

September 2018

## **Continuous Glucose Monitors**

Dear Clinician,

As of January 12, 2017, Medicare covers continuous glucose monitor (CGM) devices that are classified by CMS as “therapeutic CGMs.” Note that not all products marketed as CGM devices are considered therapeutic CGMs by Medicare. A therapeutic CGM is one that meets the definition of durable medical equipment (DME) and is labeled by the Food & Drug Administration (FDA) for non-adjunctive use (i.e., it can be used to make treatment decisions without the need for a stand-alone home blood glucose monitor to confirm testing results).

### **COVERAGE**

Therapeutic CGMs and related supplies are covered by Medicare when all of the following coverage criteria (1-6) are met:

1. The beneficiary has diabetes mellitus; and,
2. The beneficiary has been using a BGM and performing frequent (four or more times a day) testing; and,
3. The beneficiary is insulin-treated with multiple (three or more) daily injections of insulin or a Medicare-covered continuous subcutaneous insulin infusion (CSII) pump; and,
4. The beneficiary’s insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results; and,
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met; and,
6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.

When a therapeutic CGM is covered, the related supply allowance for sensors, transmitters, batteries, and calibration supplies are also covered.

Therapeutic CGM devices replace a standard home blood glucose monitor (BGM) and related supplies. Once billing starts for a CGM and the associated supply allowance, Medicare will no longer pay separately for a standard BGM and related supplies.

### **MEDICAL NECESSITY DOCUMENTATION**

For the in-person treating practitioner visit that is required as part of the initial provision of a therapeutic CGM, there must be sufficient information in the beneficiary’s medical record to determine that the beneficiary has diabetes mellitus (criterion 1), requires frequent testing (criterion 2), frequent dosing of their insulin (criterion 3) and frequent adjustment of their diabetes treatment regimen (criterion 4).

For the in-person treating practitioner visit that is required as part of the ongoing provision of a therapeutic CGM, there must be sufficient information in the beneficiary's medical record to determine that the beneficiary continues to adhere to their diabetes treatment regimen and use of the CGM device on a daily basis.

### **SUPPLIES FOR THERAPEUTIC CGM DEVICES**

Medicare pays a monthly allowance for supplies used with a therapeutic CGM system. This allowance encompasses all items necessary for the use of the device and includes, but is not limited to: CGM sensor, CGM transmitter, home BGM and related BGM supplies (test strips, lancets, lancing device, calibration solutions) and batteries.

There is no Medicare benefit for supplies and accessories used with equipment that is not classified as DME. Coverage of a CGM system supply allowance is available for those therapeutic CGM systems where the beneficiary uses a receiver classified as DME to display glucose data. In addition, Medicare coverage is available for a CGM system supply allowance if a non-DME device (watch, smartphone, tablet, laptop computer, etc.) is used in conjunction with the durable CGM receiver. The following are examples of this provision:

1. Medicare coverage of a CGM supply allowance is available where a beneficiary uses a durable CGM receiver to display their glucose data and also transmits that data to a caregiver through a smart phone or other non-DME receiver.
2. Medicare coverage of a CGM system supply allowance is available where a beneficiary uses a durable CGM receiver on some days to review their glucose data but may also use a non-DME device on other days.

If a beneficiary never uses a DME receiver for a therapeutic CGM, the supply allowance is not covered by Medicare.

This article is only intended to be a general summary. It is not intended to take the place of the written law, regulations, and national or local coverage determinations. Coverage, coding and documentation requirements for CGM devices may be found in the LCD for Glucose Monitors in the Medicare Coverage Database on the CMS web site at <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33822&ContrID=140>

Sincerely,

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