Evaluate Vantage

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Dexcom clearance blazes a trail

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Earlier than expected US FDA clearance of its latest continuous blood glucose meter – the G6 – means Dexcom is now on an equal footing with Abbott. The G6 is the second CGM to gain US approval without the requirement for regular fingerstick calibration, following Abbott's FreeStyle Libre in September.

The approval is also significant for other reasons, both of which mean that more artificial pancreas-type systems could be ushered in. For one, the G6 is the first CGM to gain approval specifically permitting its interoperability with devices from other developers. And second, the FDA will now allow these interoperable glucose meters to be cleared for market via the quicker, cheaper 510(k) pathway. Innovation in an already fast-moving space is going to speed up.

The G6 is the first device to use this pathway, and as such was awarded a *de novo* clearance. The decision was based on two clinical trials in a total of 324 patients – adults and children over 2 – with diabetes. According to the FDA system readings were compared with laboratory tests that measure blood glucose values.

The Dexcom G6 system. L-R: receiver, sensor, smartphone app, sensor applicator.

Neither the FDA nor Dexcom itself has released the actual findings of these trials – Dexcom had not replied to a request for the data by the time of publication. Presumably the G6's accuracy was in the same ballpark as other approved CGMs, which have mean absolute relative differences (Mards) – a measure of how close the sensor reading is to a lab blood sugar test – of between 9% and 13.6% (*Nemaura's shares up on trial data but sensor will face stiff competition, February 1, 2018*).

The lack of trial data also means it is hard to tell how often, in practice, G6 users have to prick their fingers and test their blood sugar levels for calibration purposes. Despite the no-fingerstick approval awarded to Abbott's rival FreeStyle Libre, users actually ended up averaging one finger stick every other day in its clinical trials.

Launch of Abbott's device last autumn caused Dexcom's stock to crater 35% (*Dexcom crashes as Abbott FreeStyles its way to the US, September 28, 2017*). It is only yesterday's approval that has allowed Dexcom to recover.

Mix 'n' match

US launch of the G6 is planned to start in the coming quarter, and patients using Dexcom's current flagship device, the G5, will be upgraded as the various parts of the system – sensor, transmitter and a receiver or smartphone app – need to be replaced. Pricing decisions are in the works, with more information expected in Dexcom's next quarterly earnings call in May.

But the main point of the G6 is the fact that it is designed, and approved, specifically to work seamlessly with other devices. Dexcom has partnerships with many other diabetes device makers including the insulin pump makers Tandem Diabetes Care and Insulet and the software developers Glooko and Bigfoot Biomedical, and the FDA's endorsement could enable doctors to recommend mix 'n' match artificial pancreas systems incorporating the G6 in a way they might not with Abbott's FreeStyle Libre.

One note of caution: the new 510(k) pathway only applies to the CGM component of interoperable systems; approval for the system as a whole might have to be sought via the PMA route.

Dexy's fortnight stunners

Yet another partnership might be even more meaningful for Dexcom. The company has been quietly working with Verily, the health tech company owned by Google parent, Alphabet, on a smaller, slicker CGM.

The Verily device incorporates the G6 platform along with new tech, and is planned to have sensors with a 14-day life – the current sensor in the G6 is approved for use for 10 days. It will incorporate a single-use transmitter, in effect meaning it will be a disposable CGM, with the patient only retaining the receiver. They can do without that too if they use the phone app instead.

Launch of the first-generation version was slated for some time after the G6's, so with the G6 hitting the market sooner than expected the Verily system might too arrive ahead of schedule – perhaps this year.

The second-generation version of the Verily sensor will be the game-changer, though this is probably a couple of years away from market. It will be smaller still, and is expected to be cheaper than earlier Dexcom CGMs.

"The second-generation Verily device, we still have a few kinks to sort out. There's still more work to do before we can pick the regulatory path on generation two," said Kevin Sayer, the group's chief executive, on a conference call today.

Now comes the hard part. Dexcom must live up to the promise of its technology. It is up against two vast competitors – not just Abbott but also Medtronic, which is forging ahead with various iterations of an artificial pancreas produced entirely in-house. Dexcom faces an uphill battle. It is now, at least, slightly better armed.