

Continuous Glucose Monitors For Kids

IN MARCH, the U.S. Food and Drug Administration approved two continuous glucose monitoring systems for children with diabetes between the ages of 7 and 17. These new models of systems already in use by adults should be available by the end of this summer.

Continuous glucose monitoring (CGM) systems work via a sensor worn under the skin that measures glucose in interstitial fluid (fluid between cells) every 5 minutes. The sensor transmits these data wirelessly to a device, kind of like a pager, which gives a readout of blood glucose values. The FDA requires that patients be instructed to use traditional monitors and finger-stick measurements to calibrate CGM devices and to confirm CGM readings before making treatment decisions.

Both of the new systems are made by the company Medtronic. The pediatric model of the Guardian REAL-time system is a stand-alone CGM system, while the pediatric model of the MiniMed Paradigm REAL-time system is integrated with an insulin pump. It does not automatically deliver insulin doses in response to glucose readings, however; patients must still program pumps manually. Both pediatric versions feature a preprogrammed alarm that sounds when blood glucose reaches 90 mg/dl or below. This FDA-mandated



safety feature alerts children—and their parents—to possible low blood glucose. The adult versions allow patients to set their own alarm threshold for low blood glucose.

“I’m very much in favor of these devices for anyone who is motivated to improve their diabetes,” says Bruce Buckingham, MD, a professor of pediatric endocrinology at Stanford University School of Medicine who has written roughly 25 scientific papers on CGM. And indeed, Buckingham’s studies have shown that CGM can help motivated kids get better blood glucose control. He says he has seen patients improve their management at mealtimes and avoid lows at night.

Buckingham does offer one caution about the new systems:

He’s concerned that frequent and unnecessary alarms might disrupt children’s sleep because of the preset pediatric alarm threshold of 90 mg/dl.

The devices are only available by prescription for adults and children. No major insurance carriers cover CGM at this time. Insurance coverage for adult and pediatric versions could be 2 to 3 years away, says Steve Sabicer, senior manager of public relations with Medtronic in Los Angeles. The Guardian system costs \$1,399 and the Paradigm system costs \$999 (insurance typically covers the cost of the insulin pump). A monthly supply of sensors costs \$350. The pediatric versions should cost roughly the same, says Sabicer.

—Kate Ruder

DEXCOM
EXHIBIT 1238