With MiniMed 530G, Medtronic Seeks New CMS Code

AB Newswire

Medtronic Diabetes tells Evidenced-Based Diabetes Management that it has applied to CMS for a new code that would cover sensor-augmented insulin pumps, which would broaden Medicare coverage for the new "artificial pancreas" system it unveiled on Friday.

With its unveiling of the first FDA-approved system that includes the name "artificial pancreas," Medtronic Diabetes has applied for a new reimbursement code with the Centers for Medicare and Medicaid Services (CMS), according to a company spokeswoman.

On Friday, Medtronic announced approval of the MiniMed 530G with Enlite, approved under a new FDA category, called "OZO: Artificial Pancreas Device System, Threshold Suspend." The system combines an insulin pump with a continuous glucose monitor (CGM) that automatically suspends insulin for up to two hours when sensor glucose values reach a preset level – and the patient doesn't respond to an alarm.

Right now, Medtronic Diabetes spokeswoman Amanda Sheldon said insurance coverage for the new system will be based on existing reimbursement codes for insulin pumps and CGM. But, in a statement released to *Evidenced-Based Diabetes Management* late Monday, Sheldon said that could change.

"We have applied for a new code with CMS for sensor-augmented pumps. We will evaluate additional reimbursement codes based on this new category of devices," Sheldon said.

This step, combined with Medtronic's ongoing dialogue with CMS regarding coverage for continuous glucose monitoring, could be important news for Medicare patients, who right now do not have coverage for CGM. (After Friday's announcement, several type 1 diabetes patients contacted Medtronic Diabetes on Twitter to ask about Medicare coverage, and to seek information about payment plans for the CGM portion.)

Medtronic touts the Enlite sensor as smaller, more comfortable, 31 percent more accurate, and says it detects up to 93 percent of hypoglycemia episodes when alerts are on.

The "threshold suspend" system is one of three under FDA review, according to the *EBDM* September issue, which examined potential payer reaction to an artificial pancreas announcement. Some payers said they would evaluate new systems as combinations of their component parts, while others said they would look at them as a new technology. For the full story, http://www.ajmc.com/publications/evidence-based-diabetes-management/2013/2013-1-vol19-sp7/The-Next-Frontier-for-the-Artificial-Pancreas-Payer-Coverage [1]

Reaction to the Medtronic announcement has been varied among the highly connected online T1DM community. While many advocates cheered Friday's news, some took issue with the use of the term "artificial pancreas" despite the language of the FDA approval.

Reviewers and Medtronic spokespersons agreed that the march toward an automated system with minimal patient involvement will not be an all-at-once event, but rather steps along a continuum; the difference of opinion appeared to be at what point the words "artificial pancreas" should be used.

"At Medtronic, our goal is to develop a fully automated artificial pancreas system for people with diabetes so that they can spend less time thinking about diabetes and more time living their lives," Sheldon said in her statement. "However, this type of technology is not going to happen all at once. Instead, we plan to take an iterative approach, introducing automation with each step toward a fully automated system."

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