



**5.99.016**

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Miscellaneous Products	<b>Original Policy Date:</b>	January 1, 2022
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**Last Review Date:** March 6, 2026

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## Disposable Insulin Delivery Devices

### Description

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

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#### 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

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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 is 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).

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## Related policies

CGM Monitors and Supplies, Diabetes Test Strips

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Disposable insulin delivery devices may be considered **medically necessary** if the conditions indicated below are met.

Disposable insulin delivery devices may be considered **investigational** for all other indications.

## Prior-Approval Requirements

### Diagnosis

Patient must have the following:

Type 1 or Type 2 Diabetes Mellitus

**AND ALL** of the following:

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1. Patient has utilized **ONE** of the following insulin administration methods for at least the last 90 days:
  - a. Use of an insulin pump/pod/patch
  - b. Insulin dependent with > 3 insulin injections per day and history of suboptimal blood sugar control
2. Patient has completed a comprehensive diabetes education program
3. Patient will use a rapid-acting insulin with the patch/pod/device
4. Prescriber agrees to monitor the patient's HbA1c

**AND** the following for CeQur Simplicity **only**:

1. If requesting more than 32 patches per 90 days: patient must be using more than 180 units of insulin per 96 hours

**AND** the following for Omnipod 5 and Omnipod DASH **only**:

1. If requesting more than 30 pods per 90 days: patient must be using more than 200 units of insulin per 72 hours

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## Prior-Approval *Renewal* Requirements

### Diagnosis

Patient must have the following:

1. Type 1 or Type 2 Diabetes Mellitus
  - a. Patient's HbA1c is improved or stabilized using an insulin pump/pod/patch

**AND** the following for CeQur Simplicity **only**:

1. If requesting more than 32 patches per 90 days: patient must be using more than 180 units of insulin per 96 hours

**AND** the following for Omnipod 5 and Omnipod DASH **only**:

1. Patient has the corresponding system [i.e., Omnipod DASH Personal Diabetes Manager (PDM), Omnipod 5 System (controller or smartphone app)] for the requested pods

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- If requesting more than 30 pods per 90 days: patient must be using more than 200 units of insulin per 72 hours

## Policy Guidelines

### Pre-PA Allowance

None

### Prior-Approval Limits

#### Quantity

Product	Quantity
CeQur Simplicity (≤ 180 units of insulin per 96 hours)	1 Starter Kit <b>AND</b> 32 patches per 90 days <b>OR</b>
CeQur Simplicity (> 180 units of insulin per 96 hours)	1 Starter Kit <b>AND</b> 96 patches per 90 days <b>OR</b>
Omnipod 5 (≤ 200 units of insulin per 72 hours)	1 Starter Kit <b>AND</b> 30 pods per 90 days <b>OR</b>
Omnipod 5 (>200 units of insulin per 72 hours)	1 Starter Kit <b>AND</b> 90 pods per 90 days <b>OR</b>
Omnipod DASH (≤ 200 units of insulin per 72 hours)	1 Starter Kit <b>AND</b> 30 pods per 90 days <b>OR</b>
Omnipod DASH (>200 units of insulin per 72 hours)	1 Starter Kit <b>AND</b> 90 pods per 90 days <b>OR</b>
V-Go Insulin Delivery System	90 devices per 90 days

**Duration**      12 months

### Prior-Approval *Renewal* Limits

#### Quantity

Product	Quantity
CeQur Simplicity (≤ 180 units of insulin per 96 hours)	32 patches per 90 days <b>OR</b>

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CeQur Simplicity (> 180 units of insulin per 96 hours)	96 patches per 90 days <b>OR</b>
Omnipod 5 (≤ 200 units of insulin per 72 hours)	30 pods per 90 days <b>OR</b>
Omnipod 5 (>200 units of insulin per 72 hours)	90 pods per 90 days <b>OR</b>
Omnipod DASH (≤ 200 units of insulin per 72 hours)	30 pods per 90 days <b>OR</b>
Omnipod DASH (>200 units of insulin per 72 hours)	90 pods per 90 days <b>OR</b>
V-Go Insulin Delivery System	90 devices per 90 days

**Duration** 12 months

## Rationale

### 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.

### References:

1. McAdams BH, Rizvi AA. An Overview of Insulin Pumps and Glucose Sensors for the Generalist. J Clin Med. 2016 Jan 4;5(1):5. doi: 10.3390/jcm5010005. PMID: 26742082; PMCID: PMC4730130. McAdams BH, Rizvi AA. An Overview of Insulin Pumps and Glucose

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2. Grunberger, G., Sherr, J., Allende, M., Blevins, T., Bode, B., Handelsman, Y., Hellman, R., Lajara, R., Roberts, V. L., Rodbard, D., Stec, C., & Unger, J. (2021). American Association of Clinical Endocrinology Clinical Practice Guideline: The use of Advanced Technology in the management of persons with diabetes mellitus. *Endocrine Practice*, 27(6), 505–537. <https://doi.org/10.1016/j.eprac.2021.04.008>
3. CeQur Simplicity website. 2026. CeQur Simplicity Features [online]. Available at: <https://www.myceqursimplicity.com>
4. Omnipod website. 2026. Omnipod [online] Available at: <https://www.omnipod.com>
5. V-GO website. 2026. Getting Ready V-Go. [online] Available at: <https://www.go-vgo.com>

### Policy History

Date	Action
December 2021	Addition to PA. Annual review
February 2022	Changed policy name to Disposable Insulin Delivery Devices per FEP
March 2022	Annual editorial review and reference update. Revised Omnipod requirement to “Patient has the corresponding system (i.e., Omnipod DASH Personal Diabetes Manager [PDM]) for the requested pods, or will be acquiring the corresponding system from the manufacturer”
June 2022	Addition of Omnipod 5 pods to policy
July 2022	Addition of Omnipod 5 Starter kit to Prior Approval Limits; removed Omnipod 5 requirement to have corresponding system on initiation
August 2022	Addition of Omnipod DASH starter kit to Prior Approval Limits; removed initiation requirement for Omnipod DASH to have the corresponding system; revised wording to remove references to pods to reduce redundancy
September 2022	Annual review
March 2023	Annual review and reference update
July 2023	Addition of Omnipod GO to policy
September 2023	Annual review
March 2024	Annual review
September 2024	Annual review. Increased quantity limits for CeQur patch to accommodate for the new 8 count package
December 2024	Annual review

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March 2025	Annual review and reference update
December 2025	Annual review. Per FEP, removed Omnipod GO from policy
March 2026	Annual review and reference update

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.**