CLOSER LOOK

MEMORANDUM

Medicare to reimburse therapeutic CGM (Dexcom G5) for type 1s AND type 2s on intensive insulin therapy! Major win for CGM field - March 24, 2017

Executive Highlights

- In very exciting news, Medicare and Dexcom announced this morning that coverage will be provided for "therapeutic CGM" (i.e., Dexcom's G5) for people with type 1 AND type 2 diabetes on intensive insulin therapy (MDI or pump). Wow! The news comes earlier than expected and very quickly following the FDA's non-adjunctive label approval for G5 in December and Medicare's subsequent benefit category determination (DME, Part B) in January.
- Dexcom told us that eligible patients can now visit www.dexcom.com to get started - great to see this up and running so quickly. We estimate this landmark coverage decision could open up CGM coverage to roughly one million Medicare beneficiaries or more (type 1s plus type 2s on MDI).
- The Medicare announcement makes it very clear that this only applies to Dexcom's G5 (i.e., only therapeutic CGMs that are FDA approved for making treatment decisions), a significant near-term competitive advantage for Dexcom. Will other CGMs be able to get this label? Will private payers follow Medicare's cue and change/expand reimbursement?

Dexcom announced early this morning that Medicare will cover "therapeutic CGM" (i.e., Dexcom's G5) for all people with diabetes - type 1 and type 2! - on intensive insulin therapy. Wow! The coverage criteria are, incredibly, very broad. Patients are eligible if they:

- *Have diabetes;*
- *Have been using a home BGM and performing at least four checks per day;*
- *Are insulin-treated with MDI or a pump; and*
- *Have an insulin treatment regimen that requires frequent adjustment on the basis of therapeutic CGM testing results (Our read: most people on MDI, based on the value of CGM and how difficult insulin is to dose).*

According to yesterday's post on Medicare's Administrative Contractor website, the coverage applies to claims going back to January 12, which is when CMS classified therapeutic CGM (right now only Dexcom's G5 Mobile in the US) as "Durable Medical Equipment" (DME) under Medicare Part B. Dexcom management told us that patients with diabetes can now visit www.dexcom.com to get started. We'll be interested to see how hard it is for patients to get covered in clinical practice and how quickly this impacts Dexcom's sales.

This final Medicare step came far earlier than we expected. Dexcom's 4Q16 call only suggested that conversations with Medicare were ongoing, with a hope to resolve them by "mid-2017." FDA approved the non-adjunctive label claim for ages two and up in December, and Medicare has moved quickly since then: less than a month later in January, CMS designated therapeutic CGM as DME under Medicare Part B, and today's ruling comes about two months later.

Dexcom and the entire diabetes community are clearly ecstatic - this has been years in the making. CEO Kevin Sayer put it well in the press release: "This is a new era and a huge win for people with diabetes on Medicare who can benefit from therapeutic CGM. This decision supports the emerging consensus that CGM is the standard of care for any patient on intensive insulin therapy, regardless of age." Hear, hear!

The supply allowance includes the G5 receiver, sensors, transmitters, and, notably, BGM and related supplies (60 test strips/month) for calibration and "checks." Based on the 4Q16 call, we assume Dexcom will

contract with a distributor to provide the meter and strips. As noted in the January update from Medicare, the pricing (see below) is quite favorable and better-than-expected for Dexcom, given what has happened with pricing in BGM.

We estimate that this ruling could open up therapeutic CGM coverage for roughly one million Medicare beneficiaries. Dexcom estimates Medicare-aged patients are ~20% of the overall type 1 market, translating to ~300,000 patients (assuming 1.5 million US type 1s). Meanwhile, there are ~12 million total people with diabetes on Medicare (per CMS data), and assuming 95% of them have type 2 - with a conservative one in ten qualifying as intensive insulin users - translates to more than one million people now eligible for CGM coverage with this broad ruling. Wow! This clearly unlocks a massive portion of the US market for Dexcom, effectively doubling the potential market beyond type 1s not on Medicare. As people with diabetes stay older longer due to better management, these numbers should grow.

Our thanks, appreciation, and admiration go out to the many patient advocates who have had a hand in making clear their needs to manage insulin as optimally as possible - for a refresher, take a look at last July's FDA Advisory Committee. This victory was several years in the making - a result of countless person-hours poured into R&D, human factors, simulations, advocacy, and negotiations!

- **A 16-page CMS Ruling letter released in January shares the pricing information 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 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).
- **As noted above, Dexcom G5 Mobile is currently the only "therapeutic CGM" in the US.**
    - **Abbott shared on its 4Q16 call that it is pursuing both an adjunctive claim and a replacement claim for the FreeStyle Libre from FDA in parallel.** A launch is expected in the "second half of 2017." Can Libre obtain a replacement claim? There are good arguments on both sides: Relative to Dexcom, Abbott's FreeStyle Libre has the major added advantage of factory calibration (no accuracy noise from fingersticks), not to mention two large RCTs in IMPACT and REPLACE (showing patients stop taking fingersticks on Libre) and 250,000+ users-worth of real-world data in Europe alone. On the other hand, (i) FreeStyle Libre has lower point accuracy than G5, particularly in hypoglycemia; (ii) FreeStyle Libre does not have hypoglycemia alarms (which Dexcom used as a safety argument at July's FDA Advisory Committee meeting); and (iii) it took Dexcom ~2 years to get this approved with probably the most productive FDA relationship in the field.
    - **Medtronic' Guardian Sensor 3 (in the MiniMed 670G hybrid closed loop) does not have a non-adjunctive claim.** See our coverage of the approval from last fall here. We assume similar labeling will apply to the Guardian Connect standalone Mobile CGM currently under FDA review. This gives Dexcom a significant competitive advantage in standalone CGM until Medtronic can get a similar label.
    - **Senseonics is not currently pursuing a non-adjunctive claim.** See our 4Q16 coverage for more details.

Close Concerns Questions

Q: How hard will it be for patients and physicians to get Medicare reimbursement in practice? Will there be additional administrative hoops or paperwork? Will Medicare be overwhelmed with demand and claims?

Q: How does Medicare pricing compare to that of paid by non-Medicare beneficiaries?

Q: How many people with type 2 diabetes on Medicare and intensive insulin therapy will be interested in CGM? What percentage of type 1s on Medicare will now get on Dexcom CGM?

Q: How will Dexcom provide the BGM and strips?

Q: How long will it take other companies to get a non-adjunctive label claim?

Q: Will this decision affect private payers, if at all? Could it help expand type 2 coverage of CGM?

Q: Does this bode positively for automated insulin delivery coverage? Will Medicare only reimburse automated insulin delivery devices if they are driven by a therapeutic CGM?

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