



Medicaid Transmittal Letter No. 3344-21-03

DATE: Xxxxxx XX, 2021

TO: Eligible Medicaid Providers of Durable Medical Equipment, Prostheses, Orthoses, and Supplies (DMEPOS)

Chief Executive Officers, Medicaid Managed Care Organizations
Other Interested Parties

FROM: Maureen M. Corcoran, Medicaid Director

SUBJECT: Adoption of New Rule 5160-10-36 of the Ohio Administrative Code

New rule 5160-10-36, "DMEPOS: continuous glucose monitoring systems," is being adopted to formalize coverage and payment policies that were previously administered under the general provisions of OAC rule 5160-10-01.

The corresponding certificate of medical necessity (CMN) is new form ODM 10277.

The effective date of both the rule and the CMN is January 1, 2022.

Additional Information

Information about ODM services may be accessed through the main ODM web page, <http://www.medicaid.ohio.gov>.

Questions pertaining to this letter should be directed to the Ohio Department of Medicaid:

P.O. Box 182709

Columbus, OH 43218-2709

noninstitutional_policy@medicaid.ohio.gov

(800) 686-1516

5160-10-36

DMEPOS: continuous glucose monitoring systems.

(A) Definition. "Continuous glucose monitoring system (CGMS)" is a device that can constantly measure glucose levels in interstitial body fluid. The sensor, transmitter, and receiver/monitor may be separate parts or may be combined. The receiver/monitor may have the capacity to record data.

(B) Coverage.

(1) This rule does not apply to either of the following items:

- (a) An insulin infusion pump into which a continuous glucose monitoring sensor is integrated, coverage and payment policies for which are addressed in rule 5160-10-29 of the Administrative Code; or
- (b) A disposable tubeless subcutaneous insulin administration device, which is covered as a pharmacy benefit in accordance with Chapter 5160-9 of the Administrative Code.

(2) Payment may be made for the purchase of a CGMS and for the periodic purchase of CGMS supplies.

(3) The default certificate of medical necessity (CMN) form is the ODM 10277, "Certificate of Medical Necessity: Continuous Glucose Monitoring Systems" (1/2022). The CMN includes the following information, for which appropriate documentation is kept in the individual's medical record.

- (a) A condition for which continuous glucose monitoring is indicated for the individual, such as diabetes mellitus or hypoglycemia;
- (b) The intended length of monitoring, either short-term (from three to seven consecutive days, once or twice a year) or long-term; and
- (c) A brief explanation of why the use of a CGMS is indicated, including contributing conditions and symptoms such as are specified in the following non-exhaustive list:
 - (i) Unexplained hypoglycemic episodes (generally, excessively low blood glucose levels despite appropriate modifications in insulin therapy);
 - (ii) HbA1c level consistently outside the target range for the individual;

- (iii) Hypoglycemic unawareness (the inability to recognize hypoglycemic events consistently and reliably), evidenced in extreme cases by seizures or loss of consciousness;
- (iv) The presence of microvascular complication (e.g., vasculopathy, retinopathy);
- (v) A treatment regimen that necessitates either of the following activities:
 - (a) Frequent adjustments to insulin dosage throughout the day; or
 - (b) Insulin pump therapy;
- (vi) A coexistent condition (e.g., uncontrolled epilepsy) that may make hypoglycemia management difficult;
- (vii) Evidence of fasting or postprandial hyperglycemia; or
- (viii) Recurrent diabetic ketoacidosis.

(C) Constraints and limitations.

- (1) No payment will be made for a CGMS if neither the individual nor anyone assisting the individual is able to operate it.
- (2) Rental or payment for a CGMS includes related software.
- (3) Some CGMSs have the capability to use a cellular phone as a receiver/monitor. No payment is made for purchase, rental, lease, subscription, or maintenance associated with a cellular phone.
- (4) The warranty period for a covered CGMS that has been purchased is at least one year from the date of purchase authorization.
- (5) No payment may be made for the purchase of a CGMS that has been previously used by another individual.
- (6) CGMS supplies are dispensed in units representing the quantity an individual is expected to use in one month. A provider may dispense up to three units at a time. Before dispensing additional units, the provider makes contact, either orally or in writing, with the individual (or the individual's authorized representative) to verify the current need. The provider keeps on file a summary of this contact.

Effective:

Five Year Review (FYR) Dates:

Certification

Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5164.02

Ohio Department of Medicaid
CERTIFICATE OF MEDICAL NECESSITY: CONTINUOUS GLUCOSE MONITORING SYSTEMS

Identifying Information [This section may be completed by the provider.]

Individual	Prescriber	Provider
Name	Name	Name
Medicaid ID number	Medicaid provider number	Medicaid provider number
Date of birth	NPI	NPI
Address*	Telephone number	Authorized staff member, name (optional)

*Note: Provision of or payment for equipment and disposable supplies used by a resident of a long-term care facility (LTCF) is the responsibility of the LTCF.

Certification [This section may be transcribed by the provider.]

Mark all items that apply.

Diagnosis code(s) <input type="checkbox"/> E10.65 <input type="checkbox"/> E10.9 <input type="checkbox"/> E11.9 <input type="checkbox"/> Other _____	Date of face-to-face assessment
Intended length of monitoring <input type="checkbox"/> Short-term (from three to seven consecutive days, once or twice a year) <input type="checkbox"/> Long-term	
Indication(s) for the use of a CGMS	
<input type="checkbox"/> Unexplained hypoglycemic episodes (generally, excessively low blood glucose levels despite appropriate modifications in insulin therapy) <input type="checkbox"/> HbA1c level consistently outside the target range for the individual <input type="checkbox"/> Hypoglycemic unawareness (the inability to recognize hypoglycemic events consistently and reliably), evidenced in extreme cases by seizures or loss of consciousness <input type="checkbox"/> The presence of microvascular complication (e.g., vasculopathy, retinopathy) <input type="checkbox"/> A treatment regimen that necessitates either of the following activities: <input type="checkbox"/> Frequent adjustments to insulin dosage throughout the day <input type="checkbox"/> Insulin pump therapy <input type="checkbox"/> A coexistent condition (e.g., uncontrolled epilepsy) that may make hypoglycemia management difficult <input type="checkbox"/> Evidence of fasting or postprandial hyperglycemia <input type="checkbox"/> Recurrent diabetic ketoacidosis <input type="checkbox"/> Other _____	
Additional information (optional)	

Attestation [This section must be completed by the prescriber or authorized staff member.]

I hereby attest that the certification information above is true, correct, and complete.

Signature of prescriber or authorized staff member	Date of signature
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False certification constitutes Medicaid fraud.