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Clinical Policy ID:	CCP.1366

Clinical Policy Title: **Continuous glucose monitoring**

Policy Contains: Continuous interstitial glucose monitoring; diabetes mellitus; self-monitoring of blood glucose.

About this policy:

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

COVERAGE POLICY:

AmeriHealth Caritas considers the use of a U.S. Food and Drug Administration-approved continuous glucose monitoring device to be clinically proven and, therefore, medically necessary under the following conditions:

A. AmeriHealth Caritas considers the short-term use (72 hours to seven days) of a Food and Drug Administration-approved continuous glucose monitoring device (Dexcom G4®, Dexcom G5®, Dexcom, San Diego, California) for the detection of patterns and trends in glucose levels to be clinically proven and, therefore, medically necessary for members who are either ≤ age 17 or who are pregnant or on dialysis, who have received diabetes self-management education and instruction from an expert in the management of diabetes, and when at least one of the following criteria are met (American Diabetes Association, 2018):
   - For members with diabetes mellitus (diabetes) who are currently using an insulin pump in their diabetes care and have a documented average of three or more glucose self-tests per day during the previous month.
   - For members with gestational diabetes, for the purpose of identifying glucose excursions and making adjustments to an individual's diabetic treatment plan.
   - In members with diabetes refractory to self-monitored blood glucose testing who have documented experiences of frequent wide glycemic swings (e.g., hypoglycemic unawareness or ketoacidosis) or frequent diabetic complications.

AmeriHealth Caritas considers the short-term (72 hours to one week) diagnostic use of continuous glucose monitoring devices medically necessary in members with symptoms suggesting recurrent hypoglycemia for the diagnosis of primary islet cell hypertrophy (nesidioblastosis) or persistent hyperinsulinemic hypoglycemia of infancy (congenital hypoglycemia).

B. AmeriHealth Caritas considers the short-term use (72 hours to seven days) of a Food and Drug Administration-approved continuous glucose monitoring device (Freestyle Libre Pro®, Abbott Laboratories, Abbott Park, Illinois) for the detection of patterns and trends in glucose levels to be clinically proven and, therefore, medically necessary for members ages ≥ 18 and not pregnant or on dialysis, who have received diabetes self-management education and instruction from an expert in the management of diabetes, and when at least one of the following criteria are met (American Diabetes Association, 2018):
   - For members with diabetes who are currently using an insulin pump in their diabetes care and have a documented average of three or more glucose self-tests per day during the previous month.
   - In members with diabetes refractory to self-monitored blood glucose testing who have documented experiences of frequent wide glycemic swings (e.g., hypoglycemic unawareness or ketoacidosis) or frequent diabetic complications.

   AmeriHealth Caritas considers the short-term (72 hours to one week) diagnostic use of continuous glucose monitoring devices medically necessary in members with symptoms suggesting recurrent hypoglycemia for the diagnosis of primary islet cell hypertrophy (nesidioblastosis).

C. AmeriHealth Caritas considers the long-term use of an Food and Drug Administration-approved continuous glucose monitoring device (Dexcom G4®; Dexcom G5®; Dexcom G6®) to be clinically proven and, therefore, medically necessary for the detection of patterns and trends in glucose levels when all of the following criteria are met (American Diabetes Association, 2018; Centers for Medicare & Medicaid Services, 2018; Peters, 2016):
   - Member has type 1 diabetes.
   - Member is at least 2 years old and under 19 years old.
   - Despite the member consistently measuring glucose ≥ 4 times per day and injecting insulin or receiving insulin via a pump ≥ 3 times per day, the insulin dose must be adjusted frequently.
   - Continuous glucose monitoring is used in conjunction with intensive insulin regimens.
   - The member and family of pediatric members have received diabetes self-management education and instruction from an expert in the management of diabetes.
   - Either:
     - A pattern of recurrent (at least two events within a 30-day period), severe hypoglycemic events (i.e., blood glucose < 50mg/dL) despite appropriate modifications in insulin therapy and member compliance.
     - A history of hypoglycemic unawareness that requires the intervention of another person for resuscitative actions (e.g., glucagon administration).

D. AmeriHealth Caritas considers the long-term use of a Food and Drug Administration-approved continuous glucose monitoring device (Freestyle Libre®) to be clinically proven and, therefore, medically necessary for the

detection of patterns and trends in glucose levels when all of the following criteria are met (American Diabetes Association, 2018; Centers for Medicare & Medicaid Services, 2018; Peters, 2016):

- Member has diabetes.
- Member is at least 18 years old.
- Despite the member consistently measuring glucose ≥ 4 times per day and injecting insulin or receiving insulin via a pump ≥ 3 times per day, the insulin dose must be adjusted frequently.
- Continuous glucose monitoring is used in conjunction with intensive insulin regimens.
- Member has received diabetes self-management education and instruction from an expert in the management of diabetes.
- Either:
  - A pattern of recurrent (at least two events within a 30-day period), severe hypoglycemic events (i.e., blood glucose < 50mg/dL) despite appropriate modifications in insulin therapy and member compliance.
  - A history of hypoglycemic unawareness that requires the intervention of another person for resuscitative actions (e.g., glucagon administration).

Requests for coverage for other continuous glucose monitoring devices and for use outside of the above delimited age groups will be reviewed on an individual basis.

LIMITATIONS:

The Freestyle Libre and Dexcom G6 are not recommended during pregnancy, or in members who are receiving dialysis or who are critically ill.

- All other uses of short- and long-term continuous glucose monitoring are considered experimental/investigational and therefore not medically necessary.
- The recommended monitoring period is 72 hours; monitoring for less than 24 hours is not medically necessary.
- Short-term continuous glucose monitoring must be reported only once per monitoring period, regardless of the number of days involved.
- For long-term continuous glucose monitoring, member (or family of pediatric member) must demonstrate the ability to use a continuous glucose monitoring device on a *nearly* daily basis in conjunction with intensive insulin regimens.
- For Freestyle Libre and Dexcom G6, the member must have seen the prescribing provider within the previous six months and follow up within the next six month period.
- Remote continuous glucose monitoring devices, accessories, and additional hardware or software are ancillary to continuous glucose monitoring and are not considered medically necessary.
- Continuous glucose monitoring is not medically necessary for individuals who are unable or unwilling to perform any necessary calibration of a continuous glucose monitoring device, which may include self-monitored blood glucose at least twice per day, or when symptoms do not match device readings, or who do not maintain contact with their health care professionals.

ALTERNATIVE COVERED SERVICES:

- Serum glucose monitoring.

BACKGROUND:

In 2015, nearly 10 percent of the United States population, or 30.3 million individuals, had diabetes mellitus (National Center for Chronic Disease Prevention and Promotion, Division of Diabetes Translation, 2017). Diabetes was the seventh-leading cause of death, and a major contributor as an underlying cause of death. It is estimated that the total costs of diagnosed diabetes were $245 billion in 2012, which included $176 billion for direct medical costs and $69 billion in reduced productivity. It is crucial to more effectively prevent diabetes and to better manage disease in those who have been diagnosed.

Glycemic control is fundamental to the medical management of diabetes mellitus. Tools that assist with glucose monitoring and trending play an important role in managing diabetes and avoiding or limiting diabetic complications attributed to blood sugar levels that are too high or too low. Self-monitoring of blood glucose allows a person with diabetes to evaluate whether target glucose levels are being reached, to decide whether treatment is needed, and to evaluate the response to treatment (American Diabetes Association, 2018). Traditional finger stick serum glucose monitoring provides individuals with diabetes an immediate serum glucose level reading and can be used to measure variations throughout the day and to regulate insulin dosing. For many, it is necessary to perform six to eight (or more) finger sticks a day. Hemoglobin A1C tests, performed in a provider's office, measure the attachment of glucose to hemoglobin, which reflects the average of a person's blood glucose levels over the previous three months, thereby estimating overall glucose trends. Among persons with type 1 diabetes, there is an association between higher frequency of self-monitoring of blood glucose and lower hemoglobin A1C levels and lower frequency of acute complications among all age groups, for those who inject insulin and those who use insulin pumps (Miller, 2018). However, traditional self-testing of serum glucose with finger sticks is associated with several adherence barriers, which include the need to stick one's finger with a needle a few to several times a day and to carry bulky equipment (Shah, 2015). New technologies have been developed to attempt to address these barriers.

Continuous glucose monitoring has been developed to measure interstitial glucose levels and reveal glucose level trends (National Institute of Diabetes and Digestive and Kidney Diseases, 2017). Continuous glucose monitoring devices measure glucose either minimally invasively through continuous measurement of interstitial fluid by a sensor implanted under the skin or noninvasively by applying electromagnetic radiation through the skin to blood vessels in the body. Results are available to the patient in real time or retrospectively. Some devices require daily calibration via finger stick and, because interstitial glucose measurements are slower to react to dietary intake than capillary serum, it may still be necessary to take a confirmatory serum sample with a finger stick to determine whether there is a need for insulin.

Continuous glucose monitoring generally has three main components: an external receiver (monitor), an external transmitter, and a disposable subcutaneous sensor. The sensor coating wears off over a period that varies by device, after which it must be replaced. In early-generation devices, the sensors are implanted in the abdomen or on the lower back for three to seven days; newer devices allow the sensor to be placed on the upper arm. Interstitial glucose levels are sent from the sensor to the receiver in one- to five-minute intervals. The transmitter may also be an insulin pump. Newer systems may allow the transmitter to be a cellular telephone with a dedicated software application. The glucose values are read on the receiver (monitor). Data from continuous interstitial glucose monitoring may be stored in the

device. Some devices cause an alarm to sound as an alert that the individual may be experiencing a potentially harmful, sudden fluctuation in blood sugar level. Some can be customized; each user may alter the threshold settings to detect high and low glucose levels that trigger the alarm.

A short-term continuous glucose monitoring device is temporarily lent to an individual to gather information for their treating professional health care provider to use to formulate a personalized treatment plan. Short-term continuous glucose monitoring provides occasional rather than ongoing testing. Long-term continuous glucose monitoring is used on an almost daily basis for ongoing diabetes management. The individual using continuous glucose monitoring takes an active, collaborative role with their professional health care provider to develop a diabetes care plan. The plan should include updates on the use of continuous glucose monitoring and contain targeted, personalized goals and outcomes. It should also reflect the individual's active role in his or her current diabetes management status. Both types of continuous glucose monitoring devices may be used to monitor unexplained glycemic excursions and episodes of hypoglycemic unawareness. If not addressed, hypoglycemia may cause complications such as seizures, diabetic coma, or brain damage.

FINDINGS:

This policy is based on numerous professional guidelines and published evidence regarding multiple devices as well as current Medicare policy.

Overview of devices

In 2015, the U.S. Food and Drug Administration expanded the use of the Dexcom G4® Platinum Continuous Monitoring System (Dexcom Inc., San Diego, California) for patients with diabetes ages 2 to 17 years; prior approval had been limited to persons over 18 years of age. This was the first continuous interstitial glucose monitoring system approved for use in children and adolescents and includes the upper buttock in addition to the abdomen as sensor insertion sites. The U.S. Food and Drug Administration cautioned that the pivotal clinical study serving as the basis for approval demonstrated lower accuracy in pediatric subjects than in adults, but that the health benefits outweighed the risks.

In 2016, the U.S. Food and Drug Administration (2016a, 2016b) approved the first continuous interstitial glucose monitoring system that can be used to make diabetes treatment decisions without confirmation with a traditional finger stick test (i.e., non-adjunctive use): the G5® Mobile Continuous Glucose Monitoring System (Dexcom Inc., San Diego, California). The Dexcom G5 also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. The U.S. Food and Drug Administration concluded that the benefits of the device outweigh the probable risks, based on established clinical point and trend accuracy of the G5 when used as an adjunctive device and significant human experience using the device non-adjunctively to make treatment decisions. The G5 sensor must be replaced after 7 days when the coating wears off. The device still requires twice daily calibration with a blood glucose meter, compelling the user to have access to a blood glucose meter, and readings are affected by acetaminophen levels.

The Dexcom G6 (U.S. Food and Drug Administration, 2018a) does not require twice daily finger stick calibration. Finger sticks are only necessary if the user's symptoms do not match the readings. The G6 has a sensor which lasts 10 days and is not affected by acetaminophen. An accompanying applicator is used to insert the sensor. The transmitter, which lasts for three months, continually sends the data read by the sensor to the display device, which may be a smartphone. The system has programmable alerts and alarms, and data, which are retained for 30 days, may be shared with caregivers. A publication authored by employees of Dexcom (Welsh, 2019) included an analysis of 10,000 individuals who switched from the G5 to the G6 that showed comparable outcomes which slightly favored the G6.

Recent technological developments in continuous interstitial glucose monitoring, known as intermittently viewed continuous interstitial glucose monitoring, or flash glucose monitoring, offer a streamlined method of collecting and analyzing glucose data. The FreeStyle Libre Flash Glucose Monitoring System (U.S. Food and Drug Administration, 2017), does not require an additional confirmatory finger stick after an abnormal reading to determine whether insulin is necessary, nor are finger sticks necessary for daily calibration. However, use of finger sticks is required during the first 12 hours after placing a new patch. Additionally, the system may alert the user that a finger stick is necessary to confirm the interstitial readings. The FreeStyle Libre uses an adhesive patch with a sensor of 0.2 inches that penetrates the skin. The sensor is applied to the upper arm.

The FreeStyle Libre sensor collects data every minute. To read the data, one holds a device the size of a smartphone near the patch (the application is currently available for smartphones in Europe), eliminating the need for a specialized peripheral receiver. The software provides the most recent reading and produces a graphic display of readings over the previous eight-hour period. Use of the software every eight hours provides 24 hours of readings. If the sensor is not scanned within eight hours, the previous eight hours of data are overwritten when next scanned. Each sensor lasts for 14 days (Adolfsson, 2018; U.S. Food and Drug Administration, 2018a). The FreeStyle Libre software does not automatically notify the user of readings that are outside of target range, nor does it send data to others, such as caregivers or health care providers. The sensor is said to be less painful to apply than the sensor used in previous generations of devices.

Because the G6 and the FreeStyle Libre do not require twice daily or confirmatory finger sticks in order to make insulin treatment decisions, they function as substitutes for standard blood glucose monitors and are categorized by the Centers for Medicare & Medicaid Services as therapeutic devices. The Centers for Medicare & Medicaid Services have approved coverage of the G6 and FreeStyle Libre for Medicare beneficiaries with type 1 or type 2 disease.

The Eversense® Continuous Glucose Measurement device (Senseonics, Germantown, Maryland) has been approved by the U.S. Food and Drug Administration (2018c) use in people ages 18 and over with diabetes. The Eversense device consists of three components (an implanted sensor, a transmitter, and a software application for mobile devices) that together provide glucose values and trends, and alerts when readings are out of target range. The sensor, which must be implanted by a provider, is designed to measure interstitial glucose and to last for 90 days before it must be replaced. (A version that lasts 180 days is available in Europe.) The sensor is read by a transmitter worn over the implant and attached with adhesive. The transmitter sends readings to the device's software application loaded on the wearer's mobile device, and vibrates when readings are out of range so that even if the mobile device is not nearby or is not turned on, the wearer will be alerted to the reading. The transmitter's battery is rechargeable and lasts for a year. The device must be calibrated twice daily using finger sticks.

Guidelines

Regarding the many devices available on the market, the most recent guideline from the American Diabetes Association (2018) stated that "due to significant differences between flash continuous glucose monitoring and other continuous glucose monitoring devices, more discussion is needed on outcomes and regarding specific recommendations." The guideline states that continuous glucose monitoring, used properly with intensive insulin regimens, is useful in lowering hemoglobin A1C levels in adults with type 1 disease who are not successful at achieving target glycemic levels (based on level A evidence). Continuous glucose monitoring may be a useful tool in those unaware of hypoglycemia and/or with frequent episodes of hypoglycemia (based on level C evidence). Individual readiness should be assessed before prescribing a continuous glucose monitoring device, and robust education, training, and support are necessary for optimum adoption and successful use (based on level E evidence).

The National Institute for Health and Care Excellence's (2017) Medtech Innovation Briefing notes the evidence that using the FreeStyle Libre for up to one year reduces the number of finger sticks and the time spent in hypoglycemia; states that it is uncertain how adults with poorly controlled type 1 diabetes would fare with use of the FreeStyle Libre, as only those with well-controlled type 1 disease were included in the randomized study of those with type 1 disease; and notes that the impact on resources will depend on the extent to which improving blood glucose control will translate into reducing complications, emergency admissions, and use of glucose test strips. The National Institute for Health and Care Excellence's recommendation is that rather than being offered routinely to adults with type 1 diabetes, continuous glucose monitoring should be considered for those with type 1 diabetes who are willing to commit to using it at least 70 percent of the time and to calibrate it as necessary and who, despite optimal use of conventional blood glucose monitoring and insulin therapy, still have one of a number of possible criteria.

The Endocrine Society's updated guidelines for continuous glucose monitoring in adults (Peters, 2016) recommend the following:

- Real-time monitoring in outpatients for those with type 1 disease and HbA1C levels above target levels.
- Real-time monitoring in those with well-controlled type 1 disease.
- Short-term, intermittent monitoring in type 2 disease, for those not on prandial insulin with A1C above target levels.
    - For all of the above, users must be willing and able to employ the devices on a nearly daily basis.

The Endocrine Society's guidelines for children, which have not been revised (Klonoff, 2011), recommend the following:

- Real-time monitoring with approved devices for children and adolescents with type 1 diabetes who have HbA1C levels below 7 percent to assist in maintaining target levels while limiting the risk of hypoglycemia; for children and adolescents with type 1 diabetes who have HbA1C levels of 7 percent or higher who are able to use these devices on a nearly daily basis.
- They made no recommendations for use by children under 8 years old.
- Short-term intermittent continuous glucose monitoring designed for retrospective analysis in children in whom there is a concern about nocturnal hypoglycemia, dawn phenomenon, and postprandial hyperglycemia; in those with hypoglycemic unawareness; and in those experimenting with changes to their diabetes regimen, including changing insulin types or transitioning to pump therapy from injections.

The American Association of Clinical Endocrinologists and American College of Endocrinology's most recent consensus statement (2016) includes the following recommendations for continuous glucose monitoring:

- In diabetes type 1, for pediatric and adult patients, especially among those with a history of severe hypoglycemia or hypoglycemia unawareness and to help correct hypoglycemia in those not at the desired level. Both groups should have an understanding of device and sensor use in order to adopt the technology effectively.
- In type 2 disease, among those receiving insulin, sulfonylureas, or glinides, consensus was that more data are needed. Among those with a low risk of hypoglycemia, there was no recommendation offered.
- In gestational diabetes, the recommendation was that continuous glucose monitoring may serve as a supplement to blood glucose monitoring, especially in monitoring nighttime hypoglycemia or hyperglycemia and postprandial hyperglycemia. The statement noted that the benefits of continuous glucose monitoring in pregnant women with preexisting diabetes are unknown.

Results from clinical research

Early data reviewed by the Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group suggested that adults and children with baseline HbA1C of 7.0 percent had outcomes combining HbA1C and hypoglycemia that favored continuous interstitial glucose monitoring (Beck, 2009). Their results suggested that continuous interstitial glucose monitoring is beneficial for individuals with type 1 disease who have already achieved excellent control. The body of research on individuals with type 2 diabetes mellitus is less substantial. Ehrhardt (2011) found that times per day in range improved, and those individuals not on prandial insulin demonstrated a clinically meaningful reduction in HbA1C levels. Current evidence shows continuous interstitial glucose monitoring can have a positive effect on glycemic control for pregnant women with type 1 disease or for gestational diabetes, but data on certain clinical indications, such as recurrent severe hypoglycemia in type 2 diabetes in pregnancy, are still lacking (Hoeks, 2011; Langendam, 2012).

The larger studies of intermittently viewed continuous interstitial glucose monitoring have taken place in Europe. The Institute for Quality and Efficiency in Health Care (2015) assessed data from 15 randomized clinical trials (n = 1,952) of participants with type 1 diabetes and multiple daily injections of insulin. Continuous glucose monitoring, as compared to blood serum glucose measurement, was associated with reduced hypoglycemic time (statistically significant). A European multi-site manufacturer-funded controlled study of n = 328 participants with type 1 diabetes found that use of the Freestyle product was associated with a 38 percent reduction in time spent with hypoglycemia (Bolinder, 2016). In a separate publication analyzing a subset of the data, the reduction in time spent with hypoglycemia was confirmed, and high levels of patient satisfaction with the intervention instrument were documented (Oskarsson, 2017). Findings from a technology assessment published by the Norwegian Institute of Public Health (2017) suggest that the FreeStyle Libre increases treatment satisfaction, reduces some measures of hypo- and hyperglycaemia, and has a similar rate of serious adverse events as self-monitored blood glucose. In several studies (Bolinder, 2016; Haak, 2017a, 2017b; Oskarsson, 2017), some participants had skin reactions to the patch.

In those with type 2 diabetes, a randomized controlled trial of the FreeStyle product (Haak, 2017a) showed overall no difference in hemoglobin A1C levels between the study and control arms, but subgroup analyses by age showed lower hemoglobin A1C levels in the study group among those under age 65. Overall, hypoglycemic time was reduced in the study group. Finger stick numbers fell among the intervention group, but remained stable in the control group. Park's (2018) systematic review of continuous interstitial monitoring among persons with type 2 diabetes on any treatment for diabetes included 1,384 participants in real-time or professional continuous glucose monitoring, and 4,902 participants in flash monitoring. Real-time and professional continuous glucose monitoring were associated with a reduction in HbA1C of .20 percent (95 percent confidence interval - 0.31 to - 0.09) (modest but statistically significant) compared to the control arm. Participants in the flash arm had a reduction of 0.02 percent (95 percent confidence interval - 0.07 to 0.04) (smaller and not statistically significant) compared to the control arm. The authors concluded that the evidence suggests that real time and professional continuous glucose monitoring are effective in type 2 diabetes, and that more evidence is needed to determine the efficacy of flash monitoring.

Overall, intermittently viewed continuous glucose monitoring appears to offer the benefit of less time spent with hypoglycemia in type 1 diabetes, and compares similarly with other technology that may be more inconvenient, painful, and cumbersome (due to the need for comparably more equipment).

Some concerns have been expressed regarding reliance on mean absolute relative difference between readings with a given glucose measurement system as compared to traditional blood glucose monitoring. Comparison of mean absolute relative difference between studies has limitations. Most research compares continuous glucose monitoring using a single device with serum glucose, and there are few randomized studies comparing real-time and intermittently viewed monitoring devices. It has been recommended that clinicians fully comprehend the factors influencing mean absolute relative difference in order to assess its accuracy, and also consider additional analyses, e.g. precision absolute relative difference, or consensus error grid analysis, in considering the appropriate glucose monitoring technology (Aijan, 2018; Obermaier, 2014).

The Eversense Continuous Glucose Monitoring System has an implantable glucose sensor that lasts for 90 days. A sensor that lasts 180 days is available in Europe. An external sensor is worn over the implant and transfers data via Bluetooth to a software application in a nearby personal device such as a smartphone or notebook. The U.S. Food and Drug Administration (2018) approved the device for marketing in the U.S. based on the PRECISE trials. PRECISE (Kropff, 2017) was a prospective multicenter trial that enrolled 71 adults with either type I or type 2 diabetes and followed them for 180 days. There was no control arm. PRECISE II (Christensen, 2018) was a prospective, multicenter study that followed 90 adults for 90 days. While the device performance in both PRECISE trials is generally encouraging, there are several points that limit the ability to adopt it on a widespread level, including the following. Together, PRECISE and PRECISE II had a sample size of n=125. The population was predominantly homogeneous (not reported for PRECISE; 85.7 percent Caucasian in PRECISE II). Importantly, the limited follow-up time cannot measure long-term impact of exposure to the device or the effects or burden of repeated removal and reinsertion. Further study is needed.

Needed areas of research include comparison of devices, and outcomes of device use among those with type 2 diabetes. Preliminary results of a study comparing Dexcom 5, the Freestyle Libre, and Eversense were reported at the American Diabetes Association 2018 Scientific Sessions in June, 2018; these have yet to be formally published.

BILLING AND CODING:

Below are National Coverage Determinations, Local Coverage Determinations, and the most commonly submitted codes subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate Centers for Medicare & Medicaid Services references and coding manuals, and bill accordingly.

NATIONAL COVERAGE DETERMINATIONS:

Publication number 100.3. Manual Section number 40.2 Home blood glucose monitors.

Policy Article A52464. Glucose Monitor.

Durable Medical Equipment (DME) Center. Announcement of important changes impacting Medicare coverage of continuous glucose monitors. Undated. https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.html. Accessed January 28, 2019.

LOCAL COVERAGE DETERMINATIONS:

L33822. Glucose Monitors.
L34834. Blood glucose monitoring in a Skilled Nursing Facility (SNF).
L35132. Home health plans of care: Monitoring glucose control in the Medicare home health population with type II Diabetes Mellitus.

COMMONLY SUBMITTED CODES:

Codes	**Code description**	**Comments**
95250	Glucose monitoring for up to 72 hours by continuous recording and storage of glucose values from interstitial tissue fluid via a subcutaneous sensor (includes hook-up, calibration, patient initiation and training, recording, disconnection, downloading with printout of data).	
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; physician interpretation and report	
O24.011 – O24.93	Diabetes mellitus in pregnancy, childbirth, and the puerperium	
O99.810 – O99.815	Abnormal glucose complicating pregnancy, childbirth and the puerperium	
E08.00 – E08.9	Diabetes mellitus due to underlying condition	
E09.00 – E09.9	Drug or chemical induced diabetes mellitus	
E10.10 – E10.9	Type 1 diabetes mellitus	
E11.00 – E11.9	Type 2 diabetes mellitus	
E13.00 – E13.9	Other specified diabetes mellitus	

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	

POLICY UPDATES:

Date	Researcher	Update
2/5/2019	DP	Initial policy.

REFERENCES:

On November 20, 2018, we searched PubMed and the databases of the U.K. National Health Services Centre for Reviews and Dissemination, Agency for Healthcare Research and Quality, and Centers for Medicare & Medicaid Services. Search terms were: “continuous interstitial glucose monitoring,” and “continuous glucose monitoring.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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APPENDIX:

Device features and characteristics	**Dexcom G6**	**Abbott Freestyle Libre[1]**	**Medtronic Guardian Connect®**
Device components	• Applicator w/1-button inserter • Sensor (10-day) • Transmitter sends data to display device. Replace every 3 months. • Display device: receiver and/or smart device	• Sensor (14-day) • No applicator • Reader (smart device app not available in the US)	• Sensor (≥ 10 days) • Transmitter • Reader: **Requires an iPhone or iPad** • Separate from an insulin pump (but can connect).
Age indications	**All ages ≥ 2 years**	**≥ 18 years**	**14 to 75**
Contraindications include pregnancy, dialysis, when critically ill. Can't be worn during MRI, CT, diathermy.	**Yes**	**Yes**	• Ok for pregnancy, dialysis. • Can't be worn during MRI, CT, diathermy
Data reading and retention	• Continuous data automatically sent to apps • Data retained for 30 days	• Updates 60 seconds, records 15 minutes. • Sensor stores 8 hours of data if not read. • Must be manually scanned to view value.	• Continuous reading • Sends data by Bluetooth every 5 minutes.
Medicare covering for DM1 and DM2, including use w/ smartphone apps, for those performing ≥ 4 fingersticks daily and on ≥3 daily injections of insulin/insulin pump, who must adjust insulin dosage frequently	Yes	Yes – but no smartphone app available in US so must use Abbot's reader	Medicare not covering, but recommended for both DM1 and DM2

Requires daily calibration with fingersticks[2]	**No.** Fingersticks only required if symptoms do not match readings. (G5 requires 2x/day.)	**No.** Fingersticks only required if symptoms do not match readings.	• **Yes**: at least 2x/day. • Stops transmitting data if not calibrated. • Therefore , this is not categorized as a therapeutic CGM device.
Programmable high/low glucose alarms and alerts	Yes	No	Yes
Data sharing with caregivers	• Yes • Needs internet for sharing function.	No	• Software can share data with caregivers and providers • Internet or wireless connection needed
Warm-up time after application of sensor	2 hours	1 hour	2 hours
Interference from acetaminophen	No	No, but Vitamin C and aspirin may interact.	Yes
Risks include hypo- or hyperglycemia in cases where data provided by device is inaccurate and used to make treatment decisions	Yes	Yes	Device is not used to make treatment decisions.
Risks include skin irritation	Yes	Yes	Yes
Can integrate with other compatible medical devices and electronic interfaces, e.g. automated insulin dosing devices, insulin pumps, serum glucose meters.	Yes	No	Compatible with Medtronic pumps and apps

[1] The Abbott FreeStyle Libre Pro is a separate new device for short-term use (generally 3 days to a week). Like the FreeStyle Libre, it cannot be used in ages <18, pregnancy or dialysis.

[2] An additional new device, the Senseonics Eversense® Continuous Glucose Measurement device, requires 2x/daily fingersticks. The sensor must be implanted and replaced every 90 days. Research results are only available on extremely small sample sizes (a total of N=125 as of January, 2019).