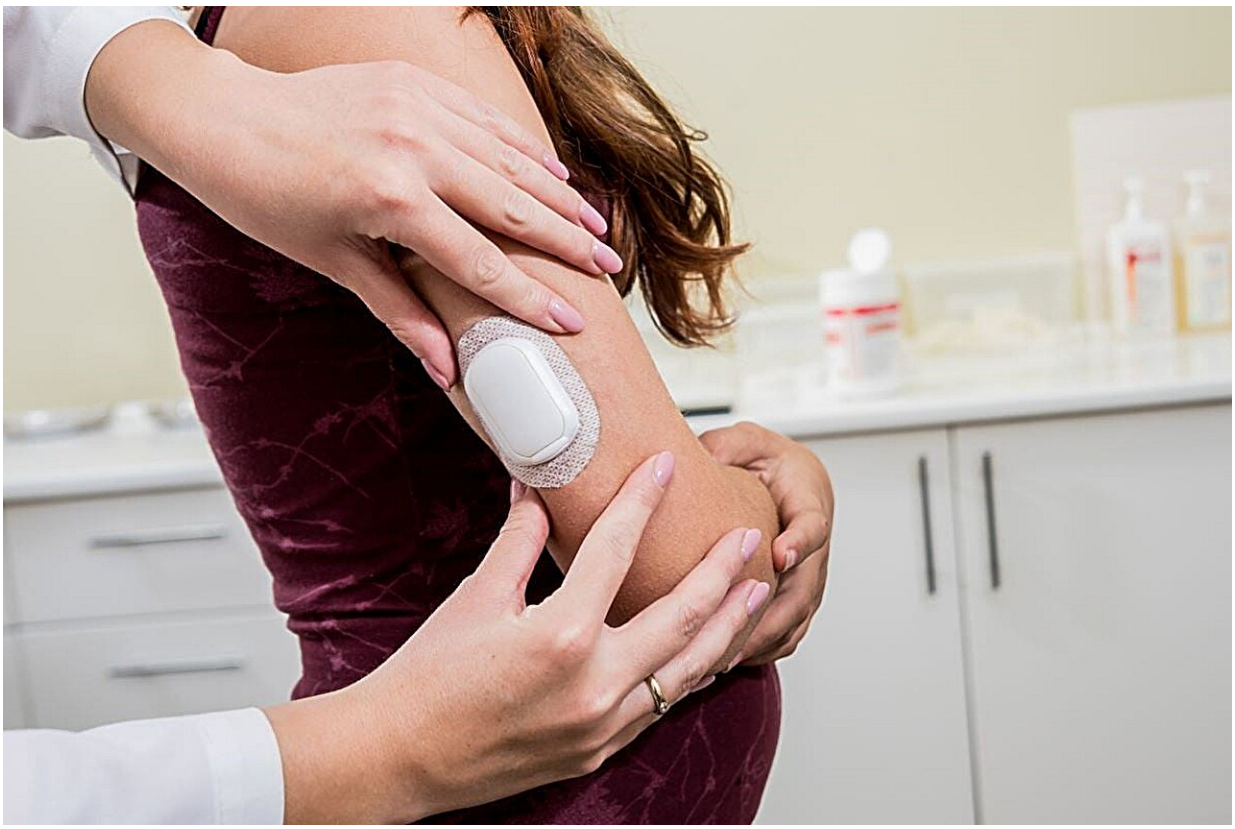
FDA expands approval of Omnipod 5 insulin delivery system to include patients with type 2 diabetes

August 28 2024



On August 26, the U.S. Food and Drug Administration approved the Insulet Omnipod 5 insulin delivery system for patients with type 2

diabetes. It is the first such system for use by people with the more prevalent 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 glucose levels], potentially reducing the burden of living with this chronic disease."

"The FDA has long worked with the diabetes community to ensure access to additional options and flexibilities for diabetes management," Michelle Tarver, M.D., acting director of the FDA 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 nonstop insulin delivery without the need to handle a needle. The Omnipod 5 works in concert with a continuous glucose monitor to manage blood glucose with no daily injections and no finger pricks.

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. Volunteers' blood glucose control improved, and these improvements were seen across all demographic groups. Adverse events were generally mild to moderate and included hyperglycemia, hypoglycemia, and skin irritation.

More information: More Information

Citation: FDA expands approval of Omnipod 5 insulin delivery system to include patients with type 2 diabetes (2024, August 28) retrieved 3 September 2024 from https://medicalxpress.com/news/2024-08-fda-omnipod-insulin-delivery-patients.html