

Emerging Technologies In Diabetes Research

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Three Major Health Plans Cover Continuous Glucose Monitors

Health plan coverage of continuous glucose monitors took several large steps forward, thanks in large part to the positive results of JDRF's CGM clinical trial and to strong advocacy efforts by the foundation. New data on the benefits of CGM in controlling diabetes (*New England Journal of Medicine*) led three large national insurers—United Healthcare, Aetna, and Kaiser Permanente—to expand their coverage policies for this therapy for people with type 1 diabetes. Other health plans are in the process of reevaluating their current policies.

The JDRF-funded trial showed that people with type 1 diabetes who regularly used CGM devices to help manage their disease experienced significant improvements in blood sugar control. Improvements were most evident in adults 25 years of age or older; in children, benefits were seen on some measures but not all, while teenagers and young adults, as a group, experienced no changes in glucose control compared with the control group. These latter results were likely due to less consistent CGM use among the younger participants. The researchers noted that individuals of *all* ages who used CGM six days a week or more lowered their A1c by at least .5 in just six months—enough to lower the risk of microvascular complications by approximately 25 percent.

United, Aetna, Kaiser Likely to Influence Other Insurers

Before the JDRF study was released, most of the major national insurance plans had formal policies limiting CGM coverage to type 1 patients with severe recurrent low blood sugar, mirroring language in the American Diabetes Association (ADA) guidelines released in January 2008. But after the results of the JDRF trial, there has been an expansion of health plan coverage policies.

For instance, in January 2009, United Healthcare announced an excellent CGM coverage policy that includes a detailed description of the JDRF-funded CGM study. The United policy provides coverage for long-term use of CGM for people with type 1 diabetes who are following a physician-ordered treatment plan and have either been

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unable to achieve optimum blood sugar control or have experienced hypoglycemia unawareness.

This is a significant step toward broader coverage for type 1 diabetes, as United Healthcare covers 70 million Americans and is a model that many other plans often follow.

Another leading health plan, Aetna, previously covered CGM only for people with type 1 who experienced severe recurrent low blood sugar. As a result of the JDRF trial, Aetna is now offering coverage to all type 1 patients 25 and older. Aetna, which covers about 18 million people, is still limiting CGM coverage in younger patients to those with recurrent severe low blood sugar.

Kaiser Permanente is another nationally recognized managed-care plan that is considered a thought leader in the field. Kaiser Southern California was one of the 10 sites in the JDRF-funded trial; as a result of its experience, Kaiser in northern and southern California is now covering CGMs for both children and adults. Kaiser has about nine million members.

Plus last month, the ADA released its 2009 *Standards of Medical Care in Diabetes*, which now includes updated recommendations for CGM use based on the results of the JDRF trial. The new recommendations are that:

- CGM, in conjunction with intensive insulin treatment, can be a useful tool to lower A1C in selected adults (25 or older) with type 1 diabetes.
- Although the evidence for A1C lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success, the ADA said, correlates with adherence to ongoing use of the device.

- CGM may be a supplemental tool to self-monitoring of blood glucose in those with hypoglycemia unawareness and/or frequent low blood sugar episodes.

JDRF's Advocacy Efforts Continue

While JDRF is very pleased with the expanded CGM coverage policies offered by United, Aetna, and Kaiser Permanente, it believes that all health plans should offer CGM coverage. Motivated by the trial results, JDRF and its funded researchers are working harder than ever to promote broad-scale coverage. A principal focus of this effort is encouraging health plans to provide CGM coverage to patients with type 1 diabetes who, first, are intensively managing their disease, and second, are prescribed a CGM by their physician.

For more information on CGM coverage and the JDRF trial, visit www.jdrf.org/cgmcoverage.

Where to get information on CGM coverage

JDRF's Continuous Glucose Monitoring Human Clinical Trial has demonstrated that consistent use of CGM devices significantly improves blood glucose control in people with type 1 diabetes. Based on these results, JDRF is advocating that health plans offer CGM coverage to all people with type 1 diabetes who are intensively managing their disease and are prescribed CGM by their physician. Several large insurers have changed their policies to follow that position.

If you are seeking CGM coverage for yourself or a loved one, here's some information that can help:

- A list of [select plans and their coverage policies](#)
- How to [find out if your plan covers CGM](#)
- Tips for [how to apply for case-by-case coverage if your plan doesn't cover CGM yet](#)

In Brief: Updates from the Artificial Pancreas Project

For a wealth of articles and other updates about emerging technologies, visit JDRF's Artificial Pancreas Project web site at www.jdrf.org/artificialpancreas.

JDRF's CGM Study a 2008 Medical Breakthrough

JDRF's groundbreaking human clinical trial of continuous glucose monitors was named one of the top 10 medical breakthroughs of 2008 by ABC News. The JDRF trial was the first major, multi-center trial to document the benefits of CGM devices in helping people with type 1 diabetes better control blood sugar levels and reduce the risk of devastating complications. The CGM devices, manufactured by several companies and approved by the FDA as an adjunctive therapy for diabetes, provide both a real-time snapshot of glucose levels as well as trend information on whether glucose is moving upwards or downwards, and how fast. The devices also provide warnings when glucose levels are becoming too high or too low. CGMs are a key component of the artificial pancreas, along with insulin pumps and algorithms, sophisticated computer programs that connect the two devices. The study is an important step forward in JDRF's drive to develop an artificial pancreas because it demonstrates for the first time the benefit of using CGMs to control blood sugar.

Aaron Kowalski, Keynote Speaker at Diabetes Technology Meeting

Delivering the keynote address at the Diabetes Technology Society annual meeting in Bethesda, Md., Dr. Aaron Kowalski, director of JDRF's Metabolic Control program, noted that diabetes monitoring and control technologies were virtually non-existent from the development of insulin in the 1920s until the 1990s. But since the introduction of CGM devices in the late '90s, the field has moved quickly to provide people with type 1 diabetes with more accurate and more sophisticated devices to help them manage their disease. That pace should continue to accelerate, he said, as results from the JDRF trials on CGM are analyzed, reported on, and adopted more widely—paving the way not just for increased usage of monitors, but the development of a closed-loop artificial pancreas.

“What the trials are showing is that, in general, people who use CGM devices regularly can drive down their A1c levels, and they can do so without an increase in severe

low blood sugar episodes. That's incredible news from a patient standpoint, as this is really the first time we've seen a diabetes technology or diabetes treatment protocol create tighter control without increasing the risk of hypoglycemic episodes," Dr. Kowalski said. To read the article on the conference, or to view his presentation "Accelerating the Availability of an Artificial Pancreas," visit the APP web site.

Martha Stewart Show Features the Artificial Pancreas Project

In late January, the "Martha Stewart Show" included a segment in which Dr. Kowalski spoke about the evolution of diabetes treatment and the use of CGMs and artificial pancreas technologies. Visit the APP web site to watch a clip from the show.

Toward an Artificial Pancreas: An FDA-NIH-JDRF Workshop

JDRF co-hosted a workshop with the Food and Drug Administration and the National Institutes of Health that focused on the state of the art in the research and development of an artificial pancreas. The two-day workshop brought together some of the world's top scientists, regulators, industry representatives, and others with a connection to type 1 diabetes to discuss the progress and remaining challenges in the development of closed-loop systems that will automatically regulate blood sugar in people with diabetes. Video presentations by the scientists are posted on our APP web site. A conference summary report is also available.

JDRF has launched the Artificial Pancreas Project to accelerate the availability of an artificial pancreas to people with diabetes, one of the foundation's cure therapeutic pathways. The overall goal of the project is to accelerate the development, regulatory approval, health insurance coverage, and clinical acceptance of continuous glucose monitoring and artificial pancreas technology.

The long term goal is for broad patient access and a thriving competitive market for these devices and products.

For regular updates to the Artificial Pancreas Project, please visit www.jdrf.org/artificialpancreas.