
Huge first step for CGM and Medicare: Therapeutic CGMs (Dexcom G5) receive benefit category under durable medical equipment (Part B) - January 13, 2017

In a tremendous victory for people with diabetes, Dexcom [announced at 8pm this evening](#) that the Centers for Medicare & Medicaid Services (CMS) has classified "Therapeutic CGM" as "Durable Medical Equipment" under Medicare Part B. The landmark CMS ruling has been a major roadblock for years, but officially classifies CGMs that are FDA approved for making diabetes treatment decisions ("therapeutic CGM" - right now only Dexcom's G5 Mobile in the US) now have a "benefit category," the critical first step to gaining full coverage under Medicare. [The 16-page CMS Ruling letter](#) is dated today and is a fascinating read, sharing the nuances of "benefit category determination" in this case (e.g., durable vs. disposable CGM components), and importantly, offering a first look at Medicare pricing for therapeutic CGMs: a durable receiver will be reimbursed at \$236-\$277, with a monthly price of \$248.38 for sensors/transmitters (\$2,981/year). We see this as highly positive pricing for Dexcom, particularly given how Medicare has destroyed pricing in BGM. It seems like patients won't be limited on their monthly sensors, and we assume these levels will make this more than a sustainable business for Dexcom - especially with the move to G6 requiring only three sensors per month (and eventually two per month with eventual 14-day wear). Dexcom will now work with Medicare in "the coming months" on implementing coverage - we're not sure of the timeline on this, but assume it puts Medicare coverage on the earlier side of 2018 or, more likely, later this year. JDRF deserves enormous credit for this major news - as its press release notes, "Today's decision was more than a decade in the making." The benefit category determination comes [only one month after Dexcom won FDA approval](#) for a non-adjunctive (insulin dosing claim), and far earlier than we expected - EVP Steve Pacelli said earlier this week at JPM that the benefit category determination might come in ~6-9 months, followed by coverage ~6-9 months after that. We expect to hear more on Dexcom's 4Q16 call next month, but see this as highly positive news and a serious competitive advantage - only CGMs with a non-adjunctive (insulin-dosing) claim will be covered. Based on our read of the ruling, type 2s may also be eligible!

- **JDRF told us in 2015 that roughly 25-30% of the type 1 diabetes population is enrolled in Medicare**, which translates to ~400,000 patients (assuming ~1.5 million type 1s in the US). We've seen estimates from analysts that ballpark it at ~200,000-250,000. In either case, this unlocks a significant portion of the US market! As type 1s stay older longer (Kelly and Adam knocking on wood with all their friends) due to better management, this market will grow.
- **We believe this coverage might also extend to type 2s (we're not positive) - [the CMS ruling](#) does not seem to limit coverage only to type 1s. The conclusion language in the CMS ruling is very broad:** "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."
- **No one knows Abbott's strategy with FreeStyle Libre** - this puts the pressure on for them to gain an insulin dosing indication, though we've been assuming that getting mere approval for them would be the first win and holding on for insulin dosing could delay them significantly. (Or not.)
- **Many patient advocates have had a hand in making clear their needs to manage insulin as optimally as possible and we salute their roles as they have expanded patient voice, particularly related to the recent CGM and insulin dosing decision.**

-- by Adam Brown and Kelly Close