Event – Diabetes panel for DexCom and Alere

Elizabeth Cairns

While efforts to produce an artificial pancreas understandably attract a good deal of attention, another innovation in the diabetes sphere is quietly approaching the US market. An FDA adcom next month will vote on whether DexCom’s G5 Mobile continuous glucose monitor ought to become the first device to gain US approval for use in dosing insulin without confirmatory finger sticks.

The same meeting will also look at Alere’s Afinion HbA1c assay. This is currently used to monitor diabetes patients, but Alere is seeking approval to use it to diagnose diabetes and pre-diabetes. Here the panel will make recommendations, but will not vote on approvability – even so, with its still-open merger with Abbott under strain Alere will be hoping for a positive outcome.

CGM meets CMS

DexCom’s G5 continuous glucose monitor (CGM) measures glucose in the patient’s interstitial fluid via a sensor placed on the skin. It is already approved and sold in the US, but its label mandates that readings from the device be confirmed using finger puncture and blood glucose meters. In other words, the label decrees that the patient may not use the G5’s information alone to decide whether to take insulin.

In practice this advice is often ignored by patients, who dose themselves without bothering with the finger stick step. But it matters for reimbursement. Medicare does not pay for CGMs as it considers them adjunctive to older tech: a positive panel verdict on July 21, followed by FDA approval for the dosing claim, would position DexCom ahead of its competitors.

The G5 does have approval for dosing insulin in Europe, as do some other CGMs – Abbott’s Freestyle Libre, for one. The US label is the next frontier.

Leerink analysts are bullish, stating that a combination of clinical data and simulations, as well as the fact that European patients can apparently use it to guide dosing safely, should be sufficient to get the G5 a positive approvability vote.

If they are right, approval could roll around in the first half of next year, with a CMS reimbursement decision a year or so later. Between 20% and 25% of type 1 diabetics – a population of up to 312,500 – are on Medicare, so if the CMS does decide to pay for the device this could boost DexCom’s top line significantly.

The market could expand further than that, however, as private insurers often follow the CMS’s lead on reimbursement decisions. Yesterday, DexCom announced the construction of a new manufacturing base for its CGMs in Arizona, and the hiring of 500 people to staff it, with an opening date of in the second quarter of 2017: it seems to be confident that sales will take off.

Monitoring to diagnosis

The following day the same committee will discuss the Afinion HbA1c test, which was granted 510(k) clearance in 2005 to determine HbA1c levels in a diabetic patient’s blood. Measuring HbA1c two or three times a year is recommended to keep tabs on whether a patient is successfully managing their condition.

The American Diabetes Association recommends that doctors use point-of-care HbA1c tests such as the Afinion to provide an opportunity to change a patient’s therapy if necessary.

Now Alere wants permission to use the test “as an aid in the diagnosis” of diabetes and also to help identify patients at risk of developing the disease. Lab-based HbA1c testing is used as a way of diagnosing diabetes – though plasma glucose tests are more commonly used – but current clinical guidelines contraindicate the use of point-of-care HbA1c tests in this way.

The FDA is using the panel meeting to solicit opinions from researchers and healthcare workers on whether to give the Afinion test the nod.

If a convincing majority of those asked are in favour of using Alere’s test in this way it could boost the company
as well as making diagnosis simpler for patients. But Alere has far more important things with which to concern itself.

Abbott Laboratories appears to be looking for a way to extricate itself from the agreement it signed in February to acquire Alere for nearly $6bn (Debt, integration and buyer’s remorse: can Abbott pull off its deals?, May 6, 2016). An expanded indication for the Afinion HbA1c assay would be nice, for sure – but it might not be Alere management's top priority.

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com or follow @LizEPVantage on Twitter