CMS Rulings

Department of Health and Human Services

Centers for Medicare & Medicaid Services

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This Ruling articulates CMS policy concerning the classification of continuous glucose monitoring systems as durable medical equipment under Part B of the Medicare program.

MEDICARE PROGRAM

Medicare Supplementary Medical Insurance (Part B)

Classification of Therapeutic Continuous Glucose Monitors as "Durable Medical Equipment" under

CITATIONS: Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) and 42 CFR 414.202.

BACKGROUND

Medicare Part A and Part B are defined benefit programs and items and services must fall within a statutory benefit category as prerequisite to Medicare payment under sections 1812 and 1832 of the Social Security Act (the Act). CMS and the Medicare Administrative Contractors (MACs) that process Medicare claims for payment make benefit category decisions based on criteria found in the Act, regulations, and CMS instructions or guidance. Section 1862(a) of the Act contains statutory exclusions that serve to prohibit payment for items or services, even if the items or services fall within a benefit category. Among the exclusions, and subject to exceptions, section 1862(a)(1)(A) of the Act generally prohibits payment for an item or service that is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

DURABLE MEDICAL EQUIPMENT

Durable medical equipment (DME) is a benefit category under Medicare Part B, defined at section 1861(n) of the Act as follows:

> The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations) and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories; except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

The term durable medical equipment is further defined and addressed in regulation and program instructions (see 42 CFR 414.202 and section 110.1 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02), respectively). 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. The requirement that equipment have an expected life of at least 3 years was added to the regulation in 2012 in order to further clarify the requirement that equipment must be durable in order to be considered

DME. The final rule implementing this change was titled: Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies and appeared in the November 10, 2011 **Federal Register** (76 FR 70228 and 70314). This final rule included a discussion of how the 3-year minimum lifetime requirement (MLR) is applied to multicomponent devices or systems consisting of durable and nondurable components (76 FR 70291). In that rule, we noted that a device may be a system consisting of durable and nondurable components that together serve a medical purpose, and that we consider a multicomponent device consisting of durable and nondurable components nondurable if the component that performs the medically necessary function of the device is nondurable, even if other components that are part of the device are durable. In regards to the 3-year MLR, the component(s) of a multicomponent device that performs the medically necessary function of the device must meet the 3-year MLR (76 FR 70291).

BLOOD-TESTING STRIPS AND BLOOD GLUCOSE MONITORS

Blood glucose monitors (also referred to as self-monitoring blood glucose meters) have been covered as DME under the Medicare program since the early 1980s and the reagent strips ("blood-testing strips") inserted into the monitors for use in testing the patient's blood glucose have been covered as supplies necessary for the proper functioning of the monitor. Prior to July 1, 1998, coverage of blood glucose monitors and test strips was limited to beneficiaries with Type I diabetes who were insulin-treated. Section 4105(b)(1) of the Balanced Budget Act of 1997 (Pub. L. 105-33, enacted on July 1, 1998) amended section 1861(n) of the Act to specify that the term DME included "…blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin…."

Therefore, beginning July 1, 1998, coverage of blood glucose monitors and test strips under the DME benefit was expanded to include beneficiaries with Type II diabetes regardless of whether they are insulin-treated. The current national coverage policy for standard blood glucose monitors is at section 40.2 of the Medicare National Coverage Determinations Manual (Pub. 100-03) and, in pertinent part, specifies:

> Item/Service Description
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> There are several different types of blood glucose monitors that use reflectance meters to determine blood glucose levels. Medicare coverage of these devices varies, with respect to both the type of device and the medical condition of the patient for whom the device is prescribed.
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> Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home because their need for frequent professional re-calibration makes them unsuitable for home use. However, some types of blood glucose monitors which use a reflectance meter specifically designed for home use by diabetic patients may be covered as durable medical equipment, subject to the conditions and limitations described below.
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> Indications and Limitations of Coverage
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> Blood glucose monitors are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to obtain a reading. Lancets, reagent strips, and other supplies necessary for the proper functioning of the device are also covered for patients for whom the device is indicated. Home blood glucose monitors enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment. Studies indicate that the patient's ability to carefully follow proper procedures is critical to obtaining satisfactory results with these devices. In addition, the cost of the devices, with their supplies, limits economical use to patients who must make frequent checks of their blood glucose levels. Accordingly, coverage of home blood glucose monitors is limited to patients meeting the following conditions:
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> 1. The patient has been diagnosed as having diabetes;
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> 2. The patient's physician states that the patient is capable of being trained to use the

particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible individual can be trained to use the equipment and monitor the patient to assure that the intended effect is achieved. This is permissible if the record is properly documented by the patient's physician; and

3. The device is designed for home rather than clinical use.

BENEFIT CATEGORY OF THERAPEUTIC CONTINUOUS GLUCOSE MONITORS

Continuous glucose monitors (CGMs) monitor a patient's glucose level on a continuous basis (for example, every 5 minutes). CGMs are class III medical devices and require premarket approval by the Food and Drug Administration (FDA).

Certain CGM devices consist of three components: a glucose sensor, a transmitter, and a receiver. The glucose sensor continuously measures glucose values (for example, every 5 minutes) in the interstitial fluid, the fluid around the cells (in contrast to blood glucose monitors which measure glucose values using fingertip blood samples). The sensor is a small flexible metal probe or wire that is inserted just below the skin and has a coating that prevents the body's immune system from detecting and attacking the foreign probe. Once the coating wears off in 6 or 7 days, the sensor must be replaced for safety reasons. The glucose sensor generates a small electrical signal in response to the amount of sugar that is present (interstitial glucose). This electrical signal is converted into a glucose reading that is then sent by tiny electrodes to the transmitter. The transmitter sends the measurements wirelessly to a dedicated receiver (or type of monitor) and/or compatible mobile device (smart phone, tablet, etc.) for display to a user. The receiver displays the glucose measurements in the form of a graph so that the patient can visualize how their glucose measurements are trending up or down.

Medicare does not cover CGMs approved by the FDA for use as adjunctive devices to

complement, not replace, information obtained from blood glucose monitors. In our view, such devices are not used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, and therefore, have not been covered under Medicare because they are not considered to serve the medical purpose of making diabetes treatment decisions. In addition, CMS has viewed the nondurable sensors that measure the patient's glucose level as performing the medically necessary function of the system, and therefore, the system as a whole has not been regarded as durable equipment. This Ruling applies to certain CGMs furnished on or after the effective date of the Ruling.

The FDA recently approved expanding the indications of one CGM product to include replacement of blood glucose monitors for diabetes treatment decisions. This Ruling addresses whether "therapeutic" CGMs, which provide information that can be used to make diabetes treatment decisions meet the definition of DME. For the purpose of this Ruling, all CGMs that are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as "non-therapeutic" CGMs.

As noted previously, the regulation at 42 CFR 414.202, specifies that 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. Therapeutic CGMs must meet all five of these criteria in order to be classified as DME. We address all of the criteria below – though we address the first two criteria of the DME definition later in the discussion given that both criteria

relate to the issue of durability.

Primarily and Customarily Used to Serve a Medical Purpose

According to the FDA approval letter for the therapeutic CGM: the indications for use of the product have been expanded to include replacement of blood glucose monitors for diabetes treatment decisions; the device is indicated as a glucose monitoring system for the management of diabetes in persons age 2 years and older; interpretation of the results of the device should be based on the glucose trends and several sequential readings over time; the product also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments; and the device is intended for single patient use and requires a prescription. The therapeutic CGM must be calibrated twice a day using a blood glucose monitor.

Based on this information, the therapeutic CGM is designed and approved to replace a blood glucose monitor currently classified as DME under the Medicare program, but the device must be calibrated twice a day using a blood glucose monitor. Therefore, for patients with a medical need to continuously test their glucose levels, the therapeutic CGM would be used to serve the medical purpose for the indications specified previously. That is, the therapeutic CGM would primarily and customarily be used to serve a medical purpose under the Medicare DME definition.

Generally Not Useful to a Person in the Absence of an Illness or Injury

The therapeutic CGM is only used for the purpose of monitoring glucose levels and is not useful to a person without diabetes because it serves no other purpose.

Appropriate for Use in the Home

The FDA approval letter indicates that the therapeutic CGM is used to replace a blood glucose monitor for use in making diabetes treatment decisions. Therefore, the device is appropriate

for use in the home for the same purpose that a blood glucose monitor is used in the home.

Expected Life of at Least 3 Years

As we noted previously, the criterion that equipment have an expected lifetime of at least 3 years was added to the regulatory definition of DME at 42 CFR 414.202 in 2012. This criterion further addresses the issue of "durability" and provides a clear minimum timeframe for how long an item of DME should last. As noted previously, for multicomponent equipment (that is, a system of durable and nondurable components), the component that performs the medically necessary function of the equipment must be durable in order for the device to be considered DME.

The medically necessary function of a glucose monitor is to inform the patient about their glucose level so that they can make diabetes treatment decisions such as changing their diet or insulin dosage. The blood glucose monitor reads the glucose level on the test strip and displays the reading for the patient. In the case of a non-therapeutic CGM, the device is approved to complement, not replace, blood glucose monitors, and therefore, no component of this device is considered to perform the medically necessary function of a glucose monitor. In the case of a therapeutic CGM, the device is approved to replace blood glucose monitors for making diabetes treatment decisions, and therefore, the system as a whole can replace the blood glucose monitor for certain patients.

As noted previously, the glucose sensor component must be replaced every 6 to7 days and therefore, is not durable because it would not meet the 3-year MLR. The transmitter has an expected life of 3 months and for the same reasons, is also not durable. As for the receiver, reliability analysis data from an engineering firm that evaluated the receiver component of the recently approved therapeutic CGM predicts a lifetime of greater than 3 years for the receiver. Therefore, we believe

that the receiver has an expected life of at least 3 years and is the only component of the therapeutic CGM that can be considered durable and satisfy the 3-year MLR criterion of the definition. This component also must perform the medically necessary function of the device in order for the device itself to be considered DME (assuming all other criteria of the definition are met). All three components of the therapeutic CGM system are necessary for the device to function, and necessary for patients who must be aware of changing glucose levels throughout the day and night in order to make diabetes treatment decisions. The durable receiver component that allows patients who need to frequently check their glucose levels to visually see their glucose level, check how those glucose levels are trending, and determine whether those glucose levels are rising or falling so that he or she can make appropriate diabetes treatment decisions in accordance with the FDA-approved indications for the device. Therefore, given that the receiver performs the medically necessary function of the device, we believe that the therapeutic CGM device approved as a replacement for blood glucose monitors for diabetes treatment decisions would satisfy the 3-year MLR.

Ability to Withstand Repeated Use

The final criterion under the definition at §414.202, which also relates to durability, is the requirement that equipment be able to withstand repeated use. In addition to the regulation at § 414.202, Medicare program instructions at section 110.1 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) provide that an item is considered durable if it can "withstand repeated use," – for example, the type of item that could normally be rented. As discussed previously, we view the receiver as the primary component that performs the primary medical function and that is the component that we assess in regards to the issue of durability. The receiver for a therapeutic CGM is durable because it can be used repeatedly to monitor the trending of a patient's glucose

levels. Therefore, this equipment meets the requirement to withstand repeated use; that is, equipment that could be rented.

In this Ruling, we recognize that the therapeutic CGM is durable medical equipment under section 1861(n) of the Act, and therefore, falls within the scope of Medicare Part B benefit category for DME. We are not addressing any other coverage criteria through this Ruling. In the future, CMS may issue a separate policy such as a national coverage determination. In the alternative, MACs may issue local coverage determination concerning section 1862(a)(1)(A) of the Act, or coverage may be determined on a claim-by-claim basis.

PAYMENT RULES

Medicare payment for DME was made on a reasonable charge basis from 1965 through 1988. The regulations related to implementation of the reasonable charge payment methodology are found at 42 CFR part 405, subpart E. The payment rules for glucose monitors and other DME are located at section 1834(a) of the Act and mandate payment on the basis of fee schedule amounts beginning in 1989. Glucose monitors are classified as routinely purchased items subject to the payment rules for inexpensive and routinely purchased DME at section 1834(a)(2) of the Act, which mandate that the fee schedule amounts for these items be based on average reasonable charges for the purchase or rental of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987. These base fee schedule amounts are increased on an annual basis beginning in 1991, based on the covered item update factors located in section 1834(a)(14) of the Act, which includes specific update factors for 2004 through 2008 for class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act. Routinely

purchased equipment is defined in the regulations at 42 CFR 414.220(a)(2) as "equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987." Section 1834(a)(1)(C) of the Act states that "subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this title [Title XVIII of the Act] for payment for covered items under this part [Medicare Part B] or under Part A to a home health agency."

PAYMENT FOR THERAPEUTIC CONTINUOUS GLUCOSE MONITORS

For a therapeutic CGM covered as a glucose monitor under the DME benefit, specifically as a monitor approved by the FDA to replace a blood glucose monitor, it would be subject to the exclusive payment rules contained at section 1834(a)(2) of the Act. Specifically, the fee schedule amounts for the purchase or rental of the durable equipment (the receiver) must be calculated using average reasonable charges from 1986 and 1987 for glucose monitors, increased by annual covered item update factors specified in section 1834(a)(14) of the Act, including update factors specified for class III devices for the years 2004 through 2008. These calculations result in 2017 statewide fee schedule amounts for the purchase of a new durable monitor/receiver for a therapeutic CGM ranging from approximately $236 to $277. The fee schedule amounts for purchase of used equipment would be based on 75 percent of the fee schedule amounts for purchase of new equipment, or approximately $177 to $208. The fee schedule amounts for the monthly rental of the equipment would be based on 10 percent of the fee schedule amounts for purchase of new equipment, or approximately $24 to $28. Total payments for the equipment (any combination of rentals or purchase claims) cannot exceed the fee schedule amount for purchase of new equipment. These fee schedule amounts will be increased in 2018 and subsequent years based on the covered item update

factors at section 1834(a)(14) of the Act.

PAYMENT FOR ACCESSORIES ESSENTIAL FOR THE EFFECTIVE USE OF THERAPEUTIC CONTINUOUS GLUCOSE MONITORS

Medicare also pays for replacement of essential accessories for necessary DME on the basis of fee schedule amounts calculated using average reasonable charges for the items for the 12-month period ending on June 30, 1987, increased by annual covered item update factors. In addition to the payment for the therapeutic CGM item of DME (the receiver), monthly fee schedule amounts will be used to pay for replacement of the sensors, transmitters, and all other accessories and supplies essential for the effective use of the receiver. For 2017, the monthly fee schedule amount is $248.38 and is established in accordance with the fee schedule gap-filling instructions located at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. 100-04). The monthly fee schedule amount is established using invoice prices for four sensors, a monthly allowance for transmitters based on manufacturer prices, the 2017 fee schedule amount for alkaline batteries used in glucose monitors (HCPCS code A4233), the 2017 fee schedule amount for purchase of a blood glucose monitor (HCPCS code E0607) necessary for calibration of the therapeutic CGM, divided by 60 (the number of months in the reasonable useful lifetime of the blood glucose monitor), and the 2017 fee schedule amount for 60 blood glucose test strips (HCPCS code A4253) necessary for calibration of the therapeutic CGM. The $248.38 fee schedule amount will be increased in 2018 and subsequent years based on the covered item update factors at section 1834(a)(14) of the Act.

CONCLUSION

For CGM products that are used in the home and approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions, these therapeutic CGMs are

primarily and customarily used to serve a medical purpose because they are used by Medicare beneficiaries with diabetes who must measure their glucose level frequently and check trends in their glucose measurements for the purpose of adjusting their diet and insulin in the treatment of their diabetes. Because they are used directly in making diabetes treatment decisions, as opposed to alerting the patient to use a blood glucose monitor to make those decisions, they are not precautionary in nature. A receiver (or type of monitor) for a therapeutic CGM that has an expected life of at least 3 years and is the component performing the medically necessary function of accurately monitoring the trends of the patients' blood glucose levels so that he or she can make necessary diabetes treatment decisions meets the 3-year MLR. The system as a whole replaces the blood glucose monitor for glucose monitoring purposes. As a result, the durable receiver for a therapeutic CGM is considered DME. For therapeutic CGMs, the glucose sensors and transmitters are considered essential accessories necessary for the effective use of the therapeutic CGM and replacement of the glucose sensors and transmitters are considered replacements of essential accessories necessary for the effective use of DME.

Although this ruling is to classify these items as DME items, specifically glucose testing equipment, and related accessories essential for the effective use of glucose testing equipment, section 1862(a)(1)(A) of the Act would still prohibit Medicare payment for these items if they are not determined to be reasonable and necessary for the treatment of the diabetes illness.

Continuous glucose monitoring systems are considered therapeutic CGMs that meet the definition of durable medical equipment at section 1861(n) of the Act and 42 CFR 414.202 if the equipment--

- Is approved by the 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.

In all other cases in which a CGM does not replace a blood glucose monitor for making diabetes treatment decisions, a CGM is not considered DME. This Ruling does not apply to items and services furnished prior to the effective date of the Ruling.

CMS-1682-R

EFFECTIVE DATE

This Ruling is effective January 12, 2017.

Dated: JAN 12 2017

Patrick Conway, MD

Patrick Conway,
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