

FDA clears first automated device to deliver insulin to people with type 2 diabetes

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The U.S. Food and Drug Administration on Monday approved the expanded use of an automated insulin pump system to include those with type 2 diabetes.

It's the first such system for use by people with the more prevalent type 2 form of the disease.

The FDA first signed off on the system, which automatically adjusts [insulin delivery](#) as needed, for type 1 diabetes in 2022.

In approving Insulet's Omnipod 5 [insulin](#) delivery system for type 2 [diabetes patients](#), the FDA said the clearance "provides a new option that can automate many of these manual tasks [of tracking and managing [blood sugar](#) levels], potentially reducing the burden of living with this chronic disease."

Insulin options for people with type 2 diabetes have been limited to injection with a syringe, an insulin pen or an insulin pump. These all require patients to administer insulin one or more times a day and to check their blood sugar levels frequently.

Now, they have a simpler alternative.

"The FDA has long worked with the diabetes community to ensure access to additional options and flexibilities for diabetes management," Dr. Michelle Tarver, acting director of the FDA's Center for Devices and Radiological Health, said in a [news release](#) announcing the expanded use. "The FDA is committed to advancing new device innovation that can improve the health and quality of life for people living with chronic diseases that require day-to-day maintenance like diabetes."

Insulet applauded the expanded approval.

"Today's announcement represents a [significant milestone](#) in providing easy-to-use, patient-centric technology for the treatment of type 2 diabetes," Insulet CEO Jim Hollingshead said in a company [news release](#).

With the new system, the wearable product provides up to three days of non-stop insulin delivery without the need to handle a needle. The Omnipod 5 works in concert with a continuous glucose monitor to manage blood sugar with no daily injections and no finger pricks.

"I've seen firsthand how difficult it is for patients to reach their targets with injections," Dr. Anne Peters, director of the University of Southern California Westside Center for Diabetes, said in the Insulet news release. "Omnipod 5 makes it easier for people with type 2 diabetes to take their insulin and stay in range, leading to remarkable improvements in clinical outcomes and overall quality of life."

In approving the expanded use, the FDA reviewed data from a clinical study of 289 individuals 18 years and older with type 2 diabetes for 13 weeks.

What did the researchers discover? Volunteers' blood sugar control improved, and these improvements were seen across all demographic groups. Adverse events were generally mild to moderate, and included hyperglycemia (high blood sugar); hypoglycemia (low blood sugar) and skin irritation.

In the United States, about 38.4 million people are diagnosed with diabetes, according to the [U.S. Centers for Disease Control and Prevention](#). It is a condition in which the body does not make enough or effectively use the blood glucose-regulating hormone insulin.

In type 1 diabetes, the pancreas does not make insulin because the body's immune system attacks islet cells in the pancreas.

With type 2 diabetes, the pancreas makes less insulin than it used to and the body becomes insulin-resistant. People still make insulin but their bodies don't respond well to it. Some people with type 2 diabetes will

need supplemental insulin.

People with type 2 diabetes may also take other medications that can help increase [insulin secretion](#) or improve insulin sensitivity, the FDA noted.

More information: The American Diabetes Association has more on [insulin pumps](#).

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