# Disposable Insulin Pumps

## NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The intent of the Disposable Insulin Pumps policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The policy will help guide safe, clinically appropriate, and cost-effective use of the requested insulin pump device in accordance with FDA-approved product labeling.

Products

**Omnipod DASH Insulin Management System** includes a wearable, tubeless insulin Pod that is controlled by a smartphone-like Personal Diabetes Manager (PDM).

The **Omnipod 5 System** is a tubeless, automated insulin delivery (AID) system comprised of a wearable insulin pod with SmartAdjust technology.

**Twiist** is an automated insulin delivery system (AID) which consists of a pump, cassette, and infusion set augmented by the Loop algorithm.

## POLICY

Criteria for Initial Approval

A. Omnipod and Twiist insulin delivery systems will be covered with prior authorization when all of the following criteria are met:
   1. Prescribed by or in consultation with an endocrinologist or a provider with Diabetes Care and Education Specialist (CDCES) certification (formerly known as Certified Diabetes Educator);

2. Member has utilized at least one of the following insulin administration methods for at least the last 6 months:
    i. Use of an insulin pump **OR**
    ii. Multiple daily insulin injections (**both** of the following):
        1. Administration of at least 3 daily injections of a basal and bolus insulin regimen
        2. History of suboptimal blood sugar control despite appropriate management. Examples of suboptimal control may include:
            a. Repeated hypoglycemic events [BG < 70 mg/dL];
            b. Episodes of diabetic ketoacidosis;
            c. Wide blood glucose fluctuations
            d. Hypoglycemia unawareness;
            e. Glycosylated hemoglobin level [HbA1c] ≥ 7.0;
            f. "Dawn phenomenon" with fasting blood glucoses repeatedly > 200 g/dL
3. Member has monitored blood glucose ≥ 4 times a day OR the member has been using a continuous glucose monitor (CGM) for at least the last 6 months
4. Member or caregiver has completed physician-directed comprehensive diabetes management education
5. Quantity does not exceed 10 per month
    i. Omnipod: Additional pods may be approved if member requires >200 units of insulin every 3 days.
    ii. Twiist: Additional cassettes may be approved if member requires >300 units of insulin every 3 days.

**Approval will be for 12 months**

Continuation of Therapy

Ongoing coverage for Omnipod and Twiist insulin delivery systems will be approved if member is experiencing clinical benefit (e.g., improved glucose control, better adherence to therapy) and continues to meet the initial criteria.

**Approval will be for 12 months**

Quantity Limits

| Product | Standard Benefit Allowance | Post-Limit PA Quantity Limit |
|---|---|---|
| Omnipod 5 Pods | 10 Pods / 30 days | 30 Pods / 30 days |
| Omnipod 5 Intro Kit | 1 kit / 5 years | N/A |
| Omnipod DASH Pods | 10 Pods / 30 days | 30 Pods / 30 days |
| Omnipod DASH Intro Kit | Not Covered | Not Covered |
| Twist Starter Kit | 1 kit / 5 years | N/A |
| Twist Refill Kit | 1 kit (10 cassettes) / 30 days | 2 kits (20 cassettes) / 30 days |

## CLINICAL RATIONALE

**Diabetes Diagnosis and Management Goals**

Diabetes is diagnosed in patients who have a fasting plasma glucose greater than or equal to 126 mg/dL, a 2-hour plasma glucose greater than 200 mg/dL during an oral glucose tolerance test, or a hemoglobin A1c (HbA1c) level greater than or equal to 6.5%. The goal of glucose management in all types of diabetes is to minimize and hopefully eliminate the acute and chronic complications associated with diabetes. For

most nonpregnant patients, glycemic control is often defined as a HbA1c level less than 7%; however, target glycemic goals vary based on individual patient characteristics. All patients with type 1 diabetes mellitus (T1DM) and many patients with type 2 diabetes mellitus (T2DM) require insulin to maintain adequate glucose control.

**Insulin Therapy Approaches**

Most patients with T1DM will require intensive insulin therapy with multiple daily injections (MDI) of prandial and basal insulin. For most patients, this will involve rapid-acting analog insulin injections at mealtimes and a long-acting basal analog insulin once daily. For some patients the expense and/or intensity of the use of insulin analogs is prohibitive. There are multiple approaches to treatment, and the central precept in T1DM management is that some form of insulin be given in a planned regimen tailored to the individual patient. Patients with T2DM typically start with oral antidiabetic therapy, progressing to injectable GLP-1 agonists before progressing to insulin if their HbA1c is still not adequately controlled, starting with basal insulin and progressing to the addition of prandial insulin if needed. For patients with HbA1c levels more than 1.5% above glycemic targets, initial combination therapy may be required. Insulin can be used as initial therapy in patients with severe hyperglycemia, especially if catabolic features (weight loss, hypertriglyceridemia, ketosis) are present. Patients on intensive insulin regimens have an increased risk of hypoglycemia, and continuous subcutaneous insulin infusion or automated insulin delivery can help improve glucose control and minimize hypoglycemia.

**Automated Insulin Delivery Systems**

Automated insulin delivery (AID) systems integrate three main components: an insulin pump, a continuous glucose monitoring (CGM) system, and an algorithm that determines insulin delivery. AID systems adjust insulin delivery either by modulating preprogrammed basal rates or by replacing basal rates with microboluses or microdoses of insulin every 5 minutes based on CGM feedback, predicted glucose direction, and rate of glucose change. Current AID systems have either fixed or adjustable glucose targets ranging from 87 to 180 mg/dL depending on the system. All current AID systems provide automated correction doses and still require manual entry of carbohydrates for meal announcements to calculate prandial doses.

According to the 2026 American Diabetes Association Standards of Care, AID systems are the preferred insulin delivery method over MDI, CSII, and sensor-augmented pumps in people with type 1 diabetes, adults with type 2 diabetes, children and adolescents with type 2 diabetes, and those with other forms of insulin-deficient diabetes. AID systems have consistently demonstrated superiority to standard insulin delivery with improvement in A1C, increase in time in range (TIR), especially overnight, and reduction of time spent in hypoglycemia. The greatest improvements are seen with AID when used in individuals with the highest baseline A1C or lowest TIR. AID systems have largely replaced other methods of continuous subcutaneous insulin delivery due to the advantages they offer in insulin modulation to adjust insulin doses and minimize hypoglycemia and hyperglycemia.

**Continuous Subcutaneous Insulin Infusion (CSII)**

Traditional CSII devices, or insulin pumps, deliver rapid-acting insulin throughout the day to help manage blood glucose levels. CSII devices deliver insulin continuously at a steady basal rate and also allow for administration of bolus doses around mealtimes and to correct higher glucose levels. While there is no consensus to guide choosing which form of insulin administration is best for a given patient, the choice of MDI, an insulin pump, or an AID system is often based on the individual characteristics of the patient and which is most likely to benefit the patient. A consensus statement by the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) and practice guidelines by the Endocrine Society outline indications and patient characteristics for insulin pump treatment. An ideal candidate for insulin pump or AID therapy would be a patient who currently performs multiple insulin injections daily and at least 4 self-monitored blood glucose (SMBG) measurements daily or uses continuous glucose monitoring, and should be motivated to achieve glucose control.

**Glucose Monitoring Requirements**

Patients using intensive insulin therapy (either multiple daily injections, insulin pump therapy, or AID systems) should use SMBG or CGM prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when low blood glucose is suspected, while treating hypoglycemia until they are normoglycemic, and prior to and while performing critical tasks. For many patients using SMBG this will require testing up to 6-10 times daily. Patients using intensive insulin regimens also can use continuous glucose monitors (CGMs) to continually monitor their glucose levels. CGM is now considered standard of care for most people with type 1 diabetes. When testing blood glucose levels, the target for normal glucose control with pre-prandial levels is between 80 mg/dL and 130 mg/dL. Blood glucose levels less than 70 mg/dL indicate level one hypoglycemia, while levels less than 54 mg/dL indicate level 2 hypoglycemia.

**Eligibility Criteria for Insulin Pump and AID Systems**

Patients who are managing their diabetes with multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of the insulin dose for at least 6 months and who have performed an average of 4 or more SMBG measurements daily for the past 6 months or have been using a continuous glucose monitor (CGM) for the past two months will be considered for approval.

Successful diabetes care requires a systematic approach to supporting patients' behavior change efforts. High-quality diabetes self-management education and support (DSMES) has been shown to improve patient self-management, satisfaction, and glucose outcomes. National DSMES standards call for an integrated approach that includes clinical content and skills, behavioral strategies (goal setting, problem solving), and engagement with psychosocial concerns. All patients with diabetes should participate in diabetes self-management education and receive the social support necessary for diabetes self-care. In addition to diabetes self-management education, it is important for patients using an insulin pump or AID system to undergo training regarding the aspects of device use to reduce the risk of adverse events. Patients who have undergone a comprehensive diabetes education program will be considered for approval.

In addition to being maintained on multiple daily injections of insulin and performing frequent SMBG measurements daily or using CGM, there are multiple other factors to consider when selecting patients for insulin pump or AID therapy. Suitable candidates for insulin pump or AID therapy include patients currently using multiple daily injections of insulin who have an elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7%) or patients with recurrent hypoglycemia (e.g., blood glucose levels less than 70 mg/dL), wide fluctuations in blood glucose levels, severe or wide glycemic excursions, or "dawn phenomenon" (defined as persistent severe early morning hyperglycemia) with fasting blood sugars frequently exceeding 200 mg/dL. Patients with any of these characteristics will be considered for approval.

Patients should be reassessed periodically to determine success of their diabetes treatment regimen and ensure continued suitability for insulin pump or AID therapy. HbA1c levels in patients who are stable on therapy should be taken at least every six months.

**Omnipod Systems**

Omnipod and Omnipod DASH are available as both a starter kit and pod refills. The starter kit includes the personal diabetes manager (PDM) and associated equipment (e.g., charger, carrying case) and 5 pods. The pod refills are available as a box containing five pods. Omnipod pods can be worn for up to 72 hours. Therefore, the limit for Omnipod pods will be 10 pods per month. Since PDMs are not a disposable part of the Omnipod system, a starter kit should only be required when first initiating therapy and if the manufacturer warranty has expired. Therefore, the limit for Omnipod starter kits is one kit per five years.

**Omnipod 5 Automated Insulin Delivery System**

The Omnipod 5 AID System is the first tubeless, on-body automated insulin delivery system approved by the FDA. It was approved in January 2022 for individuals with type 1 diabetes aged 2 years and older, and subsequently received FDA clearance for adults with type 2 diabetes aged 18 years and older. The system features a tubeless pod insulin pump connected to a Dexcom G6 or compatible CGM sensor via Bluetooth,

with a control algorithm to modulate insulin delivery based on real-time glucose levels. The algorithm can be hosted in the insulin pod or on a compatible smartphone app with an integrated bolus calculator.
The Omnipod 5 algorithm takes both glucose levels and glucose trends into account when adjusting insulin delivery. Glucose targets when the system is in automated mode can be customized from 110 to 150 mg/dL in 10 mg/dL increments. Clinical trials have demonstrated that the Omnipod 5 system significantly improves HbA1c levels and time in range. In pivotal trials, HbA1c was reduced by 0.71% in children and 0.38% in adults, with time in range improved by 15.6% (3.7 hours/day) in children and 9.3% (2.2 hours/day) in adults. Real-world data has shown mean HbA1c reductions of 0.4% overall, with reductions of 1.4% in users with baseline HbA1c ≥9%.
The Omnipod 5 system is worn for up to 72 hours per pod, similar to the traditional Omnipod systems. Quantity limits for Omnipod 5 pods will be 10 pods per month. The controller device (smartphone or dedicated controller) should only be required when first initiating therapy and if the device needs replacement due to malfunction or manufacturer warranty expiration.

**Twiist Insulin Delivery System**
The **Twiist insulin delivery system** is a traditional (tubed) insulin pump manufactured by Sequel Med Tech that received FDA clearance in March 2024 via the 510(k) pathway for patients with type 1 diabetes aged 6 years and older. It is classified as an alternate controller-enabled (ACE) pump, meaning it is designed to communicate securely with external components such as continuous glucose monitors (CGMs) to support automated insulin delivery. The twiist utilizes **hybrid closed-loop (HCL) technology** powered by twiist Loop software, which is based on the Tidepool Loop algorithm; this system features predictive glucose technology and automatically adjusts basal insulin rates, though it does not auto-deliver correction or mealtime boluses. The pump is compatible with the Eversense 365 and Libre 3 Plus CGM sensors and can be used with Humalog or NovoLog U-100 insulins, with a reservoir capacity of 300 units. Notably, although twiist is a durable device with a 3-year service life, Sequel has elected to distribute it exclusively through the pharmacy channel rather than pursuing durable medical equipment (DME) coverage under Medicare Part B.

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

- N/A

## REFERENCES


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## POLICY HISTORY

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