

FDA clears first OTC continuous blood glucose monitor

March 6 2024, by Robin Foster



The U.S. Food and Drug Administration on Tuesday approved the

country's first over-the-counter continuous glucose monitor for type 2 diabetes.

The new Dexcom Stelo Glucose Biosensor System, which will be available by summer, is intended for people 18 and older who have type 2 diabetes but do not take insulin, according to the agency.

Also known as CGMs, these monitors consist of [tiny sensors](#) that prick the skin and track blood sugar levels 24 hours a day. That information is sent wirelessly to a smartphone, which can help alert users, their families and their doctors to blood sugar swings.

"CGMs can be a powerful tool to help monitor [blood glucose](#). Today's clearance expands access to these devices by allowing individuals to purchase a CGM without the involvement of a health care provider," [Dr. Jeff Shuren](#), director of the FDA's Center for Devices and Radiological Health, said in an agency [news release](#) announcing the approval. "Giving more individuals valuable information about their health, regardless of their access to a doctor or [health insurance](#), is an important step forward in advancing health equity for U.S. patients."

However, the agency warned that the new system is not intended for patients with problematic hypoglycemia (low blood sugar), noting it was "not designed to alert the user to this potentially dangerous condition."

More than 25 million Americans have type 2 diabetes and do not use insulin, Dexcom noted. While the company's G7 CGM system is available to these folks, patients have to get a prescription for it.

That changes with the arrival of an over-the-counter version of the tracking system.

"Use of CGM can help empower people with diabetes to understand the

impact of different foods and activity on their glucose values," [Dr. Tamara Oser](#), a [family physician](#), said in a [Dexcom news release](#). "For people newly diagnosed with Type 2 diabetes or not taking insulin, these devices are often not covered by insurance and Stelo presents an opportunity to provide valuable information that can impact their [diabetes](#) management."

The sensor will be worn on the upper arm, and it lasts for up to 15 days before it needs to be replaced, according to [Dexcom's website](#).

Data from a [clinical study](#) provided to the FDA showed the device performed similarly to other iCGMs, the FDA said. Adverse events reported in the study included local infection, skin irritation and pain or discomfort.

More information: Visit the American Diabetes Association for more on [diabetes management](#).

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