Medica Central Coverage Policy

Policy Name:	**Continuous Glucose Monitoring (CGM) Systems, Implantable (e.g., Eversense) MP9791**
Effective Date:	**January 1, 2025**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other 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 other government programs, 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 may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

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

NOTE: Dexcom, FreeStyle, and Guardian non-implantable glucose monitoring systems must be billed under the pharmacy benefit and purchased from a pharmacy. Refer to the member's pharmacy benefit drug formulary for preferred products, quantity limits and coverage criteria.

Coverage Policy

LONG TERM CGM

Real Time Continuous Glucose Monitoring (CGM) System, Implantable (e.g., Eversense)

Implantable real-time CGM (e.g., Eversense) is **COVERED** as an adjunct to self-monitoring of blood glucose for managing Type 1 diabetes mellitus (DM) or insulin-dependent Type 2 DM in individuals age 18 and older, with our without use of an external insulin pump.

Implantable CGM is considered 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.

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 are therefore **EXCLUDED** from coverage.

Description

Real-Time CGM:

Implantable CGM devices

Implantable real-time CGM devices (e.g., Eversense) are designed for monitoring and providing real-time blood glucose levels in the range of 40 to 400 mg/dL for up to one year in individuals age 18 years or older with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.

The Eversense systems consists of three main components: an implantable sensor and sensor implantation tools, a transmitter, and a mobile medical app. Users may also use the system to monitor glucose trends and alerts for high or low 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)
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

Implantable Continuous Glucose Monitors:

Eversense (Senseonics;Ascensia). Eversense received initial FDA Premarket Approval (PMA) in June 2018 for use up to 90 days. The Eversense E3 received PMA approval in March 2023 for use up to 180 days and in September 2024 for use up to one year in individuals aged 18 years or older with diabetes.

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 for the implantable Eversense device. 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.

NOTE: Refer to the member's pharmacy benefit drug formulary for preferred products, quantity limits and coverage criteria for Dexcom, FreeStyle and Guardian.

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:

- **0446T** – Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
- **0447T**—Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision.
- **0448T--** Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site, insertion of new implantable sensor, including system activation

Original Effective Date:	01/01/2025
Re-Review Date(s):	
Administrative Update:	08/23/2024 - Administrative updates; Title changed; transferred short-term (professional) CGM and non-implantable CGM coverage under pharmacy benefit effective 01/01/2025

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