Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

CONTINUOUS OR INTERMITTENT GLUCOSE MONITORING IN INTERSTITIAL FLUID

Description: Glucose monitoring systems measure interstitial glucose levels at regular intervals via subcutaneously implanted sensors that are attached to a dime-sized plastic disk. A thin wire connects the sensors to a pager-sized glucose monitor which records glucose values.

Intermittent and continuous glucose monitoring
Glucose monitoring may be intermittent or continuous. With intermittent monitoring, the sensors and monitor are attached in the clinic and worn by the patient for 3 to 5 days. This may also be referred to as professional or retrospective continuous glucose monitoring. Glucose values are not visible to the patient, but are downloaded and interpreted by a physician after completion of the monitoring period.

Real-time continuous glucose monitoring (CGM) systems utilize the same technology as intermittent systems, but glucose values are immediately available to the patient and the device may be used for longer periods. A monitor displays values and issues an alarm if glucose values are above or below specified measures. Patients can also download information to a computer and print reports documenting their glucose patterns. These systems are also referred to as personal CGM.

Glucose values obtained by continuous glucose monitoring systems are not intended to be used directly for making therapy adjustments, but rather to indicate that a fingerstick may be required. All therapy adjustments must be based on the measurement obtained using a home blood glucose monitor, not the real-time continuous glucose monitoring system values. Fingerstick values also are required to calibrate the continuous glucose monitoring system 2-4 times each day.

The CGMS® Gold™ and CGMS® iPRO™ have been FDA-approved
for intermittent (professional) glucose monitoring.

The following continuous or real-time systems have been approved (this list may not be all inclusive):

- Guardian® RT System and Paradigm® REAL-Time Revel System are approved by the FDA for use in individuals age seven and older.
- DexCom Seven Plus® Real-Time Continuous Glucose Monitoring System, is approved by the FDA for use in adults age 18 and older.
- The DexCom G4 Platinum® Continuous Glucose Monitoring System is FDA approved for patients with diabetes ages 2 and older.

Closed-Loop Systems
Closed-loop systems, also called an artificial pancreas device system (APDS), consist of a continuous glucose monitor and pump system incorporating a computerized algorithm that communicates with both devices. The goal of the APDS is to monitor glucose levels and adjust insulin levels without direct patient interaction. One technology associated with APDS 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. The Minimed 530G System (Medtronic) integrating an insulin pump and glucose meter, and including a low glucose 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 preset threshold within the 60 mg/dL to 90 mg/dL range. When the glucose value reaches this threshold, an alarm sounds. If patients respond to the alarm, they can choose to continue or cancel the insulin suspend feature. If patients 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 patients 16 years and older.

Remote Glucose Monitoring
Systems are available that report CGM data to a location distant from the CGM device. The mySentry™ system has been FDA-approved and is commercially available. The system consists of the Paradigm® Real-Time Revel system and a remote outpost. The outpost must be within 3 feet of the pump to allow the signal to be sent to the monitor which may be up to 50 feet away. This allows caregivers in another room to respond to alarms or observe the glucose trend screen.

Policy:  
I. Intermittent Glucose Monitoring: (Applicable CPT codes: 95250, 95251)  
Intermittent monitoring of glucose levels in interstitial fluid for 3 to 5 days (professional glucose monitoring) may be considered MEDICALLY NECESSARY for patients with diabetes:
A. That is poorly controlled as evidenced by unexplained hypoglycemic episodes, hypoglycemic unawareness,
suspected postprandial hyperglycemia or recurrent ketoacidosis;

OR

B. Prior to insulin pump initiation to determine basal insulin levels.

II. Continuous Glucose Monitoring: (Applicable HCPCS codes: A9276, A9277, A9278)
Continuous glucose monitoring systems (long-term monitoring of glucose levels in interstitial fluid, including real-time monitoring) may be considered MEDICALLY NECESSARY when the patient meets ALL of the following criteria:
A. Type 1 diabetes;
   AND
B. Insulin injections are required three or more times per day or a medically necessary insulin pump is used for maintenance of glucose control;
   AND
C. Adequate metabolic control has not been achieved despite compliance with frequent self monitoring (4 or more fingersticks per day) and after multiple alterations in self-monitoring and insulin administration regimens to optimize care, as evidenced by at least ONE of the following:
   1. Recurrent, unexplained, severe, symptomatic hypoglycemia (e.g., blood glucose levels less than 50 mg/dL) that puts the patient or others at risk;
      OR
   2. Frequent nocturnal hypoglycemia, less than 50 mg/dL;
      OR
   3. Discordant hemoglobin A1C and fingerstick blood glucose levels (i.e. patient with consistent normal fingerstick results, but high hemoglobin A1C levels).

Note: The device used must be consistent with FDA approval for the age of the patient. See FDA approval information in the Description section.

III. Continuous Glucose Monitoring During Pregnancy
Continuous glucose monitoring systems may be considered MEDICALLY NECESSARY during pregnancy in individuals with diabetes and at least one of the following:
A. Adequate metabolic control is not achieved as described above;
   OR
B. Fasting hyperglycemia (greater than 150 mg/dL)
   OR
C. Recurring episodes of severe hypoglycemia (less than 50 mg/dL) occur.

IV. Investigative Uses
A. All other uses of intermittent or continuous monitoring of glucose levels in interstitial fluid are considered
Use of an artificial pancreas system, including but not limited to closed-loop monitoring devices with low-glucose suspend (LGS) features, are considered **INVESTIGATIVE**.

Remote glucose monitoring (e.g., mySentry™) is considered **INVESTIGATIVE**.

**Coverage:**

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member’s summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

**Coding:**

*The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

**CPT:**

95250 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording

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

**HCPCS:**

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

A9277 Transmitter; external, for use with interstitial continuous glucose
monitoring system
A9278 Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
S1034 Artificial pancreas device system (eg, low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035 Sensor; invasive (eg, subcutaneous), disposable, for use with artificial pancreas device system, 1 unit = 1 day supply
S1036 Transmitter; external, for use with artificial pancreas device system
S1037 Receiver (monitor); external, for use with artificial pancreas device system

**Policy History:**

**Developed December 13, 2006**

**Most recent history:**
Revised February 9, 2011
Revised September 14, 2011
Reviewed/Updated, no policy statement changes September 12, 2012
Revised September 11, 2013
Reviewed/Updated, no policy statement changes June 11, 2014

**Cross Reference:**

*Current Procedural Terminology (CPT®)* is copyright 2013 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use.

Copyright 2014 Blue Cross Blue Shield of Minnesota.