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April 17, 2017

Hon. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS Ruling CMS-1682-R; Classification of Therapeutic Continuous Glucose Monitors as "Durable Medical Equipment" under Medicare Part B

Dear Administrator Verma:

On behalf of the millions of Americans living with diabetes, please allow me to express our heartfelt thanks for CMS' January 12, 2017 Administrator's ruling establishing that certain continuous glucose monitoring (CGM) systems are now covered under the Medicare durable medical equipment benefit. Medicare coverage of therapeutic CGM will help Medicare beneficiaries suffering from this disease and we are proud to be the manufacturer of the first CGM approved by the FDA for therapeutic use.

In addition to our profound gratitude and that of our patients, I am writing today to express our confusion, and that of patients and providers, at the pricing and payment described by the Administrator's ruling issued in January. Specifically, we believe that the methodology used to price the CGM receiver (the durable component of the CGM system) was incorrectly chosen, and that a standard glucose meter is not a comparable item of DME for therapeutic or pricing purposes. Additionally, we have concerns as to the propriety of the bundled payment for accessories and its monthly billing interval, as well as the underlying data used in its determination. Each of these is addressed in more detail in this letter.

To be clear, we do not believe these discrepancies present insurmountable obstacles to Medicare coverage for CGM. Instead, we would welcome the opportunity to work with you to further strengthen CMS' policies regarding CGM coverage and payment; ensuring that this life-saving technology will be available to beneficiaries from a robustly-competitive and innovative field who will continue to advance the state of the art in diabetes care.

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A glucose meter is not "comparable" to a CGM receiver for pricing determinations

A CGM system enables people with diabetes (especially those most vulnerable to severe hypoglycemic episodes) to, in real-time, monitor, track, and dose medications based on their glucose information. The alerts provided by the CGM allow patients to immediately make appropriate adjustments to avoid adverse events. The CGM receiver, a small electronic device, contains the hardware and software to provide alerts to patients when more immediate attention is needed due to the patient's glucose levels. This information allows for appropriate diabetes management and treatment decision-making by the patient and their caregivers and physician.

By comparison, a glucose meter can provide only one piece of information: a patient's blood glucose levels at the time they decide to manually prick their finger and test. It cannot alert the patient to dangerously low or high levels if they are otherwise hypoglycemia-unaware or asleep. It cannot transmit information to a doctor or caregiver, and it cannot continuously track and trend glucose levels to allow for the most beneficial treatment decisions. Multiple studies have demonstrated that diabetes treatment using a traditional glucose monitor results in significantly worse health outcomes than treatment with CGM.

Nevertheless, the Administrator's ruling states that, because the FDA has approved CGM to replace traditional glucose monitors for diabetes treatment decisions, the pricing for the CGM receiver must be calculated using historical pricing data for glucose monitors. This is, frankly, an inaccurate notion. CGM receivers are significantly more complex, have additional therapeutic features, and are therefore more expensive than simple glucometers. Power-operated and manual wheelchairs are both used by Medicare patients who are unable to walk but their prices are significantly different. The Administrator's ruling recognizes that a blood glucose monitor is still necessary for calibration of the CGM receiver, and includes it in the accessories necessary for use of the CGM. This differentiation is further reflected in the devices' respective FDA classifications: blood glucose monitors are classified by the FDA as Class II devices, while CGM is a Class III device requiring premarket approval. We believe that the notion that CGM "replaces" a glucose meter and thus should be priced on a comparable basis is erroneous, and should be re-examined.

Medicare pricing rules prescribe a method of determining prices when the technology being priced is unlike any technology currently covered by the program. In this case, we believe that these rules require the use of commonly available retail pricing for the receiver and the use that price to determine the Medicare payment for the device, rather than comparison to the significantly different blood glucose monitor.

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Bundled payment for accessories is inappropriate, and the amount is likely erroneous

The Administrator's ruling also establishes a single fee for a bundle of accessories deemed necessary to use the CGM receiver. Some of these (CGM transmitters and sensors) are specific to the receiver and truly essential to its operation. Others (a blood glucose monitor, test strips, and batteries) are needed for patients to correctly use CGM. Interestingly, a number of items which would be necessary for the use of a glucose monitor (lancets, a spring-loaded lancet device, calibration solution, etc.) are not mentioned at all. Nevertheless, the Joint DME MAC Article dated March 23, 2017[1] states that the supply allowance "encompasses all items necessary for the use of the device," and specifically includes lancets, lancing device, and calibration solution. In any event, we believe that this bundled payment is incomplete and inappropriate, that the fee noted in the Administrator's ruling is incorrect based on a number of issues, and that this bundled payment methodology may leave consumers unable to access CGM care.

The bundle is logistically infeasible

The bundle pricing defined in the Administrator's ruling has a number of logistical issues. It includes 60 test strips, based on the assumption that beneficiaries must use two per day for calibration of the CGM. However, two per day is a floor on test strip usage only during days 2-7 of the CGM sensor duration. FDA labeling indicates 3 self-monitoring blood glucose (SMBG) calibration tests are needed on day 1 of a new sensor usage. Therefore an absolutely minimum of 64 test strips would be needed to use the CGM device consistent with its FDA labeling. Furthermore, additional SMBG strips are indicated when symptoms do not match the CGM reading, or even when using medicines containing acetaminophen. Dexcom's recently published data on patients using therapeutic CGM demonstrates an average usage closer to 2.8 test strips per day. However, due to the bundled nature of the pricing, it is unclear how a beneficiary could obtain additional necessary test strips, especially since the HCPCS code cited for pricing the test strips in the bundle is actually for only 50 strips.

The bundled accessories are inadequate and cannot be accurately billed

This bundled pricing also makes it unclear as to how transmitters should be billed, as they are supplied once every three months, and are therefore not billed monthly as stipulated in the Administrator's ruling. Perhaps most importantly, the sensors last 7 days, and therefore the Administrator's ruling supplying 4 per month would only be appropriate in February, and more

[1] Available at https://med.noridianmedicare.com/web/jadme/policies/dmd-articles/coding-and-coverage-therapeutic-continuous-glucose-monitors

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would be needed in every other month, leaving suppliers obligated to supply additional, unreimbursed sensors in order to provide for a patient's care for the month. Additional shipments for lost or damaged transmitters and sensors are likewise not billable under the scheme defined in the Administrator's ruling.

Considering CMS' existing policies and procedures regarding competitive bidding for blood glucose monitors, test strips, and associated supplies, it seems incongruous to significantly alter these practices as a part of the Administrator's ruling on CGM.

In addition, although the Administrator's ruling lists a number of items which were used to determine the bundle pricing, it excludes multiple items that are then required to be supplied by the Joint DME MAC article. This leaves suppliers responsible for providing items which, by the terms of CMS' Administrator's ruling, they are not being reimbursed.

The simplest solution is to abandon the bundle and bill supplies individually, or to at least allow for quarterly billing

A simple solution to these logistical issues exists. Each of the items in the bundle already has a HCPCS code and in many cases defined payment amounts. Rather than forcing an incomplete and logistically infeasible bundled pricing method, CMS should consider using existing codes (consistent with established commercial insurer practice), determining payment amounts for each component, and paying suppliers for those items and in the quantities deemed medically necessary, subject to any applicable coverage determinations.

In the alternative, should CMS decide to maintain the bundled payment for accessories, we would encourage them to allow suppliers to bill for and ship the bundle every three months. Not only would this be consistent with current practice with regard to diabetic testing supplies, it would also allow for transmitters to be billed and shipped simultaneously, rather than billed fractionally and shipped every third payment (which could cause significant confusion when beneficiaries change suppliers). In addition, it would allow for suppliers to ship test strips in more appropriate quantities than the commercially impracticable 60 per month stipulated in the Ruling.

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The Administrator's ruling does not clearly define how accessory payment rates were determined

Individual payment amounts would also help to clarify how pricing was determined for the accessories. The Administrator's ruling states that pricing was based on "invoice prices" for sensors, "manufacturer prices" for transmitters, and established fee schedule amounts for the other items. As noted above, for these items, pricing based on commonly available retail pricing is statutorily required. However, the total payment amount established by the Administrator's ruling is substantially lower than Dexcom's commonly available retail pricing for these items. As we were not consulted as to our pricing, we are unsure as to the data sources used to determine the consolidated payment amount, and would welcome the opportunity to discuss this further with CMS, as we believe an error was likely made in this calculation.

Again, thank you for creating DME eligibility for continuous glucose monitoring. We have heard from thousands of enthusiastic patients, and we look forward to providing them with this proven technology to manage their diabetes. We are confident that none of these issues presents an obstacle that cannot be resolved through cooperation between Dexcom and CMS. Dexcom eagerly awaits the opportunity to work with you and your staff to ensure that Medicare CGM coverage gets off to a smooth start that ensures access and innovation for your beneficiaries. We are available at your convenience to begin that process, please do not hesitate to contact me at cgraham@dexcom.com or (858) 200-0248.

Sincerely,

Claudia Graham

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