BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

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CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Glucose monitoring of the interstitial fluid is a technique of automatically measuring glucose levels throughout the day to provide trends in glucose measurements, in contrast to traditional isolated blood glucose levels.

Information on trends in glucose levels may benefit individuals with type I diabetes that have inadequate control, including episodes of hypoglycemia, despite compliance with best practices.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Description: (cont.)

Best Practices:

- 4 or more fingersticks per day and use of an insulin pump
- During pregnancy, 3 or more insulin injections per day for individuals not on an insulin pump prior to the pregnancy
- Prior use of an intermittent (72-hour) glucose monitor for individuals considering use of a continuous glucose monitor

FDA Approved Devices Include:

CGMS® iPro™ Continuous Glucose Recorder System:
The CGMS iPro digital recorder is attached to a tiny glucose sensor inserted just under the skin to continuously record interstitial glucose levels over three days. After the recording period is complete, the device is removed and the information collected is downloaded, using the comlink iPro, the solutions software and a personal computer to generate a detailed glucose report. This information may help the health care provider identify patterns of glucose level excursions above or below the desired range to facilitate therapy adjustments. The information is intended to supplement, not replace, blood glucose information obtained using a standard home glucose-monitoring device.

Dexcom™ STS™ Continuous Glucose Monitoring System:
A temporary sensor is implanted in the subcutaneous tissue which measures glucose levels continuously and transmits them wirelessly to the receiver. The receiver can display results in real time or show trends over a period of time as well as alerting the user to high or low readings. The sensor is replaced every three days.

Dexcom™ STS-7™ Continuous Glucose Monitoring System:
A temporary sensor is implanted in the subcutaneous tissue which measures glucose levels continuously and transmits them wirelessly to the receiver. The receiver can display results in real time or show trends over a period of time as well as alerting the user to high or low readings. The sensor is replaced every seven days. The STS-7 Continuous Glucose Monitoring System is a glucose sensor which reports glucose values every 5 minutes for up to 7 days before a new sensor must be inserted.

DexCom G4 Platinum Continuous Glucose Monitoring System:
The system includes three components: a sensor, transmitter and receiver. The glucose sensor is a small wire that is inserted under the skin of the abdomen and measures glucose values in the fluid between the body's cells (interstitial fluid). The glucose values are sent through the transmitter to the hand-held receiver, where they are displayed for the user.

GlucoWatch® G2™ Biographer:
GlucoWatch is worn like a wristwatch. It measures glucose in the interstitial fluid that is extracted through the skin with an electric current (referred to as reverse iontophoresis). Measurements are made every 5 to 10 minutes.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Description: (cont.)

Guardian™ Continuous Glucose Monitoring System:
The Guardian System is an upgraded version of the MiniMed CGMS. It is implanted in the subcutaneous tissue and utilizes a glucose sensor to continuously record interstitial glucose readings for up to three days. These glucose readings are transmitted to the monitor, which is designed to sound an alarm when glucose levels reach high or low limits preset by the individual or his/her healthcare provider. Information from the monitor is downloaded to a computer for additional trend analysis to further improve diabetes care. The system requires calibration a minimum of twice a day using a discrete blood glucose meter.

Guardian-RT Continuous Glucose Monitoring System:
Continuously or periodically monitors glucose levels in fluid under the skin and provides real-time glucose values. System alerts if glucose level falls outside preset values. Stores data for trending and analysis.

MiniMed Continuous Glucose Monitoring System® (CGMS):
A temporary sensor is implanted in the subcutaneous tissues of the abdomen. The sensor converts glucose from the interstitial fluid into an electric signal. Measurements are made every 5 minutes. The upgrade version is called the Guardian CGMS.

MiniMed Paradigm® REAL-Time Insulin Pump and Continuous Glucose Monitoring System:
System that integrates the MiniMed Paradigm 522 or 722 insulin pump with continuous glucose monitoring in one device. The REAL-Time continuous glucose monitoring component, an optional separate purchase from the insulin pump, displays REAL-Time glucose readings every five minutes, 3 and 24-hour glucose trend graphs; and alarms when blood sugar levels fluctuate too high or too low. The integrated calculator Bolus Wizard® computes a recommended insulin dosage.

OmniPod® Insulin Management System:
OmniPod is a small disposable external insulin pod that is filled with insulin and infused through a cannula based on instructions programmed into its wireless companion, the Personal Diabetes Manager (PDM). The PDM integrates blood glucose results into bolus calculations, eliminating the need to carry a separate blood glucose meter. The pod is replaced approximately every three days. The unit is considered an alternative to a standard insulin infusion pump.

Artificial Pancreas or Artificial Pancreas Device Systems (APDS):
The proposed artificial pancreas is a series of devices e.g., a CGM, blood glucose device and an insulin pump, plus a computer algorithm that communicates with all of the devices. The goal of the APDS is to automatically monitor glucose levels and adjust insulin levels. These systems are also referred to as closed-loop systems or autonomous systems for glucose control. One technology associated with artificial pancreas development is a 'low glucose suspend (LGS)' feature included with an insulin pump. The LGS feature is designed to suspend insulin delivery when plasma glucose levels fall below a pre-specified threshold.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Description: (cont.)

MiniMed 530G System:
Integrates an insulin pump and glucose meter, and including a threshold suspend feature, was cleared for marketing in September 2013. The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is equal to or lower than a pre-set threshold within the 60 mg/dL to 90 mg/dL range. When the glucose value reaches this threshold, an alarm sounds. If individuals respond to the alarm, they can choose to continue or cancel the insulin suspend feature. If individuals fail to respond to the alarm, the pump automatically suspends action for 2 hours, and then insulin therapy resumes. The device is approved only for use in individuals 16 years and older.

Criteria:

Intermittent Glucose Monitoring (up to 72 hours):

If medical necessity criteria are met, any FDA-approved CGM device is eligible for coverage.

- Intermittent monitoring of glucose levels in the interstitial fluid is considered ***medically necessary*** for an individual with type I diabetes to determine baseline insulin levels prior to insulin pump initiation.

- Intermittent monitoring of glucose levels in the interstitial fluid is considered ***medically necessary*** for an individual with type I diabetes that is poorly controlled despite use of best practices (see Description section) with documentation of **ANY** of the following:

  1. Diabetic ketoacidosis, recurrent
  2. Hypoglycemic unawareness
  3. Suspected postprandial hyperglycemia
  4. Unexplained hypoglycemic episodes

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Criteria: (cont.)

Continuous Glucose Monitoring:

If medical necessity criteria are met, any FDA-approved CGM device is eligible for coverage.

- Continuous monitoring of glucose levels in the interstitial fluid is considered ***medically necessary*** with documentation of **ANY** of the following despite use of best practices (see Description section):

    1. Individual with type I diabetes who has recurrent unexplained severe hypoglycemia (blood glucose levels less than 50mg/dl) for whom the hypoglycemia puts the individual or others at risk

    2. Pregnant individual with type I diabetes that is poorly controlled with documentation of **ANY** of the following:

        1. Diabetic ketoacidosis, recurrent
        2. Hypoglycemic unawareness
        3. Suspected postprandial hyperglycemia
        4. Unexplained hypoglycemic episodes

If medical necessity criteria are met, any FDA-approved CGM device is eligible for coverage.

- Continuous monitoring of glucose levels in the interstitial fluid in combination with an external insulin infusion pump in an individual 7 years of age or older with type I diabetes is considered ***medically necessary*** with documentation of recurrent unexplained severe hypoglycemia and **ALL** of the following:

    1. Hemoglobin A1c (HbA1c) > 8
    2. Hypoglycemia puts the individual or others at risk
    3. Use of best practices (see Description section) does not resolve the recurrent hypoglycemia

- Continuous monitoring of glucose levels in the interstitial fluid alone or in combination with an external insulin infusion pump for all other indications not previously listed is considered ***experimental or investigational*** based upon:

    1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
    2. Insufficient evidence to support improvement of the net health outcome, and
    3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Criteria: (cont.)

Continuous Glucose Monitoring: (cont.)

- Arizona statutory coverage mandates do not require coverage of continuous glucose monitoring devices unless ***medically necessary***.[4]

  Although rental of the device is ***not eligible for coverage***, the professional services for consultation and review of data are ***eligible for coverage*** as evaluation and management (E/M) services with appropriate documentation.

Artificial Pancreas or Artificial Pancreas Device Systems (APDS):

- Use of an artificial pancreas system, including but not limited to closed-loop monitoring devices with low-glucose suspend (LGS) features, is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

1. 1.01.20 BCBS Association Medical Policy Reference Manual. Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid. Re-issue date 03/13/2014, issue date 08/18/2000.

2. American Association of Clinical Endocrinologists (AACE). Statement by the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring. *Endocrine Practice.* 2010;16(5).

3. American Diabetes Association. Executive Summary: Standards of Medical Care in Diabetes—2010. *Diabetes Care.* January 2010;33(Supplement I):S4-S10.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Resources:

4. Arizona Revised Statutes. Annotated sections 20-828, 20-1057, and 20-2325.

5. BCBS Association Technology Assessment Program. Use of Intermittent or Continuous Interstitial Fluid Glucose Monitoring in Patients With Diabetes Mellitus. December 2003;18(16).

6. Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes. *N Engl J Med.* 2010 Jul 22;363(4):311-320.

7. California Technology Assessment Forum. Continuous Glucose Monitoring in Patients with Diabetes Mellitus on Insulin. *Blue Shield of California Foundation.* 03/11/2009.

8. Centers for Medicare & Medicaid Services. Continuous Glucose Monitoring (A28892). 2007.

9. Centers for Medicare & Medicaid Services (CMS) Public Agenda Payment and Coding Determinations for Durable Medical Equipment (DME). HCPCS Request #06.102. April 25, 2006.

10. Davis SN, Horton ES, Battelino T, Rubin RR, Schulman KA, Tamborlane WV. STAR 3 randomized controlled trial to compare sensor-augmented insulin pump therapy with multiple daily injections in the treatment of type 1 diabetes: research design, methods, and baseline characteristics of enrolled subjects. *Diabetes Technol Ther.* Apr 2010;12(4):249-255.

11. Deiss D, Bolinder J, Riveline JP, et al. Improved glycemic control in poorly controlled patients with type 1 diabetes using real-time continuous glucose monitoring. *Diabetes Care.* 2006 Dec;29(12):2730-2732.

12. Hermanides J, Norgaard K, Bruttomesso D, et al. Sensor-augmented pump therapy lowers HbA(1c) in suboptimally controlled Type 1 diabetes; a randomized controlled trial. *Diabet Med.* Oct 2011;28(10):1158-1167.

13. Meade LT. The use of continuous glucose monitoring in patients with type 2 diabetes. *Diabetes Technol Ther.* Feb 2012;14(2):190-195.

14. Slover RH, Welsh JB, Criego A, et al. Effectiveness of sensor-augmented pump therapy in children and adolescents with type 1 diabetes in the STAR 3 study. *Pediatr Diabetes.* Feb 2012;13(1):6-11.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Resources: (cont.

15. TEC-Medical Policy Clearinghouse News. Continuous Glucose Monitoring System. May 15, 2006.

FDA Premarket Approval Database for Continuous Glucose Monitoring System® (MiniMed):

- FDA-approved indication: To continuously record interstitial glucose levels in persons with diabetes mellitus. To supplement, not replace blood glucose information obtained using standard home glucose monitoring devices.

FDA Premarket Approval Database for Guardian™ Continuous Glucose Monitoring System:

- FDA-approved indication: For continuous or periodic monitoring of interstitial glucose values in persons with diabetes mellitus. Glucose values calculated by the device will be used to trigger hypo- and hyperglycemia alerts but glucose values will not be displayed. Up to 21 days of stored data can be downloaded to a personal computer to identify patterns and optimize diabetes management.

FDA Premarket Approval Database for Guardian-RT Continuous Glucose Monitoring System:

- FDA-approved indication: For continuous or periodic monitoring of glucose levels in the fluid under the skin in adults (ages 18 and older) with diabetes mellitus for the purpose of improving diabetes management. It alerts if a glucose level falls below or rises above preset values. Values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments would be based on measurements obtained using a home glucose monitor and not on guardian values. Guardian RT provides real-time glucose values that allow users to track patterns in glucose concentrations and to possibly identify episodes of low and high blood glucose episodes. It also stores the data so that it can be analyzed to track patterns. Glucose data can be further downloaded to pc software for analysis of historical glucose.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Resources: (cont.)

FDA Premarket Approval Database for GlucoWatch® G2™ Biographer:

- FDA-approved indication: For detecting trends and tracking patterns in glucose levels in adults (age 18 and older) and children/adolescents (age 7 to 17) with diabetes. For use at home and in health care facilities. The device is for prescription use only. For use as an adjunctive device to supplement, not replace, information obtained from standard home glucose monitoring devices. For use in the detection and assessment of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of Biographer results should be based on the trends and patterns seen with several sequential readings over time.

FDA Premarket Approval Database for Dexcom™ STS™ Continuous Glucose Monitoring System:

- FDA-approved indication: 1) For detecting trends and tracking patterns in adults (18 and older) with diabetes and is intended for use by patients at home and in health care facilities. The device is for prescription use.
  2) For use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.
  3) Aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the STS system results should be based on the trends and patterns seen with several sequential sensor readings over time.

FDA Premarket Approval Database for Dexcom™ STS-7™ Continuous Glucose Monitoring System:

- FDA-approved indication: For detecting trends and tracking patterns in adults (age 18 and older) with diabetes. The sts-7 system is intended for use by patients at home and in health care facilities. The device is for prescription use only. The sts-7 continuous glucose monitoring system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices. The sts-7 continuous glucose monitoring system aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the sts-7 system results should be based on the trends and patterns seen with several sequential readings over time.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Resources: (cont.)

FDA Premarket Approval Database for Paradigm® REAL-Time Insulin Pump and Continuous Glucose Monitoring System:

- FDA-approved indication: Approval for modifications to the 515/715 external insulin pump and to the guardian sensor to enable the pump to accept data from the sensor and to enable the sensor to communicate directly to the pump.

FDA Premarket Approval Database for CGMS® iPro™ System:

- FDA-approved indication: The device is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. The information is intended to supplement, not replace, blood glucose information obtained using a standard home glucose-monitoring device.

FDA Premarket Approval Database for FreeStyle Navigator CGM System:

- FDA-approved indication: For continually recording interstitial fluid glucose levels in people (ages 18 and older) with diabetes mellitus for the purpose of improving diabetes management. Readings and alarms about glucose levels from the freestyle navigator continuous glucose monitoring system are not intended to replace traditional blood glucose monitoring. Before adjusting therapy for diabetes management based on the results and alarms from the freestyle navigator continuous glucose monitoring system, traditional blood glucose tests must be performed. The freestyle navigator continuous glucose monitoring system provides a built-in blood glucose meter to confirm the continuous glucose result. The freestyle navigator continuous glucose monitoring system provides real-time readings, graphs, trends and glucose alarms directly to the user. The freestyle navigator continuous glucose monitoring system is intended to be used in home settings to aid people with diabetes in predicting and detecting episodes of hypoglycemia and hyperglycemia and in clinical settings to aid healthcare professionals in evaluating glucose control. The freestyle navigator continuous glucose monitoring system is available only by prescription

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID (cont.)

Resources: (cont.)

FDA Premarket Approval Database for Guardian Real-Time and Paradigm Real-Time Systems:

- FDA-approved indication: The guardian real-time system is indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, in adults, age 18 and over, and in children and adolescents, age 7 to 17, with diabetes mellitus, for the purpose of improving diabetes management. It alerts if a glucose level falls below, or rises above, preset values. Values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor. The system provides real-time glucose values that allow users to track patterns in glucose concentrations and to possibly identify episodes of low and high blood glucose. It also stores the data so that it can be analyzed to track patterns. Glucose data can be further downloaded to pc software for analysis of historical glucose values. The paradigm real-time system is indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, and possible low and high blood glucose episodes in adults, age 18 and over, and in children and adolescents, age 7 through 17. The system provides an alert if glucose levels fall below or rise above preset values. Glucose values provided by the system are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on sensor glucose readings provided by the paradigm real-time system.