



Federal Employee Program.

## **DISPOSABLE INSULIN DELIVERY DEVICES**

### **CeQur Simplicity, Omnipod 5, Omnipod Dash, Omnipod GO, V-go Insulin Delivery System**

#### **RATIONALE FOR INCLUSION IN PA PROGRAM**

##### **Background**

Intensive insulin therapy involves the use of three or more injections of insulin per day or the use of an insulin delivery device. Disposable insulin delivery devices have adjustable basal rates and more tunable insulin bolus dosing. Conventional insulin delivery devices can be programmed to deliver precise basal insulin rates throughout the day and night. Other features may include bolus calculators that use the current glucose level, the manually entered grams of carbohydrates consumed, active insulin, and the patient's own insulin parameters such as insulin-to-carbohydrate ratio and blood glucose targets (1-2).

Because disposable insulin delivery devices use rapid-acting insulin with a short duration of action, any short-term interruption in the continuous flow of insulin could result in hyperglycemia and possibly diabetic ketoacidosis which is potentially life-threatening. Checking blood glucose levels frequently will alert patients, caregivers, or providers to the possibility of insulin delivery device failure or malfunctioning and prevent the development of ketosis or dangerous hyperglycemic effects. Only providers whose practice can assume full responsibility for a comprehensive insulin delivery device management program should offer this technology. Appropriate patient selection is necessary and must include a thorough assessment of the patient's knowledge of diabetes management principles (1-2).

##### **Regulatory Status**

FDA-approved indications:

CeQur Simplicity is a mechanical insulin patch delivery system designed to deliver bolus doses of rapid-acting insulin during mealtimes and when glucose levels are high. The patch is intended for subcutaneous delivery of rapid-acting insulin for the management of diabetes in adults requiring insulin (3).

Omnipod 5, Omnipod Dash, and V-Go insulin delivery system are disposable continuous subcutaneous insulin infusion (CSII) devices intended for use in patients with insulin-dependent diabetes. These devices are designed to deliver continuous insulin therapy through customizable basal rates and on-demand bolus (4-5).

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Omnipod GO is an insulin delivery device for patients with type 2 diabetes who would typically take daily injections of long-acting insulin. Omnipod GO is a standalone, wearable, insulin delivery system that provides a fixed rate of continuous rapid-acting insulin for 72 hours (6).

#### **Summary**

Disposable insulin delivery devices offer adjustable basal rates and tunable insulin bolus dosing. CeQur Simplicity is a mechanical insulin delivery system designed to deliver bolus doses of rapid-acting insulin during mealtimes and when glucose levels are high. Omnipod 5, Omnipod Dash and V-Go are CSII devices designed to deliver continuous insulin therapy through customizable basal rates and on-demand bolus doses. Omnipod GO is designed to provide a fixed rate of continuous rapid-acting insulin for 72 hours. Insulin delivery device failure can lead to diabetic ketoacidosis. Checking blood glucose levels frequently will alert patients, caregivers, or providers to the possibility of insulin delivery device failure or malfunctioning and prevent the development of ketosis or dangerous hyperglycemic effects (1-6).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of disposable insulin delivery devices while maintaining optimal therapeutic outcomes.

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