Disposable insulin delivery devices

Clinical Policy ID: CCP.1440

Recent review date: 2/2026

Next review date: 6/2027

Policy contains: Disposable; nonprogrammable; insulin pump; continuous subcutaneous insulin infusion.

First Choice Next has developed clinical policies to assist with making coverage determinations. First Choice Next's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by First Choice Next when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. First Choice Next's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. First Choice Next's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, First Choice Next will update its clinical policies as necessary. First Choice Next's clinical policies are not guarantees of payment.

Coverage policy

Disposable Insulin Delivery Devices (e.g., Omnipod®, V-Go®) are clinically proven and, therefore, may be medically necessary when specified set of criteria are met (Chatziravdeli, 2023; Mora, 2020; Peters, 2016; Wang, 2021).

For any determinations of medical necessity for these products, refer to the applicable state-approved pharmacy policy or vendor clinical policies.

Limitations

Not applicable.

Alternative covered services

- Diabetes education and counseling.
- Multiple daily injections of insulin.
- Non-disposable, programmable continuous subcutaneous insulin infusion pump.
- Non-insulin glucose lowering medications.

Background

Diabetes is usually diagnosed according to one of the following criteria (American Diabetes Association, 2020):

- Fasting plasma glucose ≥ 126 mg/dL (7.0 mmol/L).
- Two-hour plasma glucose ≥ 200 mg/dL (11.1 mmol/L) after a 75-gram oral glucose tolerance test.
- A1c ≥ 6.5% (48 mmol/mol).
- Random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

Intensive insulin therapy is an aggressive treatment approach for persons with diabetes who require close monitoring of blood glucose levels and frequent doses of insulin. Innovations in insulin delivery and glucose monitoring are designed to improve glycemic control and quality of life while limiting adverse effects, such as hypoglycemia and weight gain.

Insulin pump therapy is an alternative to insulin injections by syringes or insulin pens. Insulin pumps are connected to the body via an infusion set and tubing for delivering rapid- or short-acting insulin via subcutaneous routes, or they may be implanted using intraperitoneal routes. They may be integrated with real-time continuous glucose monitoring sensors (sensor-augmented pumps). Insulin doses may be delivered as:

- Basal rates delivered continuously over 24 hours.
- Bolus doses to cover carbohydrates in meals.
- Corrective or supplemental doses.

Many persons with diabetes continue to experience considerable fear of hypoglycemia, which may compromise care and treatment adherence, leading to worsening metabolic control (Lin, 2020). With insulin pumps, the tubing can kink or disconnect and compromise convenient and discreet use. As a result, a number of external insulin infusion disposable insulin pumps have been developed that involve no visible tubing, adhere to the body, are partially or completely disposable, and may be worn and operated discreetly under clothing and may be used with continuous glucose monitoring (CGM) systems when clinically appropriate. Some require a separate wireless controller device for programming, and others are preprogrammed with all necessary control components (Lin, 2020).

Insulin products are regulated by FDA as biological products; on March 23, 2020, insulin applications previously approved under the Federal Food, Drug, and Cosmetic Act were deemed to be biologics license applications under the Public Health Service Act. Multiple insulin pumps have received U.S. Food and Drug Administration 510(k) clearance as Class II devices. FDA-regulated medical devices must comply with applicable FDA labeling requirements.

Disposable insulin delivery devices include patch-based insulin delivery systems with differing functions, including basal-bolus insulin infusion patch pumps and bolus-only insulin delivery systems; therefore, not all disposable insulin delivery devices meet the definition of continuous subcutaneous insulin infusion (CSII) (Ginsberg, 2019). The FDA has cleared several disposable insulin pumps through the 510(k) since 2010, including The Accu-Chek® Solo, CeQur Simplicity™, Finesse™ Personal Insulin Delivery System, Omnipod System, and V-Go (U.S. Food and Drug Administration, 2010a; 2010b; 2011; 2012; 2017; 2019; 2023). Commercial utilization varies by payer, channel (pharmacy versus medical benefit), and geography; multiple disposable insulin delivery devices are available in the U.S. market (Berget 2019).

Disposable pumps employ various technologies to facilitate insulin delivery. The CeQur Simplicity, Finesse (formerly known as the OneTouch Via™), and V-Go pumps are mechanically simple devices that lack electronic components, relying on manual pumping mechanisms and requiring user filling. Conversely, the Omnipod DASH and Accu-Chek Solo are electronically programmable, wireless disposable insulin pumps that are controlled by a separate handheld device. These systems enable users to either preset or select, as needed, the continuous insulin delivery rate (basal rates) and administer larger insulin doses at specific times (bolus delivery), with all functions managed through the pump's external control interface. All of the aforementioned disposable pumps utilize an adhesive patch and soft cannula for skin interface.

Findings

The body of evidence supporting disposable insulin delivery devices encompasses professional clinical guidelines, systematic reviews, meta-analyses, and device-specific clinical studies. Professional guidelines from the Endocrine Society, American Diabetes Association, and the United Kingdom's National Institute for Health and Care Excellence address continuous subcutaneous insulin infusion therapy broadly, though recommendations specific to disposable insulin pumps remain limited. Systematic reviews and meta-analyses have evaluated patient-reported outcomes, glycemic control, and safety across various insulin delivery modalities, with findings suggesting potential benefits in hemoglobin A1c reduction and treatment satisfaction. Device-specific evidence from observational studies and clinical trials demonstrates improvements in glycemic markers for products such as CeQur Simplicity, Omnipod, and V-Go, though many studies are limited by retrospective designs, small sample sizes, and lack of control groups. Overall, the evidence indicates that disposable insulin pumps can be effective alternatives to multiple daily injections or conventional insulin pumps, though further large-scale, well-designed studies are needed to establish clinical effectiveness more conclusively across different patient populations.

Professional Clinical Guidelines

Professional guidelines largely address continuous subcutaneous insulin infusion as a device class rather than recommending specific disposable products. The scope of guideline recommendations has evolved over time, with recent updates from the American Diabetes Association reflecting changes in the therapeutic landscape as automated insulin delivery systems have become more widely available.

The Endocrine Society suggests continuous subcutaneous insulin infusion therapy for diabetes-educated individuals with insulin-requiring type 2 diabetes who have poor glycemic control despite intensive insulin therapy, oral agents, other injectable therapy, and lifestyle modifications (Peters, 2016). Important considerations for patient selection include mental and psychological status, prior adherence with diabetes self-care measures, willingness and interest in trying the device, and compliance with required follow-up visits. The guideline does not distinguish between disposable and conventional pump systems in its recommendations.

The American Diabetes Association finds that the initiation of continuous subcutaneous insulin infusion delivery early in the treatment of diabetes can be beneficial depending on a person's or their caregiver's needs and preferences (American Diabetes Association, 2026). The 2026 Standards of Care position automated insulin delivery systems as the preferred insulin delivery method over multiple daily injections, standalone continuous subcutaneous insulin infusion, and sensor-augmented pumps in people with type 1 diabetes (Grade A) and adults with type 2 diabetes (Grade A). The Standards also recommend that people with diabetes who have been using continuous subcutaneous insulin infusion devices for diabetes management should have continued access across third-party payers, regardless of age or hemoglobin A1c levels. This represents a shift in the guideline emphasis toward automated systems that integrate insulin delivery with continuous glucose monitoring, though standalone continuous subcutaneous insulin infusion devices, including disposable options, remain recognized treatment modalities.

The National Institute for Health and Care Excellence, a United Kingdom-based guideline body, recommends continuous subcutaneous insulin infusion therapy as a treatment option for adults and children 12 years and older with type 1 diabetes if attempts at multiple daily insulin injections result in disabling episodes of low blood sugar or persistently high hemoglobin A1c levels above 8.5% despite intensive therapy (National Institute for Health and Care Excellence, 2008). For children younger than 12, continuous subcutaneous insulin infusion therapy is recommended if multiple daily injections are impractical and with plans to trial injections between ages 12 and 18. In those 12 and older, continuous subcutaneous insulin infusion therapy should only continue if it improves blood sugar control or reduces rates of low blood sugar based on physician-set targets. The National Institute for Health and Care Excellence does not recommend continuous subcutaneous insulin infusion therapy pumps for individuals with type 2 diabetes. These guidelines are developed for the United Kingdom National Health Service context and may have limited applicability to United States coverage determinations.

Systematic Reviews

A subgroup analysis of CGM data from a randomized trial (n = 97) conducted on type 2 diabetes patients on basal insulin compared glycemic control via continuous glucose monitoring in those initiating mealtime insulin with the CeQur Simplicity insulin patch (n = 49) versus insulin pen (n = 48). After 24 weeks, both groups achieved recommended time-in-range targets (> 70% time 70-180 mg/dL) with no significant between-group differences in glycemic metrics (Bergenstal 2022). A separate publication detailed the results of an online survey of (n = 106) insulin-treated diabetes patients before and two months after initiating CeQur Simplicity insulin patch therapy. The respondents reported significantly greater overall treatment satisfaction, less diabetes burden, and improved psychological well-being with the CeQur Simplicity insulin patch compared to their prior insulin delivery method (Isaacs 2023).

OmniPod

In evaluating the effectiveness of the Omnipod® system for patients with type 1 diabetes and type 2 diabetes, we found several retrospective studies that highlighted improvements in glycemic control. In the larger studies (n = 660 (Danne et al., 2018) and n = 873 (Layne, 2016)), patients with type 1 diabetes showed notable improvements in hemoglobin A1c levels and other diabetes management metrics. Specifically, an improved adjusted mean hemoglobin A1c was observed at one year for those who switched from multiple daily injections to the Omnipod® system (7.5% versus 7.7%, p<.001), although this improvement did not persist over two and three years (Danne, 2018). Similarly, a decrease in hemoglobin A1c by 0.6%, along with reductions in total daily dose of insulin and hypoglycemia events, was observed (Layne, 2016).

In a separate analysis focusing on both children (n = 112) and adults (n = 129), a multicenter study demonstrated a significant reduction in hemoglobin A1c (-0.71% in children, -0.38% in adults) and an increase in time within the target glucose range (Brown, 2021). A retrospective study involving patients with type 2 diabetes (n = 81) using the Omnipod® system demonstrated significant reductions in HbA1c, total daily insulin dose, and hypoglycemia (Layne et al., 2017).These studies collectively suggest that the Omnipod® insulin pump can be beneficial in improving glycemic control among diabetic patients, although potential limitations, such as selection bias in retrospective designs and sample size considerations, need to be acknowledged (Brown, 2021; Danne, 2018; Layne, 2016; Layne, 2017).

V-Go

V-Go has demonstrated clinical effectiveness in managing diabetes in several observational studies. In a prospective study (n = 140 included in primary efficacy analysis), patients with type 2 diabetes showed significant reductions in hemoglobin A1c (-0.64%) and total daily dose of insulin (-12 units/day) (Grunberger, 2020). Similarly, two retrospective studies with 103 and (n = 44 type 2 diabetes patients, respectively, reported significant reductions in HbA1c (-1.67 and -1.37) and total daily dose of insulin (-17 and -19 units/day) (Sutton 2018; Meade 2021). Another retrospective study with (n = 204 patients with type 2 diabetes observed significant reductions in HbA1c (-1.53% at 14 weeks, -1.79% at 27 weeks) and a decrease in the total daily dose of insulin (-33% at 27 weeks) (Lajara 2015).

However, it is important to note that these studies have limitations, such as open-label designs, lack of control groups, small sample sizes, and potential for selection bias due to their retrospective nature (Lajara, 2015; Lajara, 2016; Meade, 2021; Sutton, 2018). Despite these limitations, a comparative study involving (n = 56 patients with type 2 diabetes found that V-Go users experienced greater reductions in HbA1c compared to those using multiple daily injections (-0.84% and -0.64% at 12 and 27 weeks, respectively) and required lower total daily dose of insulin (Lajara, 2016). While these findings suggest the potential benefits of V-Go in managing diabetes, further large-scale, randomized controlled trials are needed to establish its clinical effectiveness more conclusively.

<u>CeQur, Finesse, Omnipod</u>

A review analyzed 11 studies (n = 6,534) which examined patient-reported outcomes associated with the use of three disposable insulin pumps (CeQur, Finesse, Omnipod) in individuals with diabetes. The analysis included three randomized controlled trials as well as several prospective and retrospective observational studies. The majority of the studies reviewed focused on people with type 1 diabetes and type 2 diabetes who were previously treated with multiple daily injections or conventional insulin pumps (Kulzer, 2022).

The studies reviewed suggest that disposable insulin pumps may improve various patient-reported outcomes. In terms of quality of life, one study using the Diabetes Specific Quality of Life Scale found significant improvements in 6 out of 7 dimensions for disposable insulin pumps compared to multiple daily injections or syringe therapy (n = 38), while another study using the same scale found significant improvements in two out of seven dimensions for disposable insulin pumps compared to pen therapy (n = 278).

Regarding treatment satisfaction, one study using the Insulin Delivery System Rating Questionnaire found significant improvements in 5 out of 6 subscales for disposable insulin pumps compared to syringe, pen, or conventional pump therapy (n = 101). Patient preference for disposable insulin pumps ranged from 43% to 90% when compared to conventional insulin pumps in two studies (n = 29 and n = 20), and 76% to 78% when compared to syringe or pen therapy in two studies (n = 38 and n = 101). However, the authors emphasize that the methodological quality of the included studies was mostly weak, with limitations such as lack of control groups, small sample sizes, and the use of non-validated questionnaires. The authors conclude that while the findings suggest potential benefits of disposable insulin pumps in managing diabetes, further large-scale, randomized controlled trials with patient-reported outcomes as the primary endpoint are needed to establish the clinical effectiveness of disposable insulin pumps more conclusively.

In 2026, we incorporated the American Diabetes Association’s 2026 Standards of Care, which position automated insulin delivery systems as the preferred insulin delivery method over multiple daily injections and standalone continuous subcutaneous insulin infusion. We identified a 2025 pediatric meta-analysis evaluating continuous subcutaneous insulin infusion versus multiple daily injections in type 1 diabetes, demonstrating statistically significant hemoglobin A1c reductions with no significant differences in severe hypoglycemia or diabetic ketoacidosis rates. No changes to the coverage policy criteria were warranted.

References

On January 11, 2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "Insulin Infusion Systems" (Medical Subject Headings or MeSH term) and the free text terms "continuous subcutaneous insulin devices" "disposable insulin pump, "OmniPod," "V-Go." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

12/2019: initial review date and clinical policy effective date: 2/2020

1/2021: Policy references updated.

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Related Codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1440. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code Description
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories