

Protocol

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

(10120)

Medical Benefit		Effective Date: 03/01/20	Next Review Date: 01/21
Preauthorization	Yes	Review Dates: 07/07, 07/08, 07/09, 01/10, 01/11, 01/12, 01/13, 05/13, 01/14, 05/14, 03/15, 03/16, 03/17, 09/17, 11/17, 05/18, 01/19, 01/20, 03/20	

Preauthorization is required for continuous, long-term monitoring.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With type 1 diabetes who are willing and able to use the device, and have adequate medical supervision 	Interventions of interest are: <ul style="list-style-type: none"> Long-term (continuous) glucose monitoring 	Comparators of interest are: <ul style="list-style-type: none"> Self-monitoring of blood glucose 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Morbid events Quality of life Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With type 1 diabetes who have poor control of diabetes despite use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation 	Interventions of interest are: <ul style="list-style-type: none"> Short-term (intermittent) glucose monitoring 	Comparators of interest are: <ul style="list-style-type: none"> Self-monitoring of blood glucose 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Morbid events Quality of life Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With type 2 diabetes 	Interventions of interest are: <ul style="list-style-type: none"> Long-term (continuous) glucose monitoring 	Comparators of interest are: <ul style="list-style-type: none"> Self-monitoring of blood glucose 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Morbid events Quality of life Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With type 2 diabetes who are willing and able to use the device and have adequate medical supervision and who experience significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency 	Interventions of interest are: <ul style="list-style-type: none"> Long-term (continuous) glucose monitoring 	Comparators of interest are: <ul style="list-style-type: none"> Self-monitoring of blood glucose 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Morbid events Quality of life Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With type 2 diabetes who require multiple daily doses of insulin and have poor control of diabetes despite use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation 	Interventions of interest are: <ul style="list-style-type: none"> • Short-term (intermittent) glucose monitoring 	Comparators of interest are: <ul style="list-style-type: none"> • Self-monitoring of blood glucose 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Morbid events • Quality of life • Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> • Who are pregnant with gestational diabetes 	Interventions of interest are: <ul style="list-style-type: none"> • Long-term (continuous) or short-term (intermittent) glucose monitoring 	Comparators of interest are: <ul style="list-style-type: none"> • Self-monitoring of blood glucose 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Morbid events • Quality of life • Treatment-related morbidity

DESCRIPTION

Tight glucose control in patients with diabetes has been associated with improved health outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every five to ten minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to or replacements for traditional self-monitoring of blood glucose levels. Devices can be used on a long-term (continuous) or short-term (often referred to as intermittent) basis.

SUMMARY OF EVIDENCE

TYPE 1 DIABETES

For individuals with type 1 diabetes who are willing and able to use the device, and have adequate medical supervision, who receive long-term continuous glucose monitoring (CGM), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life (QOL), and treatment-related morbidity. Systematic reviews have generally found that at least in the short-term, long-term CGM resulted in significantly improved glycemic control for adults and children with type 1 diabetes, particularly highly compliant patients. A 2017 individual patient data analysis, pooling data from 11 RCTs, found that reductions in hemoglobin A1c (HbA1c) levels were significantly greater with real-time CGM than with a control intervention. Two RCTs in patients who used multiple daily insulin injections and were highly compliant with CGM devices during run-in phases found that CGM was associated with a larger reduction in HbA1c levels than previous studies. One of the two RCTs prespecified hypoglycemia-related outcomes and reported that time spent in hypoglycemia was significantly less in the CGM group. One RCT in pregnant women with type 1 diabetes, which compared real-time CGM with self-monitoring of blood glucose, has also reported a difference in change in HbA1c levels, an increased percentage of time in the recommended glucose control target range, a smaller proportion of infants who were large for gestational age, a smaller proportion of infants who had neonatal intensive care admissions lasting more than 24 hours, a smaller proportion of infants who had neonatal hypoglycemia requiring treatment, and reduced total hospital length of stay all favoring CGM. The evidence is sufficient that the long-term use of CGM provides an improvement in net health outcomes for persons with type 1 diabetes mellitus.

For individuals with type 1 diabetes who have poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation who receive short-term glucose monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity as well as intermediate outcomes related to measures of glucose control such as frequency and time in hypoglycemia and hyperglycemia. The evidence for short-term monitoring of glycemic control is mixed, and there was no consistency in HbA1c levels. Some trials have reported improvements in glucose control for the intermittent monitoring group but limitations in this body of evidence preclude conclusions. The definitions of control with short-term CGM use, duration of use and the specific monitoring protocols varied. In some studies, short-term monitoring was part of a larger strategy aimed at optimizing glucose control, and the impact of monitoring cannot be separated from the impact of other interventions. Studies have not shown an advantage for intermittent glucose monitoring in reducing severe hypoglycemia events but the number of events reported is generally small and effect estimates imprecise. The limited duration of use may preclude an assessment of any therapeutic effect. Two RCTs of short-term CGM use for monitoring in pregnancy included women with both type 1 and 2 diabetes, with most having type 1 diabetes. One trial reported a difference in HbA1c levels at 36 weeks; the proportion of infants that were large for gestational age (>90th percentile) favored CGM while the second trial did not. The differences in the proportions of infants born via cesarean section, gestational age at delivery, and infants with severe hypoglycemia were not statistically significant in either study. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

TYPE 2 DIABETES

For individuals with type 2 diabetes who receive long-term CGM, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Most RCTs of CGM in patients with type 2 trials found statistically significant benefits of CGM regarding glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reduction between groups might not be clinically significant. Moreover, additional evidence would be needed to show what levels of improvements in HbA1c levels over the short-term would be linked to meaningful improvements over the long-term in health outcomes such as diabetes-related morbidity and complications. Also, the variability in entry criteria as well as among interventions makes it difficult to identify an optimal approach to CGM use; the studies used a combination of intermittent and continuous monitoring with a review of data in real-time or at study visits only. Only the DIAMOND RCT (n=158) has used real-time CGM in type 2 diabetes. Selected patients were highly compliant during a run-in phase. The difference in change in HbA1c levels from baseline to 24 weeks was -0.3% favoring CGM. The difference in the proportion of patients with a relative reduction in HbA1c level by 10% or more was 22% favoring CGM. There were no differences in the proportions of patients with an HbA1c level of less than 7% at week 24. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. The treatment groups did not differ in any of the QOL measures. RCTs using flash glucose-sensing technology as a replacement for self-monitoring of blood glucose for the management of insulin-dependent treated type 2 diabetes found no difference in HbA1c change at six and 12 months between groups. However, time in severe hypoglycemia (<45mg/dL) was reduced for intervention participants. Two trials of CGM have enrolled pregnant women with type 2 diabetes, but the total number of women with type 2 diabetes included in both trials is only 58. One study reported a difference in HbA1c levels at 36 weeks, and the proportion of infants that were large for gestational age (>90th percentile) favored CGM while the second study did not. Neither trial reported analyses stratified by diabetes type. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input for long-term (continuous) CGM in patients with type 2 dia-

betes who do not require insulin did not provide strong support of a safety benefit and clinically meaningful improvement in net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with type 2 diabetes who are willing and able to use the device and have adequate medical supervision and who experience significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency who receive long-term (continuous) glucose monitoring, the evidence includes a systematic review and non-randomized study with 12-month follow-up. Relevant outcomes are the frequency of and time spent in hypoglycemia, the incidence of hypoglycemic episodes, complications of hypoglycemia, and QOL. The available studies demonstrate that CGM can significantly reduce time in hypoglycemia and frequency of hypoglycemia events both during the day and at night. At 12-month follow-up, hypoglycemic events were reduced by 40.8% to 61.7% with a greater relative reduction in the most severe thresholds of hypoglycemia. The published evidence supports a meaningful improvement in the net health outcome. Evidence reported through clinical input provides additional clinical context and based on both the published evidence and clinical input the following patient selection criteria are associated with a clinically meaningful improvement in net health outcome and are consistent with generally accepted medical practice: selected patients with type 2 diabetes who are (1) willing and able to use the CGM device and have adequate medical supervision and (2) experiencing significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with type 2 diabetes who require multiple daily doses of insulin and have poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation who receive short-term CGM monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Systematic reviews of three to four RCTs have found statistically significant benefits from CGM regarding glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reductions between groups may not be clinically significant. Also, the limited number of RCTs and variability among interventions make it difficult to identify an optimal approach to CGM or a subgroup of type 2 diabetes patients who might benefit. Moreover, studies of CGM in patients with type 2 diabetes have generally not addressed the clinically important issues of severe hypoglycemia and diabetic complications. Very few pregnant women with type 2 diabetes have been included in RCTs. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input for use of short-term CGM in patients with type 2 diabetes who require multiple daily doses of insulin supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of diabetes despite use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

GESTATIONAL DIABETES

For individuals who are pregnant with gestational diabetes who receive long-term CGM or short-term (intermittent) glucose monitoring, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. In the RCT, the type of glucose monitoring was unclear. Trial reporting was incomplete; however, there was no difference between the groups for most reported outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Tight glucose control in patients with diabetes has been associated with improved health outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every five to ten minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to or replacements for tradi-

tional self-monitoring of blood glucose levels. Devices can be used on an intermittent (short-term) basis or a continuous (long-term) basis.

POLICY

Long-term CGM device monitoring of glucose levels in interstitial fluid, as a technique of diabetic monitoring, may be considered **medically necessary** when the following situations occur, despite use of best practices:

- patients with type 1 diabetes who have demonstrated an understanding of the technology, are motivated to use the device correctly and consistently, are expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider, and are capable of using the device to recognize alerts and alarms; or
- patients with type 1 diabetes who have recurrent, unexplained, severe, (generally blood glucose levels less than 50 mg/dl) hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk; or
- patients with poorly controlled type 1 diabetes who are pregnant. Poorly controlled type 1 diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

Short-term CGM monitoring of glucose levels in interstitial fluid may be considered **medically necessary** in patients with type 1 diabetes whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines section). Poorly controlled type 1 diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

Short-term CGM monitoring of glucose levels in interstitial fluid may also be considered **medically necessary** in patients with type 1 diabetes prior to insulin pump initiation to determine basal insulin levels.

Long-term (continuous) CGM monitoring of glucose levels in interstitial fluid may be considered **medically necessary** in patients with type 2 diabetes who are willing and able to use the device and have adequate medical supervision and who experience significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency.

Short-term CGM monitoring of glucose levels in interstitial fluid may be considered **medically necessary** in patients with type 2 diabetes who require multiple daily doses of insulin whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines section). Poorly controlled type 2 diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, and persistent hyperglycemia and A1c levels above target.

Short-term CGM monitoring of glucose levels in interstitial fluid may be considered **medically necessary** in patients with type 2 diabetes who require multiple daily doses of insulin to determine basal insulin levels prior to insulin pump initiation.

Other uses of long-term and short-term CGM monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring including use in gestational diabetes are considered **investigational**.

The use of implantable CGM devices is considered **investigational**.

POLICY GUIDELINES

This protocol only evaluates continuous (real time or intermittent) interstitial glucose monitors and does not evaluate insulin pumps. Insulin pump systems with a built-in CGM and a low-glucose suspend feature, are addressed in the Artificial Pancreas Device Systems Protocol.

Short-term intermittent monitoring is generally conducted over 72-hour periods. It may be repeated subsequently depending on the patient's level of diabetes control.

Best practices in diabetes control include compliance with a self-monitoring blood glucose regimen of four or more fingersticks each day and use of an insulin pump. However, some patients may do just as well with multiple insulin injections daily rather than an insulin pump. During pregnancy, three or more insulin injections daily could also be considered best practice for patients not on an insulin pump prior to the pregnancy. Prior short-term (72-hour) use of an intermittent glucose monitor would be considered a part of best practices for those considering long-term use of a continuous glucose monitor.

Significant hypoglycemia may include recurrent, unexplained, severe (generally blood glucose levels <50 mg/dL) hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk.

Women with type 1 diabetes taking insulin who are pregnant or about to become pregnant with poorly controlled diabetes are another subset of patients to whom the policy statement on intermittent monitoring may apply.

The strongest evidence exists for use of CGM devices in patients age 25 and older. However, age may be a proxy for motivation and good control of disease, so it is also reasonable to select patients based on their ability to self-manage their disease, rather than their age. Multiple CGM devices have FDA labeling related to age.

Providers board certified in endocrinology and/or providers with a focus on the practice of diabetes care may be considered qualified to evaluate and oversee individuals for continuous (i.e., long-term) monitoring.

MEDICARE ADVANTAGE

Therapeutic CGMs (continuous glucose monitor) and related supplies are considered **medically necessary** when all of the following coverage criteria (1-6) are met:

1. The patient has diabetes mellitus; and,
2. The patient has been using a BGM (blood glucose monitor) and performing frequent (four or more times a day) testing; and,
3. The patient is insulin-treated with multiple (three or more) daily injections of insulin or an approved continuous subcutaneous insulin infusion (CSII) pump; and,
4. The patient's insulin treatment regimen requires frequent adjustment by the patient on the basis of BGM or CGM testing results; and,
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the patient to evaluate their diabetes control and determined that criteria (1-4) above are met; and,
6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the patient to assess adherence to their CGM regimen and diabetes treatment plan.

If any of coverage criteria (1-6) are not met, the CGM will be denied as **not medically necessary**.

BACKGROUND

BLOOD GLUCOSE CONTROL

The advent of blood glucose monitors for use by patients in the home revolutionized the management of diabetes. Using fingersticks, patients can monitor their blood glucose levels both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight glucose control, defined as a strategy involving frequent glucose checks and a target hemoglobin A1c (HbA1c) level in the range of 7%, is now considered the standard of care for diabetic patients. Randomized controlled trials assessing tight control have demonstrated benefits for patients with type 1 diabetes in decreasing microvascular complications. The impact of tight control on type 1 diabetes and macrovascular complications such as stroke or myocardial infarction is less certain. The Diabetes Control and Complications Trial (2002) demonstrated that a relative HbA1c level reduction of 10% is clinically meaningful and corresponds to approximately a 40% decrease in risk for progression of diabetic retinopathy and a 25% decrease in risk for progression of renal disease.¹

Due to an increase in turnover of red blood cells during pregnancy, HbA1c levels are slightly lower in women with a normal pregnancy compared with nonpregnant women. The target A1c in women with diabetes is also lower in pregnancy. The American Diabetes Association recommends that, if achievable without significant hypoglycemia, the A1c levels should range between 6.0% to 6.5%; an A1c level less than 6% may be optimal as the pregnancy progresses.²

Tight glucose control requires multiple daily measurements of blood glucose (i.e., before meals and at bedtime), a commitment that some patients may find difficult to meet. The goal of tight glucose control has to be balanced with an associated risk of hypoglycemia. Hypoglycemia is known to be a risk in patients with type 1 diabetes. While patients with insulin-treated type 2 diabetes may also experience severe hypoglycemic episodes, there is a lower relative likelihood of severe hypoglycemia compared with patients who had type 1 diabetes.^{3,4} An additional limitation of periodic self-measurements of blood glucose is that glucose levels are seen in isolation, and trends in glucose levels are undetected. For example, while a diabetic patient's fasting blood glucose level might be within normal values, hyperglycemia might be undetected postprandially, leading to elevated HbA1c levels.

Management

Recently, measurements of glucose in the interstitial fluid have been developed as a technique to measure glucose values automatically throughout the day, producing data that show the trends in glucose levels. Although devices measure glucose in the interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).

Currently, CGM devices are of two designs; real-time CGM (rtCGM) provides real-time data on glucose level, glucose trends, direction, and rate of change and, intermittently viewed (iCGM) devices that show continuous glucose measurements retrospectively. These devices are also known as flash-glucose monitors (FGM).

Approved devices now include devices indicated for pediatric use and those with more advanced software, more frequent measurements of glucose levels, or more sophisticated alarm systems. Devices initially measured interstitial glucose every five to ten minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured range from every one to two minutes to five minutes, and most provide measurements in real-time directly to patients. While CGM potentially eliminates or decreases the number of required daily fingersticks, it should be noted that, according to the Food and Drug Administration labeling, some marketed monitors are not intended as an alternative to traditional self-monitoring of blood glucose levels but rather as adjuncts to monitoring, supplying additional information on glucose trends not available from self-monitoring. Also, devices may be used intermittently (i.e., for periods of 72 hours) or continuously (i.e., on a long-term basis).

REGULATORY STATUS

Multiple CGM systems have been approved by the Food and Drug Administration through the premarket approval process (see Table 1).

CGM devices labeled as “Pro” for specific professional use with customized software and transmission to health care professionals are not enumerated in this list.

Table 1. CGM Systems Approved by the Food and Drug Administration

Device	Manufacturer	Approval	Indications
Continuous Glucose Monitoring System (CGMS®)	MiniMed	1999	Three day use in physician’s office.
GlucoWatch G2® Biographer		2001	Not available since 2008.
Guardian®-RT (Real-Time) CGMS	MiniMed (now Medtronic)	2005	
Dexcom® STS CGMS system	Dexcom	2006	
Paradigm® REAL-Time System (second-generation called Paradigm Revel System)	MiniMed (now Medtronic)	2006	Integrates CGM with a Paradigm insulin pump.
FreeStyle Navigator® CGM System	Abbott	2008	
Dexcom® G4 Platinum	Dexcom	2012	Adults 18 years and older. Can be worn for up to seven days.
		2014	Expanded to include patients with diabetes two to 17 years.
Dexcom® G5 Mobile CGM	Dexcom	2016 ^a	Replacement for fingerstick blood glucose testing in patients two years and older. System requires at least two daily fingerstick tests for calibration purposes, but additional fingersticks are not necessary because treatment decisions can be made based on device readings. ⁵
Dexcom® G6 Continuous Glucose Monitoring System	Dexcom	2018	Indicated for the management of diabetes in persons 2 years and older. Intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems with 10-day wear.
Freestyle Libre® Flash Glucose Monitoring System	Abbott	2017	Adults 18 years and older. Indicated for the management of diabetes and can be worn up to 10 days. It is designed to replace blood glucose testing for diabetes treatment decisions.
Freestyle Libre® Flash Glucose Monitoring System	Abbott	2018	Adults 18 years and older. Extended duration of use to 14 days.
Guardian Connect	Medtronic MiniMed	2018	Adolescents and adults (14-75 years) Continuous or periodic monitoring of interstitial glucose levels. Provides real-time glucose values, trends, and alerts through a Guardian Connect app installed on a compatible consumer electronic mobile device.

Device	Manufacturer	Approval	Indications
Eversense Continuous Glucose Monitoring System	Senseonics	2018	Adults 18 years and older.
		2019	Continually measuring glucose levels up to 90 days. Use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Adults 18 years and older. Continually measuring glucose levels up to 90 days. Indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. Historical data from the system can be interpreted to aid in providing therapy adjustments.

CGM: continuous glucose monitoring.

^a As a supplement to the G4 premarketing approval.

Food and Drug Administration product codes: MDS, PQF, QCD.

RELATED PROTOCOL

Artificial Pancreas Device Systems

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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54. Noridian Healthcare Solutions, LLC, (Jurisdiction A - New York - Entire State, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania) Local Coverage Determination (LCD): GLUCOSE MONITORS (L33822), Revision Effective Date For services performed on or after 01/01/2019.

55. Noridian Healthcare Solutions, LLC, (Jurisdiction A - New York - Entire State, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania) (Jurisdiction D - Alaska, American Samoa, Arizona, California - Entire State, Guam, Hawaii, Iowa, Idaho, Kansas, Missouri - entire state, Montana, North Dakota, Nebraska, Nevada, Oregon, South Dakota, Utah, Washington, Wyoming, Northern Mariana Islands) Local Coverage Article: GLUCOSE Monitor - Policy Article (A52464), Revision Effective Date 01/01/2019.