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# Omnipod<sup>®</sup> 5 Automated Insulin Delivery System: a Review for the Community Pharmacist

**TECHNOLOGICAL ADVANCEMENTS THAT HAVE EXPANDED** available options for managing type 1 diabetes (T1D) can simplify the treatment of patients with diabetes and help them achieve American Diabetes Association (ADA)-recommended target glycemic levels.<sup>1,2</sup> Patients who may benefit from additional strategies involving novel technology to support them achieve their goals may include those who are unable to achieve ADA-recommended glycated hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels, desire better glycemic control, or want to reduce their current burden of diabetes management.<sup>3</sup>

Automated insulin delivery (AID) systems, also called hybrid closed-loop systems, allow for continuous communication between an insulin-infusing pump and a continuous glucose monitor (CGM).<sup>4,5</sup> Patients can use AID systems to help manage their blood glucose levels and minimize hypoglycemic events.<sup>5</sup> With AID systems, insulin delivery can not only be suspended, but also increased or decreased based on sensor glucose values. Current AID systems require users to bolus for meals and snacks.<sup>5</sup>

Pharmacists can help patients manage their diabetes by providing information and training on the available AID models prescribed to them, including the Omnipod<sup>®</sup> 5 Automated Insulin Delivery System. The Omnipod<sup>®</sup> 5 System—the first wearable, on-body, tubeless AID system available in the United States—is integrated with the Dexcom<sup>®</sup> G6 CGM System to manage blood glucose without the need for multiple daily injections in patients with T1D aged 6 years and older.<sup>6</sup> The Omnipod<sup>®</sup> 5 System and Dexcom<sup>®</sup> G6 CGM System require separate prescriptions. The Omnipod<sup>®</sup> 5 System is covered as a pharmacy benefit through commercial insurance plans, Medicare Part D, and Medicaid insurers.

## OMNIPOD<sup>®</sup> 5 AUTOMATED INSULIN DELIVERY SYSTEM FEATURES

The Omnipod<sup>®</sup> 5 System consists of the Omnipod<sup>®</sup> 5 Pod, Dexcom<sup>®</sup> G6 CGM System, and the Omnipod<sup>®</sup> 5 App.<sup>6</sup>

### **Omnipod<sup>®</sup> 5 Pod**

The Pod provides automated, continuous subcutaneous delivery of insulin for up to 72 hours (3 days).<sup>3,6</sup> It is compatible with the rapid-acting U-100 insulins NovoLog<sup>®</sup> (insulin aspart), Humalog<sup>®</sup> (insulin lispro), and Admelog<sup>®</sup> (insulin lispro).<sup>6</sup> The Pod requires no tubing; it can be

placed on almost any part of the body where the patient would inject insulin.<sup>6</sup> The Pod is waterproof up to a depth of 25 feet for 60 minutes (IP28 rating), which provides patients with the freedom to participate in athletics, including swimming. The controller is not waterproof.<sup>6</sup>

Each Pod contains SmartAdjust™ technology that adjusts insulin every 5 minutes using the patient's customizable glucose target that can range from 110 mg/dL to 150 mg/dL, in 10 mg/dL increments, with up to 8 segments per day.<sup>3,6</sup> SmartAdjust™ technology automatically increases, decreases, or pauses insulin delivery based on a prediction of where glucose values will be 60 minutes in the future; it considers CGM value and trend, the adaptive basal rate, and the patient's insulin on board.<sup>2,6</sup>

### **Dexcom<sup>®</sup> G6 CGM System**

The Omnipod<sup>®</sup> 5 System is designed to work with the Dexcom<sup>®</sup> G6 CGM System that provides real-time glycemic data collecting and sending glucose readings to the Pod every 5 minutes.<sup>6</sup> The Dexcom<sup>®</sup> G6 app must be used to control the CGM.<sup>6</sup>

### **Omnipod<sup>®</sup> 5 App**

The Omnipod<sup>®</sup> 5 App comes installed on the dedicated handheld Omnipod<sup>®</sup> 5 Controller, which is provided at no additional cost with the patient's first prescription. Patients can also download the Omnipod<sup>®</sup> 5 App to a compatible smartphone. Refer patients to **omnipod.com/compatibility** for a full list of compatible smartphones.<sup>6</sup> Within the App, patients can select a basal profile, target glucose and bolus settings, activate and deactivate the Pod, connect with the Dexcom<sup>®</sup> G6 CGM System, and select an insulin delivery mode (Automated or Manual). In Automated Mode, the system adjusts the insulin dose every 5 minutes using the customized glucose target. During Manual Mode, the system delivers insulin based on user-defined Basal Programs.<sup>6</sup>

The App includes the SmartBolus Calculator, which calculates a suggested bolus dose based on the patient's current glucose value, the CGM trend (if the "use CGM" button within the calculator is selected), a programmable correction factor, an insulin-to-carbohydrate ratio, the duration of insulin action (insulin on board; remaining

**TABLE.** Clinical Results With the Omnipod® 5 Automated Insulin Delivery System<sup>2,6</sup>

Patient population	Average HbA <sub>1c</sub> (SD)		P value	Average percentage of time in glucose range of 70-180 mg/dL <sup>a</sup>	P value
	Standard therapy	Omnipod® 5 System			
Children (n = 112)	7.67% (0.95)	6.99% (0.63)	< .0001	15.6% (~3.7 h/d) improvement	< .0001
	0.71% decrease				
Adults and adolescents (n = 128)	7.16% (0.86)	6.78% (0.68)	< .0001	9.3% (~2.2 h/d) improvement	< .0001
	0.38% decrease				

AID, automated insulin delivery system; d, day(s); h, hour(s); HbA<sub>1c</sub>, glycated hemoglobin A<sub>1c</sub>; SD, standard deviation.

<sup>a</sup>Change between standard therapy phase (2 weeks) and Omnipod® 5 System phase (3 months).

insulin in the body from previous boluses), and a target glucose value.<sup>6</sup> In both Automated and Manual Modes, the SmartBolus Calculator allows for the immediate delivery of the bolus insulin dose and aims to bring the glucose value to the customizable glucose target.<sup>6</sup>

## CLINICAL RESULTS

A 3-month, single-arm, multicenter, prospective clinical study investigated the safety and efficacy of the Omnipod® 5 System. A total of 112 children (age, 6-13.9 years) and 128 adolescents and adults (age, 14-70 years) with T1D were enrolled.<sup>2</sup> Of the 240 participants enrolled, results were obtained from the 98% who completed the study (111 children and 124 adolescents and adults).<sup>6</sup> The study included a 2-week standard therapy phase to collect baseline glucose data followed by a 3-month Omnipod® 5 AID phase.<sup>2</sup>

The primary end points were improvements in overall HbA<sub>1c</sub> level, time in range at a target of 70 to 180 mg/dL, and the incidence of severe hypoglycemia and diabetic ketoacidosis after 3 months of Omnipod® 5 System use vs the 2-week standard therapy phase.<sup>2</sup> As shown in the **TABLE**, use of the Omnipod® 5 System resulted in reduced HbA<sub>1c</sub> in children by 0.71% (mean, 7.67%-6.99%) and in adults by 0.38% (7.16%-6.78%); time in range increased by 15.6% in children (52.5%-68.0%) and 9.3% in adults (64.7%-73.9%).<sup>2,6</sup> There were 3 cases of severe hypoglycemia and 1 case of diabetic ketoacidosis reported with Omnipod® 5 System use; they were not related to AID malfunction.<sup>2,6</sup>

## ROLE OF THE PHARMACIST

With the evolving role of the pharmacist as part of the diabetes care team, community pharmacists are uniquely positioned to counsel patients with T1D on clinical and practical information regarding their prescribed diabetes management strategies.

When patients present to pick up their prescribed Omnipod® 5 System, pharmacists should reinforce the need for training prior to use and advise on how to receive training

before the patient leaves the pharmacy. First-time Omnipod® 5 users need to set up their account on **omnipod.com** and schedule training to learn how to use the Omnipod® 5 System.<sup>6</sup> To support patients during counseling sessions, pharmacists can register for an Omnipod® Connect account to learn more about how to set up the Omnipod® 5 System, how it works, and its unique features. After counseling, pharmacists can direct patients to review the Omnipod® 5 User Guide, Quick Start Guide, and additional resources, which are available at **omnipod.com**.<sup>6</sup>

## IMPORTANT SAFETY INFORMATION

The Omnipod® 5 Automated Insulin Delivery System is indicated for use by individuals with type 1 diabetes mellitus in persons 6 years of age and older. The Omnipod® 5 System is intended for single patient, home use and requires a prescription. The Omnipod® 5 System is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®.

Refer to the Omnipod® 5 Automated Insulin Delivery System User Guide and **www.omnipod.com/safety** for complete safety information including indications, contraindications, warnings, cautions, and instructions. ■

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