Medica Coverage Policy

Policy Name: Continuous Glucose Monitoring (CGM) Systems for Managing Diabetes
Effective Date: 7/1/2016

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

SHORT TERM CGM

Professional Continuous glucose Monitoring (CGM)
Professional continuous glucose monitoring is COVERED for:
• Adults and children with type 1 diabetes mellitus who have not achieved adequate glycemic control despite frequent self-monitoring of fingerstick blood glucose levels.
• Adults with type 2 insulin-dependent diabetes mellitus who have not achieved adequate glycemic control despite frequent self-monitoring of fingerstick blood glucose levels.
• Pregnant women with type 1 or 2 diabetes mellitus or gestational diabetes.

All other indications are investigative and therefore NOT COVERED.

LONG TERM CGM

Real-Time Continuous Glucose Monitoring (CGM)
Real-time CGM (with or without use of an external insulin pump) is COVERED as an adjunct to self-monitoring of blood glucose for managing Type 1 diabetes mellitus (DM) when adequate metabolic control is not achieved despite frequent self-monitoring, as evidenced by one of the following:
1. Hemoglobin A1C above goal and inconsistent with fingerstick patterns
2. Unexplained wide fluctuations in blood sugar patterns over time
3. Sudden onset hypoglycemic sign/symptoms lending to safety concerns (e.g., otherwise unexplained seizures, loss of consciousness, extreme hypoglycemia, etc.)
4. Nocturnal hypoglycemia.

Real-time CGM is investigative and therefore NOT COVERED for all other indications including, but not limited to: (1) monitoring Type 2 DM, (2) post-gastric bypass surgery glucose monitoring in nondiabetic individuals, (3) gestational diabetes, and (4) critically ill individuals in the hospital setting (e.g., on mechanical ventilation

Closed-Loop Continuous Glucose Monitoring (CGM) and Insulin delivery System
Real-time CGM using FDA-approved sensor-augmented insulin pump therapy with low glucose threshold suspend delivery system is COVERED for the management of Type 1 DM when adequate metabolic control is not achieved despite frequent self-monitoring, as evidenced by one of the following:
1. Hemoglobin A1C above goal and inconsistent with fingerstick patterns
2. Unexplained wide fluctuations in blood sugar patterns over time
3. Sudden onset hypoglycemic sign/symptoms lending to safety concerns (e.g., otherwise unexplained seizures, loss of consciousness, extreme hypoglycemia, etc.)
4. Nocturnal hypoglycemia.

All other real-time CGM using closed-loop insulin delivery systems (e.g., fully-automated closed loop mono-hormonal or bi-hormonal systems) are investigative and therefore NOT COVERED.

REMOTE GLUCOSE MONITORING AND PERSONAL DATA TRACKING/MANAGEMENT INTERFACE SYSTEMS USED WITH A CGM DEVICE
Remote glucose monitoring add-on systems (e.g., mySentry) and personal data tracking/management interface systems (e.g., the Dexcom SHARE) used in conjunction with a real-time CGM system are considered convenience items and are therefore EXCLUDED from coverage.

Description
Professional CGM:
Professional continuous glucose monitoring measures glucose levels in the interstitial fluid beneath the surface of the skin, providing continuous information about glucose fluctuations that is not otherwise obtained with intermittent testing. The intent of professional CGM is to aid in improving overall glycemic control. These systems require a trained health care provider. Following calibration with the individual’s standard home glucose monitor, the clinician inserts the glucose sensor into the subcutaneous tissue of the abdomen, which then measures glucose in the interstitial fluid every 10 seconds. This produces averaged glucose readings (which are stored in a monitor worn by the patient) over each five-minute interval for 72 hours or more. Software provided with the monitor retrieves data, performs error checks, and produces an output file that is downloaded and reviewed by a clinician to identify glucose excursions and guide patient management. At the end of the testing period, the device is returned to the clinician.

Real-Time CGM:
Real-time CGM systems continuously monitor glucose levels within interstitial fluid via a subcutaneous sensor similar to that described above. Real-time CGM systems designed for long-term patient use are designed to display glucose measurement in real-time, thus allowing the individual to take appropriate action (e.g., adjust insulin levels) based on the available data. Glucose measurements obtained during real-time CGM are not intended as a replacement for standard self-monitoring of blood glucose (SMBG) obtained by fingerstick blood testing. Rather, results alert the individual of the need to perform additional SMBG testing and insulin adjustment, as indicated.

An open-loop glucose monitoring and insulin delivery system combining an external insulin pump with real-time CGM is available. The sensor communicates glucose readings to the pump using a radio transmitter. The pump is also able to calculate recommended insulin doses, which the individual can accept or modify. The individual must adjust his/her insulin dosage based on a fingerstick blood glucose level, not solely based on the readings provided by the real-time CGM system.

Closed-Loop CGM and Insulin Delivery Systems:
Real-time CGM using Sensor-Augmented Insulin Pump Therapy with Low Glucose Threshold Suspend:
Low glucose suspend device systems are designed to assist individuals with type 1 diabetes mellitus in reversing significant drops in blood glucose level (i.e., hypoglycemia) and reducing its severity by temporarily suspending insulin delivery when the glucose levels falls to or approaches a pre-set low glucose threshold. These systems continuously monitor glucose levels within interstitial fluid via specialized, upgraded subcutaneous sensor. These systems serves as potential back-ups for individuals who are unable to respond to a hypoglycemic event. However, individuals using one of these systems are still required to manually check their finger-stick blood glucose levels multiple times per day and administer a pre-meal bolus, as indicated. Examples of glucose suspend systems include the MiniMed® 530G with Enlite, MinMed 630G system, and MiniMed 670G System.
Fully-automated Real-time CGM using Closed-loop Insulin Delivery Systems (e.g., Mono-hormonal or Bi-hormonal):

Real-time CGM using closed-loop insulin delivery systems (e.g., mono-hormonal or bi-hormonal) which combine an external or implanted insulin pump and real-time CGM, are purported to measure blood glucose levels and automatically adjust insulin dosages up or down as needed based upon a glycemic control algorithm embedded in the device. Unlike the low threshold suspend systems described above, it is purported that closed-loop systems would eliminate the need for the individual to perform SMBG testing and comparisons of SMBG results to those recorded on the monitor, thus eliminating the need for self-adjustments to insulin dosage. Currently, real-time CGM using closed-loop insulin delivery systems (e.g., mono-hormonal or bi-hormonal) are unavailable in the United States. Studies are currently in progress.

Remote Glucose Monitoring:
Remote glucose monitoring systems (e.g., Medtonic’s mySentry system) are comprised of a remote outpost and monitor. Information gathered and stored by the glucose monitoring system is transmitted to the remote monitor. The system is intended for use by the individual’s caregiver in a location remote from the individual whose glucose levels are being monitored. Alerts and other information about glucose levels allow the caregiver to respond to the needs of the individual in a more timely fashion. One intended application is for monitoring children overnight when they are most vulnerable to unobservable fluctuation in glucose levels.

Personal Data Tracking/Management Systems:
Multiple types of personal data tracking technology are being purported as assistive tools providing enhanced means to help an individual with long-term diabetes management. Examples include, but are not limited to:
1. Software or hardware for downloading data from a CGM device to a computer
2. CGM devices combined with a cellular telephone or other personal digital assistant [PDA] device (e.g., the Dexcom SHARE system
3. CGM devices combined with another device not intended for diabetes management (e.g., blood pressure monitor; cholesterol screening analyzer).

By connecting an individual’s glucose monitoring device to the computer, readings can be transferred to a central database, and individuals and their clinicians can access glucose history over time. Mobile phone and other personal digital assistants (PDAs) are also being developed and marketed to store and communicate data for both clinician-directed and self-management. It is theorized that this technology could enhance diabetes management by improved food intake timing, insulin injection modifications, and adjustment to other diabetic medications.

FDA Approval
Professional CGM:
The FDA has approved several devices for professional CGM. Examples include, but are not limited to: (1) MiniMed: CGMS® System Gold™, (2) CGMS® iPRO™ System (Medtronic MiniMed, Inc. Northridge, CA), and (3) CGM Dexcom G5® Mobile CGM System.

Real-Time CGM:
Several real-time CGM systems are FDA-approved. Examples of FDA-approved real time systems include, but are not limited to: (1) Guardian®-RT, MiniMed Paradigm® REAL-Time Insulin Pump and Continuous Glucose Monitoring System (Medtronic), (2) DexCom STS-7® and DexCom G4™ Platinum Real-Time Continuous Glucose Monitoring Systems (DexCom), and (3) Freestyle® Navigator (Abbott Laboratories). Many devices are approved for individuals age seven years and older; the Dexcom G4® Platinum (Pediatric) CGM system has received FDA marketing clearance for use in children 2 to 17 years of age with diabetes.

Closed-Loop CGM and Insulin Delivery System:
Multiple low-glucose suspend insulin delivery systems have received FDA approval, including but not limited to:
1. MiniMed® 530G with Enlite® Sensor
2. MiniMed 630G System with Smartguard® Technology

Currently, no fully integrated closed-loop CGM and insulin delivery system has received FDA approval. Companies working on the development of a fully integrated artificial pancreas include, but are not limited to Animas, Becton
Medica Coverage Policy

Dickinson & Co., Johnson and Johnson (J&J), Medtronic Inc., and Tandem Diabetics Care Inc.

Remote Glucose Monitoring:
In December 2011, the mySentry™ System was approved by the FDA for marketing under a supplemental approval to the original 1999 approval for Medtronic’s MiniMed Continuous Glucose Monitoring System, which is currently marketed as the MiniMed Paradigm Real-Time Revel system.

Personal Data Tracking/Management Systems:
The FDA issues guidance documents regarding all premarket submissions for software devices and other PDA applications. Personal data tracking systems may be cleared for marketing as part of a related medical device (e.g., glucose monitor), as an accessory to the original device, or as a separate standalone system. In general, if a device is comprised of software or is controlled by a computer, the FDA requires submission of data appropriate to the level of risk of the software. Data is to include any information, prompts, and cautions displayed by the system, and all documentation to support all performance and safety claims. In January 2015, the FDA approved the Dexcom® Share system (Dexcom, Inc.), the first set of mobile medical apps that allows automatic and secure data sharing from the G4® Platinum continuous glucose monitor system using an Apple mobile device (e.g., iPhone®, iPod®).

Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). 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 Codes:
- 95249 - Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
- 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 Codes:
- 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
- S1030 - Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)
- S1031 - Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)
- 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
Medica Coverage Policy

Original Effective Date: 6/1/2013

Re-Review Date(s):
9/17/2014
1/21/2015
3/16/2016
3/28/2017 – Administrative update (addition of 670G)
1/1/2018 – Administrative update; codes added

© 2013-2017 Medica. Medica® is a registered service mark of Medica Health Plans. “Medica” refers to the family of health plan businesses that includes Medica Health Plans, Medica Health Plans of Wisconsin, Medica Insurance Company, and Medica Self-Insured, and Medica Health Management, LLC.