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Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Miscellaneous Products	Original Policy Date:	January 1, 2022
Subject:	Disposable Insulin Delivery Devices	Page:	1 of 8

Last Review Date: March 8, 2024

Disposable Insulin Delivery Devices

Description

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

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 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).

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).

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

CeQur Simplicity, Omnipod 5, Omnipod Dash, and V-go ONLY

Diagnosis

Patient must have the following:

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Type 1 or Type 2 Diabetes Mellitus

AND ALL of the following:

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 30 patches per 90 days: patient must be using more than 180 units of insulin per 72 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

Omnipod GO ONLY

Diagnosis

Patient must have the following:

Type 2 Diabetes Mellitus

AND ALL of the following:

1. Inadequate treatment response to oral antidiabetic therapy **OR** oral antidiabetic therapy would not allow patient to reach their HbA1c goal
 2. Patient is unable to self-inject insulin
 3. Patient has completed a comprehensive diabetes education program
 4. Patient will use a rapid-acting insulin with the pod
 5. Prescriber agrees to monitor the patient's HbA1c
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Prior-Approval *Renewal* Requirements

CeQur Simplicity, Omnipod 5, Omnipod Dash, and V-go ONLY

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 30 patches per 90 days: patient must be using more than 180 units of insulin per 72 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
2. If requesting more than 30 pods per 90 days: patient must be using more than 200 units of insulin per 72 hours

Omnipod GO ONLY

Diagnosis

Patient must have the following:

Type 2 Diabetes Mellitus

AND the following:

1. Patient's HbA1c is improved or stabilized

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Policy Guidelines

Pre-PA Allowance

None

Prior-Approval Limits

Quantity

Product	Quantity
CeQur Simplicity (≤ 180 units of insulin per 72 hours)	1 Starter Kit AND 30 patches per 90 days OR
CeQur Simplicity (> 180 units of insulin per 72 hours)	1 Starter Kit AND 90 patches per 90 days OR
Omnipod 5 (≤ 200 units of insulin per 72 hours)	1 Starter Kit AND 30 pods per 90 days OR
Omnipod 5 (>200 units of insulin per 72 hours)	1 Starter Kit AND 90 pods per 90 days OR
Omnipod DASH (≤ 200 units of insulin per 72 hours)	1 Starter Kit AND 30 pods per 90 days OR
Omnipod DASH (>200 units of insulin per 72 hours)	1 Starter Kit AND 90 pods per 90 days OR
Omnipod GO	30 pods per 90 days OR
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 72 hours)	30 patches per 90 days OR
CeQur Simplicity (> 180 units of insulin per 72 hours)	90 patches per 90 days OR
Omnipod 5	30 pods per 90 days OR

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(≤ 200 units of insulin per 72 hours)	
Omnipod 5 (>200 units of insulin per 72 hours)	90 pods per 90 days OR
Omnipod DASH (≤ 200 units of insulin per 72 hours)	30 pods per 90 days OR
Omnipod DASH (>200 units of insulin per 72 hours)	90 pods per 90 days OR
Omnipod GO	30 pods per 90 days OR
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:

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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

Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.