Ohio Administrative Code

Rule 5160-10-36 DMEPOS: continuous glucose monitors.

Effective: October 15, 2022

(A) Definition. "Continuous glucose monitor (CGM)" is a device that can constantly measure glucose levels in interstitial body fluid. The sensor, transmitter, and receiver may be separate parts or may be combined. The receiver 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 CGM and for the periodic purchase of replaceable CGM components.

(3) The default certificate of medical necessity (CMN) form is the ODM 10277, "Certificate of Medical Necessity: Continuous Glucose Monitors" (10/2022). 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 CGM 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 CGM if neither the individual nor anyone assisting the individual is able to operate it.

(2) Payment for a CGM includes related software.

(3) Even if a CGM has the capability to use a cellular phone as a receiver, no payment will be made for purchase, rental, lease, subscription, or maintenance associated with a cellular phone.

(4) The warranty period for a CGM receiver is at least one year from the dispensing date.

(5) No payment may be made for the purchase of a CGM that has been previously used by another individual.

(6) Replacement components are dispensed in units representing the quantity an individual is expected to use in one month. Before dispensing additional units, the provider makes contact, either verbally 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. If the individual has one unit or less, the provider may dispense up to three units.