Continuous Glucose Monitor (for Ohio Only)

Policy Number: CS366OH.A – P
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Instructions for Use

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Related Policies

- Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for Ohio Only)
- Insulin Delivery for Managing Diabetes (for Ohio Only)

Application

This Medical Policy only applies to, the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Note: For general coverage and payment policies for durable medical equipment (DME), prosthesis, orthotic devices, medical/surgical supplies, and supplier services refer to Ohio Administrative Code, Rule 5160-10-01 DMEPOS: general provisions.

For medical necessity clinical coverage criteria for Continuous Glucose Monitor, refer to the Ohio Administrative Code, Rule 5160-10-36 | DMEPOS: continuous glucose monitors.

Coverage Limitations and Exclusions

For coverage limitations and exclusions, refer to Ohio Administrative Code, Rule 5160-10-01 DMEPOS: general provisions and Ohio Administrative Code, Rule 5160-10-02 DMEPOS: repairs.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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

CPT Code	Description
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation
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; physician or other qualified health care professional (office) provided equipment, 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; analysis, interpretation and report

HCPCS Code	Description
A4238	Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
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
E1399	Durable medical equipment, miscellaneous (Note: The i-Port device is not durable medical equipment (DME) nor does it have a listed code.)
E2102	Adjunctive continuous glucose monitor or receiver
G0308	Creation of subcutaneous pocket with insertion of 180 day implantable interstitial glucose sensor, including system activation and patient training
G0309	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180 day implantable sensor, including system activation
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit 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)

Description of Services

Diabetes mellitus can be classified into the following general categories (American Diabetes Association, 2022):

- Type 1 diabetes (due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency).
- Type 2 diabetes (due to a progressive loss of beta-cell insulin secretion frequently on the background of insulin resistance).
- Gestational diabetes mellitus (GDM) (diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to pregnancy). GDM resembles type 2 diabetes and usually disappears after childbirth.
- Other subtypes of diabetes have been identified. The most common subtype is latent autoimmune diabetes in adults (LADA). LADA can be classified as a more slowly progressing variation of type 1 diabetes, yet it is often misdiagnosed as type 2.

If poorly controlled, diabetes can lead to complications such as heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, nerve damage and impotence. In GDM, fetal and maternal health can be compromised.

Improved glycemic control has been shown to slow the onset or progression of major complications. Management of diabetes involves efforts to maintain blood glucose levels near the normal range. Self-monitoring of blood glucose (SMBG) and laboratory testing of glycosylated hemoglobin (HbA1C) to measure longer term glycemic control are standard methods for glucose testing (ADA, 2022).

Continuous Glucose Monitors (CGM)

CGM devices continuously monitor and record interstitial fluid glucose levels and have three components: a sensor, transmitter, and receiver. Some CGM systems are designed for short-term diagnostic or professional use. These devices store retrospective information for review at a later time. Other CGM systems are designed for long-term personal use and display information in real-time allowing the individual to take action based on the data (American Medical Association, 2009). For most devices, glucose measurements provided during continuous monitoring are not intended to replace standard SMBG obtained using fingerstick blood samples, but can alert individuals of the need to perform SMBG. These long-term devices are available with or without an integrated external insulin pump. A review by Messer et al. (2019) highlights clinically relevant aspects of newer, advanced diabetes devices.

Implantable CGM includes a small sensor, smart transmitter, and mobile application. Based on fluorescence sensing technology, the sensor is designed to be inserted subcutaneously and communicate with the smart transmitter to wirelessly transmit glucose levels to a mobile device.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Continuous Glucose Monitors (CGM)

For information on CGMs, refer to the following websites:

- Product code LZG: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- Product code MDS: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm

(Accessed December 23, 2021)

CGM Models (this is not an exhaustive list):

- Abbott FreeStyle Libre, Libre 2, and Libre 3
- Dexcom G6 and G7
- Medtronic Guardian Connect
- Sensionics Eversense

The Eversense CGM system received FDA premarket approval (P160048) on June 21, 2018. The device is classified as an implanted CGM for adjunctive use, under product code QCD. The device is indicated for continually measuring glucose levels in adults (18 years or older) with diabetes for up to 90 days. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048. (Accessed December 23, 2021)

FreeStyle Libre Pro – Stand-alone CGM approved for short-term professional diagnostic use only: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150021. (Accessed December 23, 2021)

iPro®2 Professional CGM: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150029. (Accessed December 23, 2021)

References

American Diabetes Association. Standards of medical care in diabetes − 2022. Available at: http://professional.diabetes.org/ResourcesForProfessionals.aspx?cid=84160. Accessed January 12, 2022.

Messer LH, Berget C, Forlenza GP. A clinical guide to advanced diabetes devices and closed-loop systems using the CARES paradigm. Diabetes Technol Ther. 2019 Aug;21(8):462-469.

Ohio Administrative Code/5160/Chapter 5160-1-01. Medicaid medical necessity: definitions and principles. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-01. Accessed December 19, 2022.

Ohio Administrative Code/5160/Chapter 5160-10-01. Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-10-02. Accessed December 19, 2022.

Ohio Administrative Code/5160/Chapter 5160-10-36. DMEPOS: continuous glucose monitors. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-10-36. Accessed December 19, 2022.

Policy History/Revision Information

Date	Summary of Changes
02/01/2023	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.