Medica Coverage Policy

<table>
<thead>
<tr>
<th>Policy Name:</th>
<th>Continuous Glucose Monitoring (CGM) Systems for Managing Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date:</td>
<td>5/20/2019</td>
</tr>
</tbody>
</table>

**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 and Minnesota Health Care Programs, this policy will apply unless those 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 unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the effects on health care outcomes.

**LONG TERM CGM**

**Real-Time Continuous Glucose Monitoring (CGM), Non-Implantable**

Real-time CGM (with or without use of an external insulin pump) using an FDA-approved device is **COVERED** as an adjunct to self-monitoring of blood glucose for managing Type 1 diabetes mellitus (DM) or insulin-dependent Type 2 DM when adequate metabolic control is not achieved despite frequent self-monitoring.

Real-time CGM is investigative and unproven and therefore **NOT COVERED** for non-FDA approved devices and/or for all other indications including, but not limited to: (1) monitoring non-insulin dependent 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). There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

All real-time CGMs using fully integrated closed-loop insulin delivery systems (e.g., fully-automated closed loop mono-hormonal or bi-hormonal systems), also known as artificial pancreas, are investigative and unproven, and therefore **NOT COVERED**. There is insufficient, reliable evidence, in the form of high quality peer-reviewed medical literature, to establish the safety and efficacy or effects on health care outcomes.
Real-Time CGM with Implantable Glucose Sensor
CGM using an implantable glucose sensor (e.g., Eversense) is investigative and unproven, and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

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; TheraSens FreeStyle Tracker; AccuCheck Advantage Module) used in conjunction with a real-time CGM system are considered convenience items and 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 (e.g. up to seven – 14 days). 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:
CGM devices
Real-time CGM devices 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.

Open-loop glucose monitoring and insulin delivery systems combining an external insulin pump with real-time CGM are 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.

Real-time CGM using Sensor-Augmented Insulin Pump Therapy (“Hybrid Closed-Loop”):
These systems are made up of the CGM and the insulin pump. They communicate with each other and have features that can be set up to automatically suspend insulin delivery when blood sugars drop below a set value. They can also increase or decrease basal insulin doses in response to glucose values trending either up or down, and/or can give alerts to the user when glucose values are outside of their normal range or in the process of trending either up or down.

Fully-automated Real-time CGM with Closed-Loop Insulin Delivery System (aka, “artificial pancreas”):
There are currently no FDA approved devices that are fully closed loop. These systems would automatically adjust insulin needs based on automated glucose readings and would not require user input. These devices may be either mono-hormonal (delivering insulin only) or bi-hormonal (delivering insulin and glucagon). Studies are currently in progress.

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).
4. Remote glucose monitoring systems (e.g., Medtronic’s mySentry system).

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

Continuous Glucose Monitors:
Many CGMs have received FDA approval. Commonly-used non-implantable real-time CGMs include, but are not limited to:
1. Dexcom G5, Dexcom G6 (Dexcom Inc.)
2. Free-Style Libre (Abbott Diabetes Care Inc.)

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. Examples of FDA-approved systems include the Dexcom® Share system (Dexcom, Inc.) and Medtronic’s mySentry system.

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
• 0466T – Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
HCPC 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
- K0553 – Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unite of service
- K0554 – Receiver (monitor), dedicated for use with therapeutic glucose continuous monitor 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 (e.g., 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 (e.g., 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

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
3/20/2019
2/10/2020 – Administrative update; format