26 CENTURY BLVD STE ST610 | NASHVILLE, TN 37214-3685 | CGSMEDICARE.COM

CGS®
A CELERIAN GROUP COMPANY

CONTINUOUS GLUCOSE MONITORS
Revised March 2022

We IMPACT lives.

Dear Physician,

As of January 12, 2017, Medicare began covering non-adjunctive (therapeutic) continuous glucose monitor (CGM) devices under the Durable Medical Equipment (DME) benefit. Non-adjunctive (therapeutic) CGMs were defined in CMS Ruling 1682R as devices that met the definition of DME and that were labeled by the Food & Drug Administration (FDA) for non-adjunctive use (i.e., CGM devices that could be used to make treatment decisions without the need for a stand-alone home blood glucose monitor (BGM) to confirm testing results).

On December 28, 2021, the Centers for Medicare and Medicaid Services (CMS) published final rule CMS-1738-F which, in part, expanded the classification of CGM devices deemed "DME." The rule established that adjunctive (non-therapeutic) CGMs are eligible for Medicare coverage when the receiver meets the definition of DME at 42 CFR 414.202. Additionally, when adjunctive CGM sensors and transmitters are used in conjunction with an insulin infusion pump that performs the function of the CGM receiver, then the sensors and transmitters are eligible for coverage as supplies necessary for the effective use of the insulin infusion pump (subject to meeting medical necessity and other coverage requirements for the pump).

COVERAGE

CGMs and related supplies are covered by Medicare when all of the following coverage criteria (1-5) are met:

1. The beneficiary has diabetes mellitus; and,
2. The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
3. The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results; and,
4. 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 (1-3) above are met; and,
5. 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.

If the CGM functions in conjunction with an external insulin infusion pump (i.e., if the CGM is integrated into an external insulin infusion pump), then the coverage criteria for the external insulin infusion pump must be met in addition to the CGM coverage criteria (1-5) above. (Please refer to the External Infusion Pumps Local Coverage Determination (LCD) (L33794) for insulin infusion pump coverage requirements.)

When a CGM is covered, the related supply allowance is also covered.

A non-adjunctive (therapeutic) CGM system replaces a standard home BGM and related supplies. During the time a non-adjunctive (therapeutic) CGM is being billed with the associated supply allowance, Medicare will no longer pay separately for the BGM and BGM supplies.

An adjunctive (non-therapeutic) CGM system does not replace a standard BGM and BGM testing supplies. During the time an adjunctive (non-therapeutic) CGM is being billed with the associated supply allowance, the BGM and BGM testing supplies may be separately billed to Medicare (in addition to the adjunctive CGM and associated CGM supply allowance).

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

MEDICAL NECESSITY DOCUMENTATION

For the in-person treating practitioner visit that is required as part of the initial provision of a CGM, there must be sufficient information in the beneficiary's medical record to determine that the beneficiary has diabetes mellitus (criterion 1), requires frequent dosing of their insulin (criterion 2), and frequent adjustment of their diabetes treatment regimen (criterion 3). Criterion 3, of frequent adjustment to the treatment regimen, is not mandated if there is evidence in the beneficiary's medical records to support that the glucose levels have remained within the target range as established by the treating practitioner.

For the in-person treating practitioner visit that is required as part of the ongoing provision of a 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 supply allowance for supplies used with a covered CGM system. One supply allowance is payable per 30 days. Sufficient supplies must be provided to the beneficiary to last at least thirty days of therapy.

The supply allowance for a non-adjunctive CGM encompasses all items necessary for the use of the device. Items deemed necessary for use of the non-adjunctive CGM device include, but are not limited to: CGM sensors, CGM transmitters, home BGM and related supplies (test strips, lancets, lancing device, calibration solution, and batteries).

The supply allowance for an adjunctive CGM encompasses all items necessary for the use of the device. Items deemed necessary for use of the adjunctive CGM device include, but are not limited to, CGM sensors and CGM transmitters. The supply allowance for an adjunctive CGM device does not include the BGM and BGM testing supplies (test strips, lancets, lancing device, calibration solution, and batteries).

Coverage of a CGM system supply allowance is available for CGM systems when the beneficiary uses a stand-alone receiver or insulin infusion pump to display glucose data and the stand-alone receiver or insulin infusion pump (whichever is utilized) is classified as DME. 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 when 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 when a beneficiary uses a durable CGM receiver on some days to review their glucose data but uses a non-DME device on other days.

If a beneficiary never uses a DME receiver or insulin infusion pump to display CGM glucose data , then 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, national coverage determinations (NCDs) or LCDs. 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 website at https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33822.

Sincerely,

Smitha M. Ballyamanda, MD, CAQSM
Medical Director, DME MAC, Jurisdiction A
Noridian Healthcare Solutions, LLC

Robert D. Hoover, Jr., MD, MPH, FACP
Medical Director, DME MAC, Jurisdiction C
CGS Administrators, LLC

Stacey V. Brennan, MD, FAAFP
Medical Director, DME MAC, Jurisdiction B
CGS Administrators, LLC

Peter J. Gurk, MD, CPE, CHCQM
Medical Director, DME MAC, Jurisdiction D
Noridian Healthcare Solutions, LLC