

UnitedHealthcare® Community Plan Medical Policy

Continuous Glucose Monitor (for Ohio Only)

Policy Number: CS366OH.B Effective Date: October 1, 2023

Instructions for Use

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Related Policies

- <u>Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Ohio Only)</u>
- 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 the Ohio Administrative Code, Rule 5160-10-01 DMEPOS: general provisions.

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

Coverage Limitations and Exclusions

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

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

CPT Code	Description
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 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

CPT° is a registered trademark of the American Medical Association

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 = one 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
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, 2023):

- Type 1 diabetes (due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency, including latent
 autoimmune diabetes of adulthood [LADA]). LADA can be classified as a more slowly progressing variation of type 1
 diabetes, yet it is often misdiagnosed as type 2.
- Type 2 diabetes (due to a non-autoimmune progressive loss of adequate beta-cell insulin secretion frequently on the background of insulin resistance and metabolic syndrome).
- Gestational diabetes mellitus (GDM) (diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation). GDM resembles type 2 diabetes and usually disappears after childbirth.
- Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes (such as neonatal diabetes and
 maturity-onset diabetes of the young), diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis), and
 drug- or chemical-induced diabetes (such as with glucocorticoid use, in the treatment of HIV/AIDS, or after organ
 transplantation).

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. Blood glucose monitoring (BGM) and laboratory testing of hemoglobin A1c (HbA1C) to measure longer term glycemic control are standard methods for glucose testing (ADA, 2023).

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 BGM obtained using fingerstick blood samples, but can alert individuals of the need to perform BGM. 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 (use product code MDS): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed February 14, 2023)

CGM Models (this is not an exhaustive list):

- Abbott FreeStyle Libre 2, and Libre 14
- Dexcom G6
- Dexcom G7
- Medtronic Guardian Connect
- Ascensia Eversense E3

The Eversense CGM system received FDA premarket approval (P160048) on June 21, 2018. The original device was indicated for continually measuring glucose levels in adults (18 years or older) with diabetes for up to 90 days. On June 6, 2019, the device was approved for non-adjunctive use (P160048/S006). On February 10, 2022, the Eversense E3 device received FDA premarket approval (P160048/S016) expanding the indicated use up to 180 days in adults (18 years or older). Eversense is classified under product codes QCD and QHJ. Additional information is available at:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048. (Accessed February 14, 2023)

References

American Diabetes Association. Standards of medical care in diabetes – 2022. Available at: http://professional.diabetes.org/ResourcesForProfessionals.aspx?cid=84160. Accessed April 12, 2023.

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. Medical medical necessity: definitions and principles. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-01. Accessed April 12, 2023.

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 April 12, 2023.

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 April 12, 2023.

Policy History/Revision Information

Date	Summary of Changes
10/01/2023	Applicable Codes
	 Removed HCPCS codes G0308, G0309, K0553, and K0554
	Supporting Information
	Updated Description of Services and FDA sections to reflect the most current information
	 Archived previous policy version CS366OH.A - P

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.