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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Continuous Glucose Monitoring System and External Insulin Infusion Pump Policy
Indication/Usage:

A continuous glucose monitoring system (CGMS),, measures glucose levels in interstitial fluid at programmable intervals up to 90 days Minimally invasive devices use a small wire-like sensor inserted just under the skin to read glucose levels in the interstitial fluid, which then transmits this information to a monitor/receiver. When used in combination with a glucose meter, CGM information can help people with diabetes detect when values are approaching dangerously high or dangerously low levels. If reviewed retrospectively by the physician, the measurements can guide adjustments to therapy, with the goal of improving overall glycemic control. The glucose measurements provided during continuous monitoring are not intended to replace standard self-monitoring of blood glucose (SMBG) obtained using finger-stick blood samples (Hayes, 2016) (CMS, 2022)

Medical Indications for Authorization

Commercial Members
Continuous Glucose Monitoring System

Short-term Use

Intermittent, short-term, (72 hours to 1 week) use of an FDA approved continuous glucose monitoring device as an adjunct to standard of care is considered medically necessary in the care of patients with diabetes, when the following criteria are met:

- For insulin dependent patients with Type 1 or Type 2 diabetes with inadequate glycemic control despite compliance with frequent self-monitoring and conventional insulin adjustment. ***and***
- Fasting hyperglycemia (>150 mg/dl) or recurring episodes of severe hypoglycemia

Long-term Use

Long-term use of continuous glucose monitoring with an FDA-approved device is considered medically necessary for any of the following:

All patients regardless of age with Type 1 Type 2 or gestational diabetes who meet the following criteria:

- Member or caregiver must have an understanding of the pump technology and motivation to use it correctly and consistently
- Inadequate glycemic control
- Insulin injections are required 3 or more times per day or a medically necessary insulin pump is used for maintenance of blood sugar control **or**

Member has a history of problematic hypoglycemia with documentation of at least one of:

- Recurrent (more than one) level 2 hypoglycemic events
- Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL that persist despite multiple (more than one) attempts to adjust medication(s) and/or
- modify the diabetes treatment plan; **or**
  A history of one level 3 hypoglycemic event (glucose <54mg/dL) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

External Ambulatory Infusion Pump

SummaCare considers external insulin infusion pumps medically necessary for members with diabetes when **all** of the following criteria is met:

- Diabetes is managed with at least 3 insulin injections per day with frequent adjustments of the insulin dose
- Member has completed a comprehensive diabetic education program
- Documented glucose self-testing 4 times per day for 2 months or the member has CGM
- Inadequate glycemic control with 1 of the following listed below with 3 months of with multiple daily insulin injections
  - Recurrent hypoglycemia with blood glucose below 70 mg/dl

- Fasting AM blood sugars frequently exceeding 200 mg/dl
- Wide fluctuations in blood glucose before mealtime **or**

- HbA1C greater than 7% for 6 months of with multiple daily insulin injections

Medicare Members

CMS CGS LCD ID L38662 Implantable Continuous Glucose Monitors (I-CGM)

Coverage Guidance Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information Covered Indications

I-CGMs are class III medical devices that require premarket approval by the FDA. In order to be considered reasonable and necessary, the FDA approved indication must include use as a therapeutic CGM.[1] The FDA recently approved expanding the indications of an implantable CGM product to replace finger stick blood glucose measurements for diabetes treatment decisions.

Therapeutic I-CGMs are considered reasonable and necessary by Medicare when all of the following coverage criteria (1-4) are met:

1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,

2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the I-CGM prescribed as evidenced by providing a prescription; and,

3. The I-CGM is prescribed in accordance with its FDA indications for use; and,

4. The beneficiary for whom a I- CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:

    - The beneficiary is insulin-treated; or,
    - The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following:
        - Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
        - A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

CGM Continued Coverage

Every six (6) months following the initial prescription of the CGM, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their CGM regimen and diabetes treatment plan.

Limitations

I-CGM devices will not be considered reasonable and necessary for short-term (72 hours to 1 week) diagnostic use.

Exception

For those beneficiaries who have previously met the coverage criteria for a non-implantable therapeutic continuous glucose monitor through the Medicare DME benefit and subsequently choose to switch to the implantable device, they may do so with a provider order. However, all other coverage criteria above must be fulfilled in order for Medicare payment.

Limitations

Long-term use of continuous glucose monitors for individuals with persons with type 2 diabetes not using intensive insulin regimens is considered experimental

I-CGM devices will not be considered reasonable and necessary for short-term (72 hours to 1 week) diagnostic use.

The American Diabetes Society recommends against using continuous glucose monitoring in a hospital setting (Cefalu, 2017)

For information on FDA 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

CMS CGS LCD ID L33794 External Infusion Pumps

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

Administration of continuous subcutaneous insulin for the treatment of diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.) if criterion A or B is met and if criterion C or D is met:

A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:

1. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.
2. For beneficiaries with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 per cent of the lower limit of normal of the laboratory's measurement method.
3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.

B. Beta cell autoantibody test is positive.

C. The beneficiary has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria (1 - 5) while on the multiple injection regimen:
   1. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
   2. History of recurring hypoglycemia
   3. Wide fluctuations in blood glucose before mealtime
   4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
   5. History of severe glycemic excursions

D. The beneficiary has been on an external insulin infusion pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

HCPCS Codes

- A9276 Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
- A9277 Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
- A9278 Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
- E0779 Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater
- E0780 Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours
- E0781 Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
- E0784 External ambulatory infusion pump, insulin
- E0787 External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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