Insurers Balk on Continuous Glucose Monitoring

BY MIRIAM E. TUCKER
Senior Writer

ST. LOUIS — Obtaining insurance coverage for continuous glucose monitoring may be something of a battle right now, but in many cases it's a winnable one, Jean R. Halford, R.D., said at the annual meeting of the American Association of Diabetes Educators.

The continuous glucose monitoring (CGM) device that provides data directly to patients is very recent technology. Medtronic Inc.'s Guardian system was approved in limited release by the Food and Drug Administration in July 2005. In early 2006, two CGM systems—Medtronic's integrated system (the MiniMed Paradigm REAL-Time Insulin Pump and Continuous Glucose Monitoring System) and DexCom Inc.'s STS system—were approved. In March 2007, Medtronic's second-generation Paradigm RT system with the MiniLink transmitter was licensed, and in May 2007, DexCom received approval for its new 7-day sensor (the Seven System). Abbott Laboratories' investigational Freestyle Navigator CGM system is expected to receive approval very soon.

As with all new expensive technology, insurers are not rushing to cover CGM. Medtronic's Guardian costs $1,399, whereas the Paradigm is $999 minus the cost of the pump, which is typically covered. The 3-day sensors cost $35 each. The Seven System is $800, plus $240 for a box of four 7-day sensors.

Because of these high costs, many health care professionals are holding back on recommending CGM to patients because they know it probably won't be covered. "I believe it is our role as educators to make our patients aware of all the devices and technologies that are out there. … We shouldn't preclude who we talk to based on whether they have insurance coverage," said Ms. Halford, a licensed dietician and certified diabetes educator at the Rocky Mountain Diabetes and Osteoporosis Center, Idaho Falls, Idaho. The center, which is the largest diabetes practice in the state, currently has 175 patients using continuous glucose monitoring.

Reimbursement may become easier in 2008, when the Centers for Medicare and Medicaid Services is expected to issue new Healthcare Common Procedural Coding System level II codes specifically for CGM. But in the meantime, the "junk codes" E1399 and A9999 (miscellaneous durable medical equipment) might work. Alternatively, Ms. Halford suggested, it's worth trying the CGM code S1030, which was developed for the previous device, the GlucoWatch. That device is no longer on the market, but the code's description—"continuous noninvasive glucose monitoring device, purchase"—doesn't specify any brand.

There are also two CPT codes (95250 and 95251) that were initially implemented for use with the Medtronic Continuous Glucose Monitoring System, which is worn by patients for 3 days, after which the physician downloads the glucose values. That device, first approved in 1999, does not provide results directly to patients. With the new systems, the same CPT codes can be used for CGM initiation and education, and for physician interpretation and report, respectively. Make sure those codes are in your contract, Ms. Halford advised.

But of course reimbursement isn't a guarantee even with a code, and—even if a patient's insurance does approve CGM—there is likely to be a huge out-of-pocket deductible for what is thus far a uniformly "out of network" expense. Until long-term data are available, insurance companies are likely to view CGM as investigational. "They think of it as a fancy traditional point-in-time glucose monitor. … They cannot comprehend the utilization for better control and peace of mind for the patient," she noted.

So educating insurers is part of Ms. Halford's "coordinated battle plan": First, identify the key individuals at each CGM manufacturer and develop a working relationship with them. Once they recognize that you are a "champion" of the technology, they will provide needed resources. Next, identify and meet the insurance company's case managers and develop a relationship with them. These individuals can be extremely helpful, Ms. Halford noted, as they are often in close contact with the company's medical director.

If possible, try to schedule a meeting with the insurance company's medical director and case manager, as well as the CGM manufacturers' managed care directors. "If we're persistent, we can make these contacts. You just have to want to make it happen," she remarked.

Initially at least, it makes sense to go after the "obvious" patients who would benefit from CGM, such as women with type 1 diabetes who are pregnant or planning a pregnancy, patients with gastroparesis, those on dialysis who are unable to get on the kidney transplant list unless their glucose control improves, or those with hypoglycemic unawareness, which is the one condition that the insurance companies "are really tuned into," she noted.

It's important to submit every prior authorization every time, so that insurance companies can see that there is a demand for continuous monitoring. With each letter, find out exactly what information they want and provide it. Create a file for each insurance company, including fax and telephone numbers, and key contacts.

There are two possible approaches for reimbursement. Patients can submit claims themselves for reimbursement without prior authorization. They will need a letter of medical necessity from the physician, along with individual invoices showing payments. It's a good idea to submit the invoice for the starter kit separately from the sensors, to improve the chances of staying "under the radar" in terms of any monetary caps (typically $500-$600) on device coverage that the insurer may have, she advised.

The other approach is for the physician's office to submit the request for prior authorization. Be prepared to write several letters. The initial letter of medical necessity should be kept relatively short. Include the patient's name, date of birth, insurance identification number, the medical necessity for the device, and information about the device, including utility, cost, and potential cost savings.

If the initial request is denied, the first letter of appeal—sent to a specific appeals person along with the case number of the denial—should go further in making the case. Provide information about hospitalizations for hypoglycemia or ketoacidosis, emergency visits, glucagon administration, lost time/injuries at work, previous complications related to low or high blood sugar, and any physician notes regarding labs, procedures, current care plan, and frequency of testing. It's also a good idea to provide journal abstracts highlighting the patient's specific needs. But don't send the entire article, because insurers will often point to the one sentence at the end saying that "more research is needed," Ms. Halford advised.

The third letter goes to the company's medical director. Include all the previous identifying information, but it's not necessary at this point to include lab work and medical information, because there will already be a file on the patient. Here, the goal is to address the patient's "right for appropriate and adequate medical care" and the insurer's "obligation" to meet those rights. Be sure to address any previous argument the company made against coverage.

It may also help to request a letter from the manufacturer's managed care director, who can review the clinical merits of CGM, clarify any misunderstandings regarding the therapy, address technology criteria set out by individual insurance companies and how CGM meets them, and assist with developing medical policy for CGM.

Although there are as yet no long-term outcomes data on CGM, there is certainly plenty of literature on the relationship between good blood glucose control and prevention of complications, including the landmark Diabetes Control and Complications Trial. Articles on the cost savings to insurance companies when hemoglobin A_{1c} levels are improved may also help. "Provide the insurance companies with a comprehensive list of reference materials," Ms. Halford recommended.

It might help to "piggyback" the CGM with other covered technologies, such as the insulin pump or the fingerstick method for self-monitoring of blood glucose. In all, 19 states (Alaska, Colorado, Connecticut, Florida, Louisiana, Maryland, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, North Carolina, Oregon, South Carolina, Vermont, Virginia, Wisconsin, and Wyoming) and the District of Columbia have now mandated coverage for self-monitoring. One major insurer (CareFirst BlueCross BlueShield) has begun covering CGM technologies in Maryland, Virginia, and the District of Columbia because of its interpretation of Maryland's statute requiring coverage of all "glucose monitoring technologies and supplies."

"If you're fortunate to live in one of those states, you want to check and see if there's a little opening you can wiggle your toe into and pry the door open," she said.

Another avenue to try is calling the state health insurance commission to discuss why the patient is being billed for out-of-network costs when "in-network" relationships don't exist because they have not yet been negotiated between manufacturers and distributors.

And one more possibility: Use the Americans with Disabilities Act for patients who risk losing their jobs secondary to poor blood glucose control. Insurance companies can't be forced to cover CGM, but if they cover things like hearing aids and special glasses, then they must "equitably" provide coverage for CGM. At least that argument is worth a try, Ms. Halford said. ■