

## Disposable Insulin Pump Devices

- Omnipod DASH Insulin Management System
- Omnipod 5 Automated Insulin Delivery System
- Omnipod GO

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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## Summary

Diabetes mellitus (DM), commonly referred to as diabetes, is a chronic (long-term) medical condition characterized by high blood glucose (sugar) levels. This may be because the pancreas (an organ in the belly) does not make enough insulin (a hormone), or because the body is not responding to insulin the way it should. Insulin helps glucose get into cells in the body, giving it energy. With diabetes, sugar builds up in the blood because the body stops responding to insulin, or because there is not enough of it. Inadequate glycemic control can lead to serious complications including cardiovascular disease, nephropathy, retinopathy, and neuropathy. The goal of diabetes management is to maintain blood glucose levels as close to the normal range as possible to prevent or delay complications. Diabetes is broadly grouped into two types:

- Type 1 diabetes mellitus: the pancreas produces little or no insulin.
- Type 2 diabetes mellitus: the body's cells do not respond effectively to insulin, and sometimes the pancreas does not produce enough insulin.

Diabetes is usually managed by eating healthy foods, getting plenty of exercise, and sometimes with medicines. Medicines are used to either control blood sugar, or to lower the chance of problems that can happen in the future because of diabetes. These medications can be insulin itself, or medications that help the body make more insulin or help insulin do its job.

Insulin therapy is essential for all individuals with type 1 diabetes and many with type 2 diabetes to achieve optimal glycemic control. Intensive insulin therapy aims to mimic normal physiologic insulin secretion through the use of basal insulin for control of glucose throughout the day and bolus or prandial insulin to cover food intake during mealtime and correct hyperglycemia. This is most often accomplished through multiple daily injections (MDI) using basal and rapid-acting insulins or continuous subcutaneous insulin infusion (CSII) via an insulin pump.

However, despite advances in insulin formulations and delivery systems, many individuals fail to reach glycemic targets. Adherence to insulin regimens is often suboptimal due to the burden of multiple daily injections. Insulin pumps, while allowing for more precise insulin delivery, require extensive training and are not acceptable to all patients.

In addition, Plan members who have been diagnosed with Type 1 or 2 DM, and meet certain medical necessity criteria and standards of care developed by the American Diabetes Association (ADA), may be eligible for specific supplies and equipment subject to plan benefits, such as those used to monitor blood sugar and inject insulin. Members with more advanced disease or those requiring more frequent insulin may qualify for continuous glucose monitoring and specialized insulin delivery systems.

Disposable insulin devices such as the Ominpod 5, Omnipod DASH, and Omnipod Go offer insulin administration as an alternative to multiple daily injections. The Omnipod 5 is an example of an automated insulin delivery (AID) system - whereby when controlled by the Omnipod application, and

connected to a continuous glucose monitor (CGM) such as a Dexcom G6/G7, you can automatically administer insulin based on a blood glucose threshold. The Omnipod DASH can be used similarly if utilized with a CGM and a third-party application (the Omnipod DASH is not considered an AID system). The Omnipod Go is a patch-pump system where once applied, it can provide a fixed-dose of insulin (from 10-40 units per day) for up to 72 hours. Additional patch-pump devices that have been approved include: the CeQur Simplicity Patch and the V-Go Patch.

This Pharmacy Clinical Guideline is specific to only Disposable Insulin Pump Devices listed in Table 1 below.

- For the Plan's Medical Clinical Guideline on medical necessity criteria of:
  - Diabetes equipment and supplies, see Oscar Clinical Guideline: Diabetes Equipment and Supplies (CG028).
  - Continuous glucose monitoring, implantable continuous glucose monitoring, and insulin infusion pumps, see Oscar Clinical Guideline: Insulin Delivery Systems and Continuous Glucose Monitoring (CG029).
- For the Plan's Pharmacy Clinical Guideline for Stand-alone CGM Systems, please refer to Oscar Clinical Guideline: Continuous Glucose Monitors (CGMs) (PG121).
- The Plan also covers home glucose monitors and products for self-monitoring of blood sugar as an alternative to CGMs. Please contact CVS/Caremark, the Plan's Prescription Benefit Manager, to obtain a standard blood glucose meter from the preferred brand.
- For the Plan's Pharmacy Clinical Guideline for the disposable insulin delivery system CeQur Simplicity, please refer to the Oscar Clinical Guideline: CeQur Simplicity Insulin Delivery System (PG192).

## Definitions

"Blood Glucose" is the main sugar found in the blood and the body's main source of energy. It is also called glucose or blood sugar. The blood level of glucose is noted in milligrams per deciliter (mg/dL). When blood sugar is too high for long periods of time, complications can occur as a result of blood vessel damage.

"Blood Glucose Monitors" are small, portable machines used to check blood glucose levels in the ambulatory setting. A member will prick his/her fingertip and place a small sample of blood into the device for a glucose reading. There are a number of different types of blood glucose monitors for specialized situations, such as those for members with visual impairments.

"Continuous Glucose Monitoring (CGM)" serves as an alternative to self-monitoring of blood glucose (SMBG) with a home glucose monitor for patients who have diabetes and require multiple daily measurements.

"Disposable Insulin Infusion Pumps" are insulin-delivery devices that consist of disposable components. Both the OmniPod and V-Go insulin delivery systems have disposable components, but they differ in that the OmniPod system is programmable, whereas the V-Go system is non-programmable.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Hemoglobin A1c (HbA1c)" is a test that measures a person's average blood glucose level over the past 2 to 3 months. It is also known as "A1C" or "glycosylated hemoglobin". A1C should be measured at least twice annually for stable glycemic control and at least quarterly for unstable glycemic control. A1C test results may be affected by age, certain conditions, ethnicity, genetic traits, and pregnancy; the ADA recommends that treating providers review for discrepancies between A1c results and blood glucose results.

"Hyperglycemia" is excessive blood glucose. Fasting hyperglycemia is blood glucose above a desirable level after a person has fasted for at least 8 hours. Postprandial hyperglycemia is blood glucose above a desirable level 1 to 2 hours after a person has eaten.

"Hypoglycemia" is a condition that occurs when one's blood glucose is lower than normal, usually less than 70 mg/dL. Signs include hunger, nervousness, shakiness, perspiration, dizziness or lightheadedness, sleepiness, and confusion. If left untreated, hypoglycemia may lead to unconsciousness. Hypoglycemia is treated by consuming a carbohydrate-rich food such as a glucose tablet or juice. It may also be treated with an injection of glucagon if the person is unconscious or unable to swallow.

"Hypoglycemia Unawareness" is a state in which a person does not feel or recognize the symptoms of hypoglycemia. People who have frequent episodes of hypoglycemia may no longer experience the warning signs of it.

"Insulin" is a hormone made by the beta cells of the pancreas. Insulin allows glucose to enter the cells in the body for use in energy production, and when it is inadequate, the sugar remains in the blood leading to diabetes. There are a variety of oral and parenteral medications that can increase insulin production, increase the body's sensitivity to existing insulin and reduce blood sugar. Insulin can also be injected or infused when lifestyle changes and non-insulin medications are inadequate.

"Multiple daily injections (MDI)" refers to an insulin regimen involving the administration of basal insulin once or twice daily and separate bolus injections of rapid-acting insulin with meals and snacks. It aims to mimic normal physiologic insulin secretion.

"Time in range (TIR)" is the percentage of time that a person's blood glucose levels are within the target range, typically 70-180 mg/dL. It is a metric of glycemic control often assessed through continuous glucose monitoring.

"[s]" indicates state mandates may apply.

"Type 1 Diabetes" is an autoimmune condition that occurs when the beta cells of the pancreas are unable to produce enough insulin and therefore blood glucose cannot enter cells to be used for energy. Type 1 diabetes is often referred to as "insulin-dependent" because these patients require insulin daily to maintain their blood glucose at acceptable levels.

"Type 2 Diabetes" is a condition that occurs when either the pancreas doesn't produce enough insulin or the body cells become resistant to insulin. Type 2 diabetes is much more common than Type 1, and is often treated with combinations of lifestyle changes and non-insulin medications, although insulin can be required later in the disease course. Many individuals with Type 2 Diabetes are "insulin-requiring".

## Medical Necessity Criteria for Initial Clinical Review

### Initial Drug-Specific Criteria

#### Omnipod DASH and Omnipod 5

The Plan considers Omnipod DASH and Omnipod 5 and its components medically necessary when ALL of the following criteria are met:

1. Prescribed by or in consultation with an endocrinologist or diabetes specialist; *AND*
2. The member has a diagnosis of diabetes mellitus; *AND*
3. Recent chart documentation within the last six (6) months of the request is provided showing BOTH of the following:
  - a. The member self-monitors blood glucose at least three (3) times per day, OR is using a continuous glucose monitor (CGM); *and*
  - b. The member meets ONE (1) of the following:
    - i. Is currently using an insulin pump; *or*
    - ii. The member meets BOTH of the following:
      1. Uses multiple (i.e., 2 or more) insulin injections per day; *and*
      2. The member meets ONE (1) of the following:
        - a. Diagnosis of type-1 diabetes; *or*
        - b. A child, where multiple daily insulin injections would be impractical or inappropriate; *or*
        - c. Complications of inadequate glycemic control (e.g., neuropathy, nephropathy, retinopathy) indicative of more intensive insulin regimens; *or*

- d. Dawn phenomenon unresponsive to management with long-acting insulin agents (e.g., insulin glargine or detemir); *or*
  - e. For initial requests, HbA1c greater than 7%, despite an adequate regimen of multiple daily injections; *or*
  - f. Hypoglycemic episodes requiring third-party assistance (e.g., seizure, loss of consciousness, glucagon administration, transport to an emergency room, hospitalization); *or*
  - g. Recurrent hypoglycemia (<70 mg/dL on at least two occasions despite adherence to recommended diabetic treatment plan); *or*
  - h. Pregnancy or planning for pregnancy; *or*  
*[NOTE: Earlier initiation of insulin infusion pumps may be indicated in women at high risk of fetal or maternal complications of diabetes and pregnancy.]*
  - i. Wide swings in blood glucose values before meal time (e.g., regular fluctuations of preprandial blood glucose to levels <70 mg/dL and/or >140 mg/dL); **AND**
4. The product being requested meets ONE (1) of the following:
- a. Is being prescribed for use within the Plan's Quantity Limit of:
    - i. Starter Kit - 1 Kit per 365 days; *or*
    - ii. Pods Refill Pack - 10 Pods per month (i.e. 2 boxes, 5 Pods per box); *or*
  - b. IF the requested dosing instructions exceeds the Plan's Quantity Limit (e.g., requiring more than 200 units of insulin every 72 hours, or request for 48-hour Pod change), a valid clinical rationale is provided demonstrating medical necessity.

If the above prior authorization criteria are met, the requested Disposable Insulin Pump Device will be approved for up to 12 months.<sup>[5]</sup>

#### Omnipod GO

The Plan considers the Omnipod GO Insulin Delivery Device medically necessary when ALL of the following criteria are met:

- 1. The medication is prescribed by or in consultation with an endocrinologist or diabetes specialist; **AND**
- 2. The member is 18 years of age or older; **AND**
- 3. The member has a confirmed diagnosis of type 2 diabetes mellitus; **AND**
- 4. The member meets ALL of the following:
  - a. Self-monitors blood glucose at least three (3) times per day, OR is using a continuous glucose monitor (CGM); *and*
  - b. The member does not require the ability to deliver bolus doses of insulin or utilize variable basal delivery rates; *and*

- c. In conjunction with their treating provider, has determined that a pre-set continuous basal insulin delivery rate of 10, 15, 20, 25, 30, 35 or 40 units per day via the Omnipod GO system is appropriate to manage their diabetes; *AND*
- 5. The member has suboptimal glycemic control despite adherence to their current insulin regimen, as evidenced by any ONE (1) of the following:
  - a. Frequent hypoglycemia; *or*
  - b. Hemoglobin A1c > 7.0%; *or*
  - c. Significant glucose variability (i.e., fluctuations) based on self-monitoring or continuous glucose monitoring (CGM) data; *AND*
- 6. The requested quantity of Omnipod GO meets ONE (1) of the following:
  - a. Is within the Plan's Quantity Limit of 10 Pods per 30-days (or 30 Pods per 90-days); *or*
  - b. IF the requested quantity exceeds the Plan's Quantity Limit (e.g., requiring more than 200 units of insulin every 72 hours, or request for 48-hour Pod change), a valid clinical rationale is provided demonstrating medical necessity.

If the above prior authorization criteria are met, the requested Disposable Insulin Pump Device will be approved for up to 12 months.<sup>[5]</sup>

#### *Continued Care*

#### Medical Necessity Criteria for Subsequent Clinical Review

##### Subsequent General Medical Necessity Criteria

The Plan considers reauthorization requests for Disposable Insulin Pump Devices medically necessary when ALL of the following criteria are met:

- 1. The member continues to meet all applicable [Initial Drug-Specific Criteria](#) criteria; *AND*
- 2. There is documented provider evaluation within the last 6 months demonstrating BOTH of the following:
  - a. The member's adherence to their diabetic treatment plan and insulin pump therapy; *AND*
  - b. Improvement in glycemic control from baseline, as evidenced by any ONE (1) of the following:
    - i. Reduction in hemoglobin A1c; *or*
    - ii. Reduction in frequency or severity of hypoglycemia episodes; *or*
    - iii. Reduction in glycemic variability; *or*
    - iv. Improvement in time in range (TIR) on the member's CGM (e.g., percent time in the member's individual goal blood glucose range); *or*
    - v. Achievement of other individual glycemic targets (e.g., average blood glucose, reduction in preprandial/postprandial or fasting blood glucose).

If the above prior authorization criteria are met, the requested Disposable Insulin Pump Device will be approved for up to 12 months.<sup>[5]</sup>

#### Experimental or Investigational / Not Medically Necessary<sup>[5]</sup>

Disposable Insulin Pump Devices (Omnipod DASH, Omnipod 5, and Omnipod GO) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Use of the devices for any indication or purpose other than those specifically listed in the [Medical Necessity Criteria](#).
- Use of the devices in combination with medications other than insulins (e.g., Novolog, Fiasp, Humalog, Lyumjev, Admelog) that have been tested and found to be compatible with the devices.
- Use of Omnipod GO in individuals under 18 years of age or those with type 1 diabetes, as the safety and effectiveness of the device have not been established in these populations.

Additionally, the Plan does not consider medically necessary the replacement or repair of Disposable Insulin Pump Devices when lost or damaged due to neglect, misuse, or improper care. Replacement may be approved when the device meets ALL of the following:

1. Is malfunctioning; *AND*
2. Is out of warranty; *AND*
3. Cannot be refurbished.

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## Appendix A

Table 1: Disposable Insulin Pump Devices

Systems	Components	Use Life
Omnipod DASH Insulin Management System	Personal Diabetes Manager (PDM)	every 5 years (warranty covers first 4 years of life)
	Pods	Up to 3 days (48-72 hours) or after delivering 200 units of insulin (whichever comes first)
	Contour Next One Blood Glucose Monitor (separate but compatible)	
Omnipod 5 System	Controller	every 2 years (based on 300-500 charge cycles) with typical use Starter kit shelf life of 18 months
	Pods	Up to 3 days (48-72 hours) or after delivering 200 units of insulin (whichever comes first)
	Dexcom G6 and Dexcom G7 Continuous Glucose Monitor (separate but compatible with the pod) Freestyle Libre 2 Plus Sensor (separate but compatible with Omnipod 5 App)	
Omnipod GO	Pods	3 days

NOTE: V-Go (20, 30, 40) Disposable Insulin Delivery Device is a Non-Formulary product and is subject to Oscar Clinical Guideline: Medical Necessity Criteria for Non-Formulary Products (PG069).

## Clinical Guideline Revision/History Information

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