Continuous Glucose Monitors (CGM) and the CY 2018 DMEPOS Fee Schedule

Dexcom Meeting with Office of Management and Budget

May 15, 2017

Agenda:

- Introductions
- CGM Technology
- Administrator's Ruling
- CGM Receiver Fee Schedule
- CGM Supply Bundle & Fee Schedule
- Smartphone Usage
- Questions and Next Steps

Introductions

Rick Doubleday – Executive Vice President, Chief Commercial Officer, Dexcom

Claudia Graham, PhD, MPH – Senior Vice President, Global Access, Dexcom

Jim Scott – President & CEO, Applied Policy

Greg Pugh – Health Policy Manager, Applied Policy

Dexcom Background

- Dexcom, a San Diego company, was founded in 1999 and commercialized its first subcutaneous glucose sensor in 2006
- Dexcom manufactures the G5 Mobile CGM System, the first and only CGM system approved for “non-adjunctive” (i.e. to make treatment decisions without a fingerstick)
- World wide, Dexcom has over 200,000 patients using CGM in 40 countries
- Dexcom is the market leader in CGM

Dexcom | G5™ mobile

FDA-Approved CGM System

Sensor

- Indicated for adults and children down to age 2 years
- Tiny insertion needle (26g)
- Seven day sensor life

Transmitter

- No recharging required
- 20-foot transmission range
- 3 month life

System Receiver

- Receiver device to alarm and view data
- Slim profile
- Customizable alerts

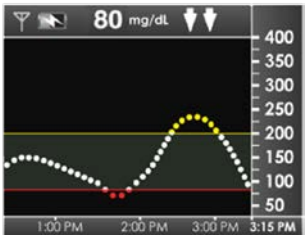
Comparison of Self-Monitoring of Blood Glucose (SMBG) and CGM

SMBG

- Patient must initiate
- Burdensome
- Snapshot only

CGM

- Real-time
- Snapshot, speed & direction of glucose
- Sets off alarm when crosses a designated threshold



Administrator's Ruling

January 12, 2017

Summary

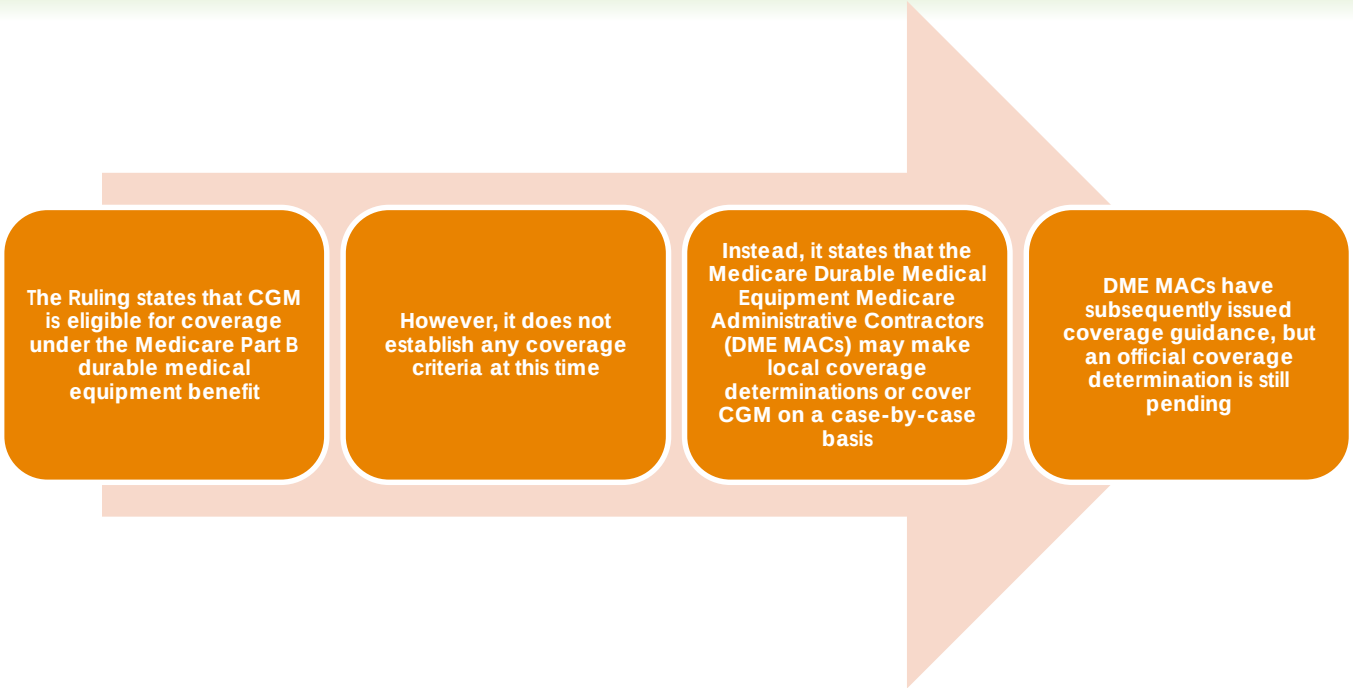
On January 12, 2017, the Centers for Medicare and Medicaid Services (CMS) issued a Ruling that certain continuous glucose monitors (CGMs), specifically the Dexcom G5, are eligible for coverage under the Medicare Part B durable medical equipment benefit

The Ruling only applies to certain “therapeutic” CGMs

Therapeutic CGMs have received an FDA indication for the replacement of fingersticks for making diabetes treatment decisions

- At this time, only the Dexcom G5 Mobile has received such a designation

Coverage of CGM



Payment for CGM

The ruling sets a fee schedule amount of $236-$277 for the CGM receiver

- Monthly rental of the receiver will be $24-$28/mo for 10 months
- This will be increased in 2018 and subsequent years

The ruling also sets a monthly fee schedule amount of $248.38 for a bundle of “accessories”

- 4 sensors (1 per week)
- A monthly allowance for transmitters (1/3 transmitter per month)
- All other necessary supplies including a glucose meter, 60 test strips, and batteries

Current Status of CGM and Medicare

Eligible Medicare beneficiaries are not receiving CGM

Although the Administrator's Ruling was issued on January 12, over four months later patients are still not receiving CGM

A coverage determination has yet to be issued, so patients, physicians, and suppliers are still unsure whether beneficiaries qualify for the service

In addition, the fees set by the ruling are so far below acquisition cost that suppliers are unwilling to service Medicare patients

The supply bundle, which is a CMS invention, is inconsistent with decades of commercial practice, has suppliers, providers, and payers confused as to how to bill for CGM services

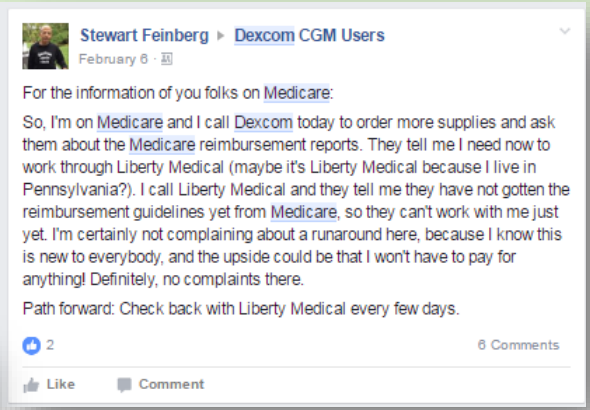
Medicare confusion on social media

Patti Anderson ▸ Dexcom
February 17 at 8:36am ·

We started the Medicare process....Dexcom will have you call Liberty who is handling all of the Medicare orders. Here's where it gets tricky.... Medicare has not given out the guidelines yet. Meaning Liberty doesn't know what needs to be done to be covered. You have the option to wait for that which should be in April or pay up front hoping to be reimbursed by Medicare With no guarantees.

1 5 Comments

Like Comment



Stewart Feinberg ▸ Dexcom CGM Users
February 6 ·

For the information of you folks on Medicare:

So, I'm on Medicare and I call Dexcom today to order more supplies and ask them about the Medicare reimbursement reports. They tell me I need now to work through Liberty Medical (maybe it's Liberty Medical because I live in Pennsylvania?). I call Liberty Medical and they tell me they have not gotten the reimbursement guidelines yet from Medicare, so they can't work with me just yet. I'm certainly not complaining about a runaround here, because I know this is new to everybody, and the upside could be that I won't have to pay for anything! Definitely, no complaints there.

Path forward: Check back with Liberty Medical every few days.

2 6 Comments

Like Comment

Barbara Martinelli ▸ Dexcom
March 9 at 7:43am ·

Has anyone tried to get approval for Dexcom who is on Medicare? A friend of mine turned 65 last year and had to stop using it because of the cost. Now that Medicare has approved it for monitoring of BS, what is needed to get it approved and paid for? I am assuming that the copay and deductibles will need to be met before the Medicare Advantage or Supplement will pay.

7 Comments

Like Comment

Ron McDaniel ▸ DexCom
March 4 at 5:44am · Tallassee, AL ·

If Medicare will pay for com supplies where can I get supplies?

5 Comments

Like Comment

Conversations increasing significantly, all centered around the lack of clarity in Medicare coverage and next steps

CGM Receiver Pricing Is Not Transparent and May Be Incorrect

New devices can be priced in two ways

There are two ways Medicare can set pricing for new devices:

1. If the new device is comparable to an existing device, the price is set consistent with the existing device
2. If the new device is unlike a current technology, prices are set on the basis of commonly available retail pricing

We believe that CMS erroneously used the first approach in setting a price for the CGM receiver

- The Administrator's ruling claims that the CGM receiver is comparable to standard blood glucose monitors

CGM is not comparable to glucose meters

CGM receivers are more complex, have additional therapeutic features, and are therefore more expensive than traditional glucose monitors

- A CGM allows for real-time blood glucose monitoring, alerts, and alarms, allowing beneficiaries to make immediate adjustments to avoid adverse effects
- Traditional self-monitoring of blood glucose (SMBG) can only provide point-in-time information if a patient decides to test, and only if they are awake and aware of their glycemic status

Just because a new device replaces an older one for certain patients, they need not be priced the same

- Power-operated and manual wheelchairs are both used by patients who have difficulty walking, but the price of a power wheelchair is understandably much higher

In addition, the ruling requires a glucose meter to be supplied as an accessory to the CGM system

- Calling CGM a comparable replacement is not logical

The FDA classifies the devices differently

- CGM is a class III device
- Glucose monitors are a class II device

- In conclusion, we believe that the pricing for the CGM receiver was set using the wrong methodology in the Administrator's Ruling, as therapeutic CGM is not comparable to traditional SMBG
- The 2018 DMEPOS fee schedule provides an opportunity to rectify this mistake
- CMS should reassess the reimbursement rate utilizing the proper gap-filling methodology based on commercial sales prices of $400-$450

The Accessory Bundle is Logistically Infeasible and Imposes Unnecessary Complexity

For ten years, insurers have paid for CGM accessories separately and as-needed, rather than on an artificial monthly basis

Each of the components already has a HCPCS code

- A9276 – Sensor
- A9277 – Transmitter
- E0607 – Blood Glucose Monitor
- A4253 – Test Strips

Adding a new, bundled HCPCS code imposes unnecessary complexity on suppliers and manufacturers

- Must maintain two separate billing systems
- Precludes Dexcom from supplying to patients and Medicare Advantage plans directly, as it includes products we do not produce

The bundle is not transparent, and appears incorrectly developed

It is unclear what pricing assumptions CMS used for sensors and transmitters

- The bundle price is significantly lower than the sales price of the sensors and transmitters

Pricing was based on 60 test strips per month for calibration

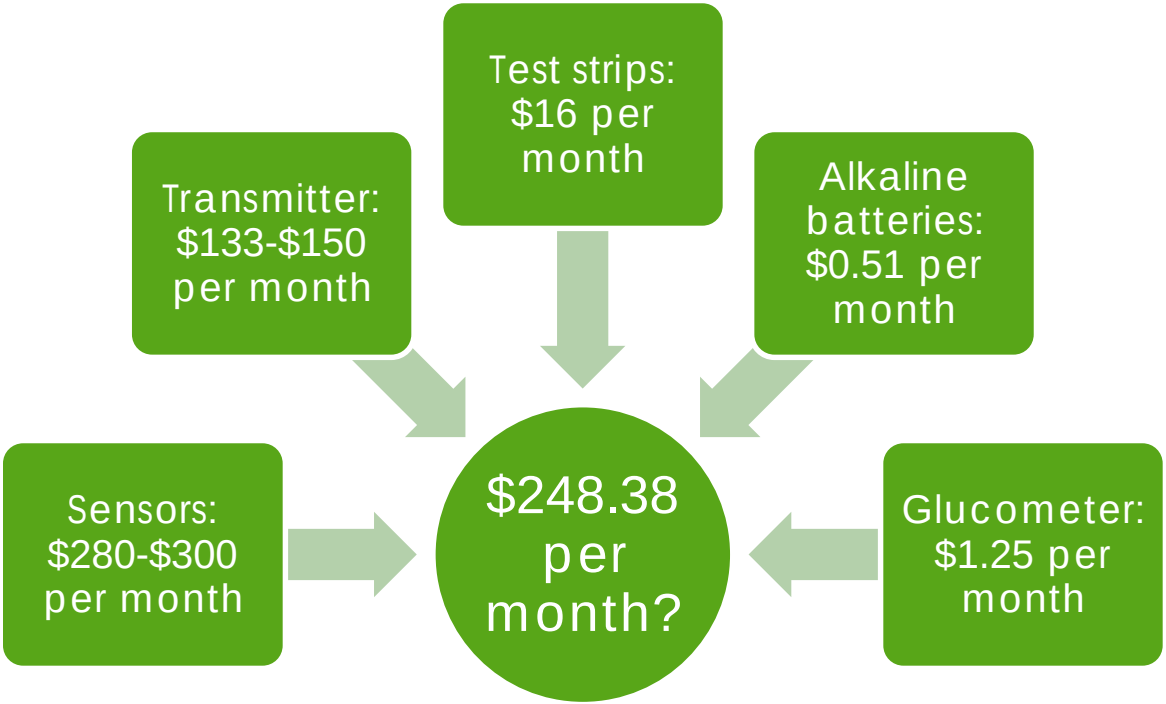
- Correct usage requires at least 64 test strips per month
- Most CGM users need ~80 per month

Pricing was based on 4 sensors per month

- Sensors last 7 days according to the FDA indication
- This is an insufficient number of sensors except in February

Pricing did not include lancets, control solution, and a number of other necessary items that are required to be supplied to beneficiaries

The prices of bundle components grossly exceed the bundle fee schedule



CMS never consulted Dexcom prior to announcing pricing

- The Administrator's ruling claims that bundled prices for sensors and transmitters are based on "invoice prices" and "manufacturer prices," respectively
- However, Dexcom was never contacted by CMS prior to the announcement of these fees
- It is therefore unclear how CMS arrived at these prices
- In fact, pricing in the bundle is approximately 50% of commercial pricing
- This price differential and artificial monthly billing system has left suppliers unwilling and unable to provide the supply bundle to patients
- Dexcom is happy to work with CMS to provide the information they need to set reimbursement accurately

Medicare already uses competitive bidding for diabetes testing supplies

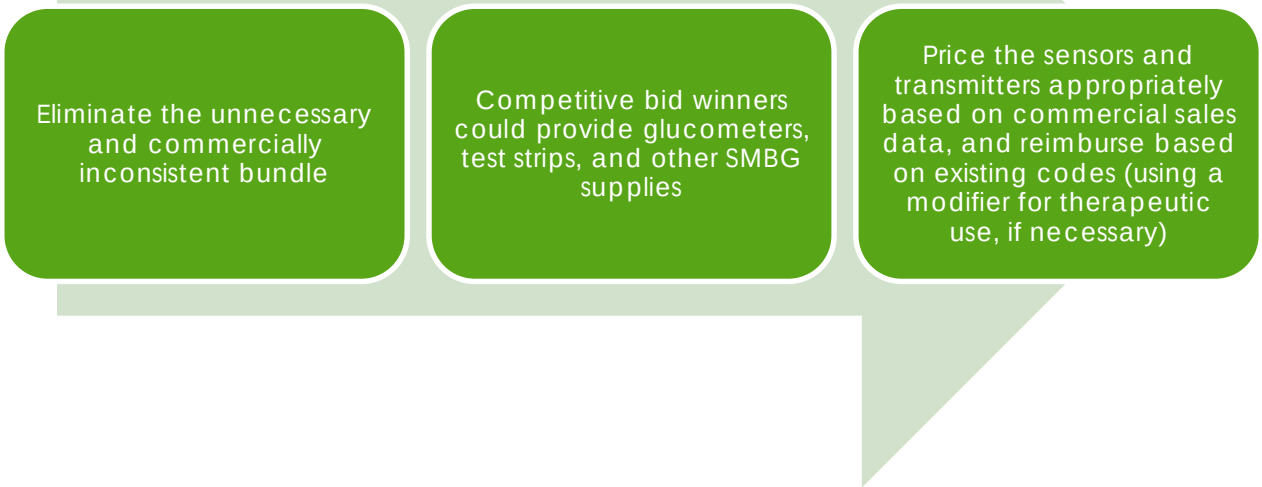
The Ruling provides an entirely separate mechanism for Medicare to pay for diabetes testing supplies like glucose meters and test strips

A bundled payment for test strips and glucose meters will negate the savings of the DMEPOS competitive bidding program

It will also exclude those suppliers who won their respective bid competitions from providing supplies to beneficiaries

As CMS already has one mechanism with which to pay for glucose meters and test strips, it is not necessary to create another by including them in a bundled payment for CGM

A simple solution exists



This solution would impose the least burden on patients, providers, and payers, and maximize the ability of beneficiaries to access their benefits.

Questions?