Disposable Insulin Pump Devices

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

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.

Summary

Diabetes mellitus (commonly referred to as diabetes) is a chronic (long-term) medical condition characterized by high blood glucose (sugar). 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. Diabetes is broadly grouped into two types:

- Type 1 diabetes - the pancreas make no insulin, or a very small amount
- Type 2 diabetes - cells in the body do not respond to insulin the way they should; sometimes, the pancreas also does not make 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. 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.

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 CG028 - Diabetes Equipment and Supplies.
    - continuous glucose monitoring, implantable continuous glucose monitoring, and insulin infusion pumps, see CG029 - Insulin Delivery Systems and Continuous Glucose Monitoring.
- For the Plan's Pharmacy Clinical Guideline for Stand-alone CGM Systems, please refer to PG121 - Continuous Glucose Monitors (CGMs).
- 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.

Table 1: Disposable Insulin Pump Devices

Systems	Components	Use Life
Omnipod Insulin Management System	Personal Diabetes Manager (PDM)	every 4 years
	Pods	Up to 3 days or after delivering 200 units of insulin (whichever comes first)
	Abbot Freestyle Blood Glucose Monitor (built-in)	
Omnipod DASH Insulin Management System	PDM	every 4 years
	Pods	Up to 3 days or after delivering 200 units of insulin (whichever comes first)

	Contour Next One Blood Glucose Monitor (separate but compatible)	
Omnipod 5 System	Controller	every 4 years
	Pods	Up to 3 days or after delivering 200 units of insulin (whichever comes first)
	Dexcom G6 Continuous Glucose Monitor (separate but compatible)	

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

Definitions

"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.

"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".

"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.

"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.

Medical Necessity Criteria for Initial Authorization

The Plan considers Omnipod, 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***; 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** of the following:
    i. is currently using an insulin pump; ***or***
    ii. uses at least three (3) insulin injections per day **AND BOTH** of the following:
        1. The member or caregiver has completed a comprehensive diabetes education program***; and***
        2. The member meets **ONE** of the following:
            a. A child, where multiple daily insulin injections would be impractical or inappropriate***; or***
            b. Complications of inadequate glycemic control (e.g., neuropathy, nephropathy, retinopathy) indicative of more intensive insulin regimens***; or***
            c. Dawn phenomenon unresponsive to management with long-acting insulin agents (e.g., insulin glargine or detemir)***; or***
            d. For initial requests, HbA1c greater than 7%, despite an adequate regimen of multiple daily injections***; or***
            e. Hypoglycemic episodes requiring third-party assistance (e.g., seizure, loss of consciousness, glucagon administration, transport to an emergency room, hospitalization)***; or***
            f. Recurrent hypoglycemia (<60 mg/dL on at least two occasions despite adherence to recommended diabetic treatment plan)***; or***
            g. Pregnancy or planning for pregnancy; ***or***
            h. Wide swings in blood glucose values before meal time (e.g., regular fluctuations of preprandial blood glucose to levels <60 mg/dL and/or >140 mg/dL); ***AND***

4. The product being requested meets **ONE** of the following:
    a. is being prescribed for use within the Plan's Quantity Limit of:
        i. Starter Kit - 1 Kit per 4-years; ***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 AND a valid clinical rationale is provided demonstrating medical necessity (e.g., for 48-hour Pod change).

<u>If the above prior authorization criteria are met, the requested Disposable Insulin Pump Device will be approved for 12 months.</u>

Medical Necessity Criteria for Reauthorization

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 initial authorization criteria; ***AND***
2. There is documented provider evaluation within the last 6 months demonstrating member adherence to diabetic treatment plan and devices.

If the above prior authorization criteria are met, the requested Disposable Insulin Pump Device will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Disposable Insulin Pump Devices for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

Additionally, the Plan does not consider medically necessary the replacement or repair of Disposable Insulin Pump Devices when lost or damaged due to neglect 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 furbished.

References

1. American Diabetes Association Professional Practice Committee et al: 15. Management of diabetes in pregnancy: standards of medical care in diabetes-2022. Diabetes Care. 45(Supplement_1):S232-43, 2022
2. American Diabetes Association Professional Practice Committee. 7. Diabetes technology: Standards of Medical Care in Diabetes—2022. Diabetes Care 2022;45(Suppl. 1):S97–S112
3. Buckingham BA, Christiansen MP, Forlenza GP, et al. Performance of the Omnipod personalized model predictive control algorithm with meal bolus challenges in adults with type 1 diabetes. Diabetes Technol Ther 2018;20:585–595
4. Grunberger G, Rosenfeld CR, Bode BW, et al. Effectiveness of V-Go® for patients with type 2 diabetes in a real-world setting: a prospective observational study. Drugs Real World Outcomes 2020;7:31–40

5. Omnipod 5 ACE Pump (Pod) 510(k) summary, No. K203768. Acton, MA: Insulet Corporation; January 2022. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203768.pdf.
6. Omnipod 5 Automated Insulin Delivery System. Available at https://www.omnipod.com/what-is-omnipod/omnipod-5. Accessed August 29, 2022.
7. Omnipod DASH Insulin Management System. Podder's Handbook User Guide. Available at https://www.omnipod.com/current-podders/resources/omnipod-dash. Accessed August 29, 2022.
8. Omnipod Insulin Management System and Omnipod DASH Insulin Management System 510(k) summary, No. K192659. Acton, MA: Insulet Corporation; October 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192659.pdf. Accessed August 29, 2022.
9. Omnipod Insulin Management System. Podder's Handbook User Guide. Available at https://www.omnipod.com/current-podders/resources/omnipod-system. Accessed August 29, 2022.
10. Raval AD, Nguyen MH, Zhou S, Grabner M, Barron J, Quimbo R. Effect of V-Go versus multiple daily injections on glycemic control, insulin use, and diabetes medication costs among individuals with type 2 diabetes mellitus. J Manag Care Spec Pharm 2019;25:1111–1123
11. Sherr JL, Buckingham BA, Forlenza GP, et al. Safety and performance of the Omnipod hybrid closed-loop system in adults, adolescents, and children with type 1 diabetes over 5 days under free-living conditions. Diabetes Technol Ther 2020;22:174–184
12. V-Go Insulin Delivery System 510(k) summary, No. K103825. Shrewsbury, MA: Valeritas, Inc.; February 2011. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103825.pdf. Accessed August 29, 2022.

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