/dL); or
    d. Severe glycemic excursions (e.g., <50 mg/dl or >150 mg/dL and judged to be excessive, potentially disabling, or life-threatening).

Special Considerations:

I. Children and adolescents with type 1 diabetes mellitus: [client] authorizes FDA-approved personal CGM systems when the endocrinologist managing the member's diabetes confirms that the member or caregiver is capable of using a long-term CGM system, and ONE of the following:
    a. The member has achieved HbA1c levels below 7.0%, and the CGM device is medically necessary to limit the risk of hypoglycemia; or
    b. The member with HbA1c levels greater than 7.0% is willing and able to use the CGM device on a daily basis.

II. Pregnancy: [client] authorizes coverage for FDA-approved personal CGM systems when the member is diagnosed with type I diabetes mellitus and meets the selection criteria (see Medical Criteria above). Pregnant members with type 2 diabetes mellitus or gestational diabetes mellitus are typically able to maintain adequate glucose control with SMBG. Although CGM may facilitate treatment adherence, its use is not absolutely indicated. According to the 2016 Consensus Statement of the American Association of Clinical Endocrinologists and the American College of Endocrinology on CGM, further research is needed regarding its use for those with type 2 or gestational diabetes.

III. Combined CGM and External Insulin Infusion Pump: [client] authorizes coverage for a personal CGM device (sensor/transmitter) with wireless communication to a compatible external insulin pump when **all** the following are met:
   a. Criteria for a personal CGM (see Medical Criteria above) are met; and
   b. The endocrinologist has determined that an external insulin infusion pump is medically necessary for the individual member; and
   c. Criteria for an external insulin pump (see policy on Insulin Pump Infusion) are met.

Exclusions:

I. [client] does not authorize coverage for personal CGM systems in the following situations:
   a. When the Medical Criteria (above) are not met, including for members without a diagnosis of diabetes following gastric bypass surgery.
   b. For members with type 2 diabetes or for pregnant women with gestational diabetes.
   c. Personal CGM systems that are considered investigational and unproven, including single closed-loop systems (combined external insulin pumps and continuous blood glucose monitors) that do not require direct patient interaction.
   d. Artificial pancreas systems, including (but not limited to) closed-loop monitoring devices with low glucose suspend (LGS) features.

Initial Authorization:

I. Initial approval shall be for a one-time purchase of a continuous glucose monitor. Initial approval for associated medical supplies shall be for a period up to one year based on medical necessity.

Continued Coverage:

I. Continued coverage of the continuous glucose monitor and supplies will require that the member continues to require insulin injections at least 3 times per day or uses an insulin pump for maintenance of blood glucose control and that the prescribing endocrinologist recommends continued use of a CGM for the member with type 1 diabetes attesting to the benefit of CGM as a supplement to SMBG for the member.
II. Submitting documentation of continued medical necessity for the continuous glucose monitor is required by the treating practitioner at least once every 12 months. Reauthorization for associated medical supplies shall be for a period up to one year based on medical necessity.
III. For newly enrolled members, [client] will provide a one-time 3-month fill of continuous glucose monitoring supplies without requiring documentation of treating provider visits or a document of medical necessity.

Background:
Diabetes may develop at any age. Type 1, type 2, and gestational diabetes are the three main categories used to classify diabetes. Type 1 diabetes, formerly called juvenile diabetes or insulin-dependent diabetes, is usually first diagnosed in children, teenagers, or young adults. With this form of diabetes, the beta cells of the pancreas no longer make insulin because the body's immune system has attacked and destroyed them.

Diabetes mellitus is one of the leading causes of death in the United States. If poorly controlled, diabetes can lead to complications such as heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, nerve damage and impotence. In gestational diabetes, fetal and maternal health can be compromised.

Improved glycemic control has been shown to slow the onset or progression of major complications. Management of diabetes involves efforts to maintain blood glucose levels near the normal range. Currently, self-monitoring of blood glucose (SMBG) and laboratory testing of glycosylated hemoglobin (HgbA1c) to measure longer term glycemic control are the standard methods for glucose testing.

Some patients who have insulin deficiency develop a "dawn phenomenon", which is an increase in plasma glucose levels in the early morning hours, usually between 4:00 – 9:00 AM. The insulin requirement increases with the physiologic rise in cortisol and growth hormone levels. Thus, a larger dose of insulin is required to control the plasma glucose. If inadequate insulin is available, the plasma glucose rises. With CGM, the need for additional insulin can be identified and additional insulin can be injected at this time. Frequently, a 100-150% increase in the basal rate is required during this time period.

Type 1 Diabetes
The American Diabetes Association (2017) states that the use of CGM may improve glycemic control when used as an adjunct to self-monitoring in persons with insulin-dependent diabetes without increasing the risk of hypoglycemic episodes. Continuous glucose monitoring (CGM) devices continuously monitor and record interstitial fluid glucose levels and have three components: a disposable subcutaneous sensor, transmitter and monitor. Some CGM systems are designed for short-term diagnostic or professional use. These devices store retrospective information for review at a later time. Other CGM systems are designed for long-term patient use and display information in real-time allowing the patient to take action based on the data. Glucose measurements provided during continuous monitoring are not intended to replace standard self-monitoring of blood glucose (SMBG) obtained using fingerstick blood samples but can alert patients of the need to perform SMBG. These long-term devices are available with or without an integrated external insulin pump. Remote glucose monitors provide real-time nocturnal glucose information and are able to transmit/receive information wirelessly.

Floyd et al, (2012) compared continuous glucose monitoring (CGM) in patients with type 1 diabetes to self-monitoring of blood glucose (SMBG) in a meta-analysis of fourteen randomized controlled trials. The use of CGM was associated with a greater reduction in HbA1c compared to SMBG. Although the number of hypoglycemic events was not significantly different between the two groups the duration of hypoglycemia was shorter for the CGM group.

Type 2 Diabetes

There is insufficient data to conclude whether CGM results in improved glycemic control or reduced hypoglycemic events for members with type 2 diabetes. Type 2 diabetes, formerly called adult-onset diabetes or noninsulin-dependent diabetes, is the most common form of diabetes. People can develop type 2 diabetes at any age, even during childhood. This form of diabetes usually begins with insulin resistance, a condition in which fat, muscle, and liver cells do not use insulin properly. At first, the pancreas keeps up with the added demand by producing more insulin. In time, however, it loses the ability to secrete enough insulin in response to meals.

C-peptide is measured to tell the difference between insulin produced by the body and insulin injected into the body. When the pancreas produces insulin, it starts off as a large molecule. This molecule splits into two pieces: insulin and C-peptide. The function of C-peptide is not known. The C-peptide level may be measured in a patient with type 2 diabetes to see if any insulin is still being produced by the body. It may also be measured in cases of hypoglycemia (low blood sugar) to see if the person's body is producing too much insulin.

Hoeks et al. (2011) evaluated seven randomized controlled trials examining the effect of real-time continuous glucose monitoring systems in diabetes management. They concluded that continuous glucose monitoring has a beneficial effect on glycemic control in adult patients but that specific patient groups including pregnant patients and those with type 2 diabetes are lacking.

Pregnancy
Some women develop gestational diabetes during the late stages of pregnancy. Although this form of diabetes usually resolves after the baby is born, it places a woman at higher risk of developing type 2 diabetes later in life. Gestational diabetes is caused by the hormones of pregnancy or a shortage of insulin.

Macrosomia defined as those infants > 90th percentile of weight for gestational age or sex, or >2 SD above the mean of a normal population of newborns is the most common neonatal complication associated with diabetes during pregnancy. Macrosomia is secondary to hyperglycemia and in pregnant women with type 1 diabetes mellitus, using CGM to prevent hyperglycemia may help diminish the risk of macrosomia.

The Consensus Statement by the American Association of Clinical Endocrinologists and the American College of Endocrinology on CGM has recommended that all adults with type 1 DM (including pregnant women) should be considered for CGM. Women with type 2 DM or insulin-requiring GDM may benefit from CGM, but further research is needed.

Reimburses Without Prior Authorization:

CPT:	95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
	95251	CGM Data Interpretation

Requires Prior Authorization:

HCPCS:	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

Coding:

ICD 10:	E10.10-E10.9	Type 1 diabetes mellitus (code range)
	O24.011-O24.019	Pre-existing diabetes mellitus, type 1, in pregnancy (code range)
	O24.03	Pre-existing diabetes mellitus, type 1, in the puerperium

References:

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Hoeks LB, Greven WL, de Valk HW. Real-time continuous glucose monitoring system for treatment of diabetes: a systematic review. Diabet Med. 2011 Apr;28(4):386-94.

Related Policies:

Insulin Infusion Pumps

Related Materials:

Evidence of Coverage: Durable Medical Equipment