
Medicare to allow CGM use with smartphone apps, including sharing features! An advocacy win 15 months in the making - June 11, 2018

Executive Highlights

- **In very positive news, CMS has *finally* updated its 2017 CGM coverage policy: Medicare beneficiaries can now use CGM in conjunction with a smartphone app. YES!** This was announced via [Dexcom press release](#) late this afternoon, reflecting an understated 225-word [CMS post](#). Therapeutic CGM users will now be able to use their smartphones as the primary display device, view data on smartwatches, and take advantage of sharing/following. Previously, such use made CGM supplies non-covered. We're elated to see CMS appreciating app connectivity and listening to advocates.
- **According to Dexcom, the coverage policy must be updated within 10 days (i.e., by June 21).** CMS wrote more vaguely that the change will go into effect "in the near future." We hope there is no delay! Dexcom's [press release](#) implies current Medicare patients can download the Dexcom G5 app on Android or iOS and begin using their existing G5 transmitter with it. As we understand it, new users will still have to purchase a G5 receiver, but using it is no longer required.
- **Dexcom's G5 is currently the only system in the US with both a therapeutic (non-adjunctive) label and a primary display app, meaning this decision brings a competitive advantage in the very new Medicare CGM market.** Abbott's FreeStyle Libre is reimbursed by CMS, but the FreeStyle LibreLink app is not yet approved in the US and there has been no guidance on timing. (This is presumably a big FDA priority for Abbott.) Medtronic's Guardian Connect has an adjunctive label (and is thus not covered by Medicare), and Senseonics' is also pursuing an adjunctive label in its initial FDA submission (launch expected by ADA). As a reminder, Dexcom's improved G6 is currently under Medicare review, with a decision expected this fall.
- **It has been nearly 15 months of hard-fought advocacy to overturn the smartphone stipulation since CMS initially approved therapeutic CGM reimbursement in [March 2017](#).** Dexcom told us patient advocacy was a "huge tipping point," and we imagine the letter from the Senate and House Diabetes Caucus leaders two months ago also pushed CMS in the right direction.

In a long overdue and hard-fought update, [Dexcom](#) and [CMS](#) just announced that Medicare's CGM coverage policy is *finally* being updated: patients will now be able to use a smartphone app to view their therapeutic CGM data, share the data with caregivers, and view it on a watch. Woohoo! The news comes right in line with Dexcom's [4Q17](#) and [1Q18](#) guidance to resolve this long saga before the end of June.

According to Dexcom, the direction passed down by CMS is effective immediately, though DME MACs (Durable Medical Equipment Administrative Contractor) technically have until June 21 to officially update their policies. CMS more vaguely [wrote](#) that the DME MACs will issue a revised policy article in the "near future," at which time the published change will be effective." We're glad to hear there is hopefully no big delay here, as beneficiaries are clamoring for this!

CMS will still supply the DME-covered G5 receiver, though users can decide whether to use the app alone, the receiver alone, or both displays. Previously, if a beneficiary were to use a phone to view CGM data, the supply allowance would have been non-covered by Medicare.

Notably, existing Medicare G5 customers can download the mobile app on iOS/Android and log into their Dexcom accounts today - we're glad to hear they won't need new transmitters to do so. Based on [prior remarks from SVP Dr. Claudia Graham](#), we were previously under the impression that the Medicare G5 transmitters were modified so that they couldn't communicate with the app. However, that patients can use the app immediately suggests the transmitters are the same as the commercial versions; presumably communication was shut down on the app side (though we're not positive).

While we assume the policy update will apply to all therapeutic CGMs, this is a competitive advantage for Dexcom for now. Though Abbott's FreeStyle Libre, the only other approved therapeutic CGM, has mobile and sharing capabilities via FreeStyle LibreLink/LibreLinkUp in Europe, the apps are not available in the US, and no submission or launch timing has ever been shared. (We'd guess this is among the biggest FreeStyle Libre regulatory priorities, so a near-term launch would not be surprising to us.) Medtronic's Guardian Connect CGM does have an iOS app but is approved with an adjunctive label (and is therefore not covered by CMS). Senseonics is also pursuing adjunctive labeling in its preliminary submission (approval expected before ADA).

This coverage update also bodes well for Dexcom's G6, which has already been filed with CMS for coverage - a decision is expected this fall, and we have to imagine it will be positive.

The CMS update appears to end a long, fiercely-fought, and fairly ridiculous saga. Since Medicare shared nearly 15 months ago ([March 2017](#)) that it would reimburse therapeutic CGM, but disallow use with smartphones, there has been a swell of protests from industry, providers, and especially people with diabetes. Dexcom told us that the patient community was "a huge tipping point," which is excellent to hear. We suspect that an impactful letter to CMS [in late March](#) from Senate and House Diabetes Caucus leaders (Susan Collins, Jeanne Shaheen, Tom Reed, Diana DeGette) also helped push this coverage revision over the finish line. Hurrah!

In great news, Dexcom told us there was no compromise needed on their end and that the move is "consistent with the direction [CMS leadership] want to go." Indeed, the CMS [post](#) notes, "These changes are consistent with the Agency's approach of putting patients first and incentivizing innovation and use of e-technology." CMS also notes it did a "thorough" review of the law and its policies, which might reflect the coverage novelty of an app-centric medical device. We're elated to see this policy finally changed and a 15-month saga coming to a close. Hopefully it bodes well for future Medicare coverage of digital innovation in diabetes...

- **[CMS Post: "Announcement of Important Changes Impacting Medicare Coverage of Continuous Glucose Monitors."](#)** "Based on input from patients and other stakeholders, The Centers for Medicare & Medicaid Services (CMS) is announcing important changes in its written policies regarding how Medicare covers continuous glucose monitors (CGMs). These changes are consistent with the Agency's approach of putting patients first and incentivizing innovation and use of e-technology. CGMs are items of durable medical equipment (DME) that provide critical information on blood glucose levels to help patients with diabetes manage their disease. In January 2017, CMS issued a ruling providing for Medicare coverage of therapeutic CGMs. The ruling was followed by a policy article issued by the Durable Medical Equipment Medicare Administrative Contractors on March 23, 2017 to provide coverage guidance for these devices. CMS heard from numerous stakeholders who shared their concerns that Medicare's CGM coverage policy limited their use of CGMs in conjunction with their smartphones, preventing them from sharing data with family members, physicians, and caregivers. After a thorough review of the law and our regulations, CMS is announcing that Medicare's published coverage policy for CGMs will be modified to support the use of CGMs in conjunction with a smartphone, including the important data sharing function they provide for patients and their families. The Durable Medical Equipment Medicare Administrative Contractors will issue a revised policy article in the near future, at which time the published change will be effective."
- **The decision could pay dividends for patient/caregiver peace of mind, as well as for patient safety.** Last year, Dexcom [showed data](#) extolling the benefits of remote monitoring in seniors: Over 43% of older adults using the Dexcom Share Cloud had at least one follower.

Compared to those with no followers, these patients had slightly higher glucose values, but they used their sensors more regularly and had 14% fewer sensor glucose readings <70 mg/dl.

Close Concerns' Questions

Q: Does this policy apply to the viewing of CGM data on other devices as well, including pumps and direct-to-smartwatch transmission? According to Dexcom, Medicare only covers sensor-integrated pumps "if the pump is classified as a CGM receiver" - we assume that is the case for the t:slim X2/G5, but we're really not positive. And as Dexcom moves ahead on display of CGM data directly from the watch, does this updated coverage also apply?

Q: How soon will Abbott, Medtronic, and Senseonics make mobile CGM available for Medicare beneficiaries? How close is the FreeStyle LibreLink app to market in the US?

Q: How many more Medicare patients with diabetes will go onto CGM because of this rule? How many will switch from paying out of pocket/through private plans to the Medicare G5 CGM bundle?

Q: How many preventable adverse events in CGM-using beneficiaries did Medicare record? Does Medicare even have such data? And if so, was this a factor in overturning the rule? What other data did CMS look at?

Q: What was CMS' rationale for preventing smartphone use in the first place, in addition to the DME-covered receiver? Was CMS worried about having to pay for a phone? Why did it take CMS so long to overturn this policy, especially since there weren't any mitigating measures or compromises required of manufacturers or patients?

Q: How quickly will G6 get Medicare coverage? How many strips will Dexcom ship with the no-calibration G6? How many strips does Abbott currently ship with FreeStyle Libre?

Q: Where is Medtronic on Medicare coverage of MiniMed 670G/Guardian Sensor 3? We assume the latter needs non-adjunctive labeling, which seems poised to wait for the Harmony sensor per [Medtronic's Analyst Meeting last week](#). Could Tandem have the first Medicare-covered AID system, either with Basal.IQ (PLGS) this summer or in 1H19 with hybrid closed loop?

-- by Brian Levine, Adam Brown, and Kelly Close