PUBLICATION

CMS Proposes that All Continuous Glucose Monitors Would Be Considered Durable Medical Equipment

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On November 4, 2020, CMS proposed that *all* continuous glucose monitors (CGMs) would be considered durable medical equipment (DME), replacing a prior policy set forth in CMS Ruling 1682-R (effective January 12, 2017) that concluded only certain types of CGMs would meet this benefit category definition. 85 Fed. Reg. 70358 (Nov. 4, 2020). Comments to the proposed rule must be received by January 4, 2021.

CGMs

A CGM system uses disposable glucose sensors attached to a patient to monitor that patient's glucose level on a continuous basis by either automatically transmitting the glucose readings from the sensor via a transmitter to a device that displays the readings or by displaying the glucose readings from the sensor on a device that the patient manually holds over the sensor. CMS previously covered only "therapeutic" or "non-adjunctive" CGM systems under CMS Ruling 1682-R if they had been approved by the FDA for use in making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, without verifying its readings with a separate blood glucose monitor. An "adjunctive" or "non-therapeutic" CGM, on the other hand, is one where a patient must still verify glucose levels and trends by use of a blood glucose monitor to make diabetes treatment decisions; under CMS Ruling 1682-R, these devices were not classified as DME. 85 Fed. Reg. at 70401.

Definition of DME

As CMS explains, DME is a benefit category under Medicare Part B. The statutory definition enacted in 1965, now contained in section 1861(n) of the Social Security Act (the Act), has undergone significant amendments and revisions over the years; likewise, the CMS program guidance has also adapted over time to various policy changes. In the 1990s, CMS codified the regulation definition of DME at 42 C.F.R. § 414.202, where it currently resides. 85 Fed. Reg. at 70399-70400.

With regard to Medicare coverage for glucose monitoring, section 1861(n) of the Act was revised in 1997 to expand coverage of blood glucose monitors and test strips to patients with type II diabetes. These items had previously been covered as DME (as glucose monitoring equipment) and disposable supplies (test strips) since the early 1980s, but coverage was limited to patients with type I diabetes. CMS notes that it added to the definition of DME at 42 C.F.R. § 414.202, effective for items furnished after January 1, 2012, a requirement that the item have a minimum lifetime of three years in order to be considered DME. This was added in a final rule published on November 10, 2011, which included a discussion of how the three-year minimum lifetime requirement is applied to multi-component devices or systems consisting of durable and non-durable components that together serve a medical purpose. CMS noted that it would find a multicomponent device consisting of durable and nondurable components nondurable "if the component that performs the medical necessary function of the device is nondurable, even if other components that are part of the device are durable." 85 Fed. Reg. at 70400.

CMS summarized the current DME definition and coverage rules in the following terms:

DME is covered under Medicare Part B. DME is defined under section 1861(n) of the Act and Medicare claims for DME are paid in accordance with the special payment rules under section 1834(a) of the Act or under the competitive bidding program mandated by sections 1847(a) and (b) of the Act. Rules related to the scope and conditions of the benefit are addressed at 42 C.F.R. § 410.38. Under § 414.202, durable medical equipment means equipment which –

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be DME.

85 Fed. Reg. at 70400. It is from this context that CMS Ruling 1682-R was issued in 2017 to address CGMs and whether these devices met the definition of DME.

CMS Ruling 1682-R

CMS Ruling 1682-R classifies CGM systems as "therapeutic" CGMs that meet the definition of DME if the equipment –

- Is approved by FDA for use in place of a blood glucose monitor for making diabetes treatment decisions (for example, changes in diet and insulin dosage);
- Generally is not useful to the individual in the absence of an illness or injury;
- Is appropriate for use in the home; and
- Includes a durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements.

The Ruling provides that in all other cases where a CGM does not replace a blood glucose monitor for making diabetes treatment decisions, a CGM would not be considered DME.

CGMs Will Meet Definition of DME

In this proposed rule, CMS now concludes that *all* CGMs meet these elements: (1) the ability to withstand repeated use; (2) expected life of at least three years; (3) primarily and customarily used to serve a medical purpose; (4) generally not useful to a person in the absence of an illness or injury; and (5) appropriate for use in the home. However, CMS is clear that while CGMs may now meet the definition of DME, the CGM prescribed for a particular beneficiary must still be reasonable and necessary for the treatment of that beneficiary's illness or injury or to improve the functioning of a malformed body member per section 1862(a)(1)(A) of the Act.

This new proposal changes CMS prior policy regarding whether adjunctive CGMs are primarily and customarily used to serve a medical purpose. Specifically, CMS proposes that CGM systems that have not been approved by the FDA for use in making diabetes treatment decisions without the use of a separate blood glucose monitor, but could be used to alert the patient about potentially dangerous glucose levels while they sleep, are primarily and customarily used to serve a medical purpose. CMS believes that because adjunctive CGMs can provide information about potential changes in glucose levels while a beneficiary is sleeping and is not using a separate blood glucose monitor, these CGMs are primarily and customarily used to serve a medical purpose. CMS recognizes that these CGMs serve a medical purpose because they help patients avoid potential

episodes of hypoglycemia or hyperglycemia, despite the fact that fingerstick blood glucose verification is still required for use in making diabetes treatment decisions. For these reasons, CMS proposes that all CGMs (adjunctive and non-adjunctive) would be considered DME, effective April 1, 2021. 85 Fed. Reg. at 70401.

Further, CMS is proposing that both therapeutic and non-therapeutic CGMs, when used in conjunction with a smartphone, satisfy the definition of DME because the durable receiver, used as a backup, is not generally useful to a person in the absence of an illness or injury. However, the smartphone must be used in conjunction with the non-disposable component of the CGM:

Medicare does not cover or provide payment for smartphones under the DME benefit. . . .If a Medicare beneficiary is using durable CGM equipment that meets the Medicare definition of DME, but also uses a smartphone or other non-DME device to display their glucose readings in conjunction with the covered DME item as described previously, Medicare will cover the disposable items since the beneficiary is primarily using their covered DME item to display their glucose readings. However, if the beneficiary is exclusively using a non-DME item like a smartphone to display glucose readings from disposable sensors, transmitters or other disposable CGM supplies, these disposable supplies cannot be covered since there is no covered item of DME in this scenario.

85 Fed. Reg. at 70402.

CMS is proposing fee schedule amounts for the CGM receivers and monitors using average reasonable charges from the years 1986 and 1987 for comparable blood glucose monitors updated in accordance with section 1834(a) of the Act. As for the supplies and accessories used with the three different types of class II and class III CGMs on the market now, CMS has proposed using monthly fee schedule amounts for calendar year 2021 with additional update factors. 85 Fed. Reg. at 70402-70403.

Key Takeaways

This proposal mirrors others released recently by the Department of Health and Human Services showing an increased willingness to provide coverage for advanced and innovative technology for Medicare beneficiaries. In a press release dated October 27, 2020, CMS explained that:

With one in every three Medicare beneficiaries having diabetes, this proposal would give Medicare beneficiaries and their physicians a wider range of technology and devices to choose from in managing diabetes. This proposal will improve access to these medical technologies and empower patients to make the best healthcare decisions for themselves.

This also follows CMS' recently proposed regulations governing Medicare coverage for medical devices participating in the Medicare Coverage of Innovative Technology pathway and/or the FDA Breakthrough Devices Program. The inclusion of all CGMs meeting the definition of DME appears aimed, at least in part, at satisfying the directives required in the President's October 3, 2019 Executive Order 13890. Further, CMS' recent proposed rule requiring retroactive review of certain regulations in Titles 21, 42, and 45 of the C.F.R. within specified timeframes suggests that CMS' policies regarding benefit classifications, coverage criteria, and pricing determinations might stand a chance to keep up with rapid advances in technology. Retroactively reviewing regulations on a regular basis might ensure that CMS continues to keep up with the "cutting-edge devices" so that there can be a "win-win for patients and innovators alike" as CMS promises.

However, with respect to CGMs in particular, CMS has acknowledged that its position concerning adjunctive CGMs (i.e., that they are not primarily and customarily used to serve a medical purpose) has been rejected by federal district courts. 85 Fed. Reg. at 70401. These courts have concluded, in part, that the Secretary's position that CGMs are not primarily and customarily used to serve a medical purpose constituted legal error

and is not supported by substantial evidence; the prior policy was "head-scratching or at least under-explained" in its current form; and the agency's interpretation of "primarily and customarily used to serve a medical purpose" was unreasonable since HHS' "putative policy interpretation [was] a tautology, not an explanation."

While CMS appears to be trying to expand and streamline its current policy toward CGMs and other new devices and technology, consistent with the directives set forth in the above-referenced Executive Order and other recent proposed rules, these district court decisions likely played some role in helping to shape the new proposed policy toward CGMs. Regardless of the initiatives that helped provoke action, for the one in three Medicare beneficiaries with diabetes and the suppliers that furnish these life-saving items, this proposal should help clarify and streamline Medicare coverage for CGMs.

For more information, please contact any member of the Baker Donelson Reimbursement Team.