Clinical Policy Title: Insulin infusion therapy (insulin pumps)

Clinical Policy Number: 06.02.01

Effective Date: March 1, 2014
Initial Review Date: November 20, 2013
Most Recent Review Date: April 27, 2016
Next Review Date: April 2017

Related policies:
CP# 06.02.02 Outpatient diabetes self-management training (DSMT)
CP# 06.02.03 Continuous interstitial glucose monitoring (CGM)
CP# 08.02.06 Pancreas transplant
CP# 08.02.07 Artificial pancreas device system

ABOUT THIS POLICY: Arbor Health Plan has developed clinical policies to assist with making coverage determinations. Arbor Health Plan’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 by Arbor Health Plan 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. Arbor Health Plan’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. Arbor Health Plan’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Arbor Health Plan will update its clinical policies as necessary. Arbor Health Plan’s clinical policies are not guarantees of payment.

Coverage policy

A. Arbor Health Plan considers the use of Food and Drug Administration (FDA)-approved, non-disposable continuous subcutaneous insulin infusion (CSII) pumps to be medically necessary durable medical equipment (DME) for the treatment of diabetes mellitus when the following criteria are met:

<table>
<thead>
<tr>
<th>Criteria for medical necessity (all criteria must be met)</th>
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</thead>
<tbody>
<tr>
<td>1. Patient is at least 4 years old.</td>
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<td>2. Patient has Type 1 diabetes mellitus, Type 2 diabetes mellitus or gestational diabetes mellitus.</td>
</tr>
</tbody>
</table>
Criteria for medical necessity (continued)
(all criteria must be met)

3. A team of specialists in diabetes care determines if both criteria are satisfied:
   - The patient is willing to work with their health care providers to improve glucose control.
   - The patient or, in the case of children, their parents or caregivers demonstrates appropriate pump usage, monitoring of glucose levels and use of the data to manage diabetes.

Either 4 or 5 below:

4. All of the following medical necessity criteria are met:
   - The member receives multiple daily injections (MDI) of insulin (i.e., at least three injections per day) and frequent self-adjustments of insulin doses for at least six months prior to initiating use of the insulin pump and has documented frequency of glucose self-testing on average at least four times per day during the two months prior to initiating use of the insulin pump.
   - The member has completed a comprehensive diabetes education program.
   - The member meets at least one of the following criteria while on MDI of insulin:
     - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL.
     - Elevated glycosylated hemoglobin level (HbA1c) > 7.0 percent.
     - History of recurring hypoglycemia (less than 60 mg/dL).
     - History of severe glycemic excursions or hypoglycemic unawareness.
     - Wide fluctuations in blood glucose before mealtime (e.g., pre-prandial blood glucose levels commonly exceeding 140 mg/dL).

5. The member has been on a pump prior to enrollment in AmeriHealth Carita, and has documented frequency of glucose self-testing on average at least four times per day during the month prior to enrollment.

**NOTE:** Repair and maintenance of a non-disposable CSII pump is medically necessary if:
   - The manufacturer’s warranty has expired.
   - The maintenance is not more frequent than every six months.
   - The repair or maintenance is not the result of misuse or abuse.
   - The repair cost is less than the replacement cost.

**NOTE:** Replacement of a non-disposable CSII pump is medically necessary*:
   - For children who require a larger insulin reservoir.
   - If the infusion pump is out of warranty or is malfunctioning and cannot be refurbished.

*Medical necessity should take into account the patient’s ability to adhere to current pump therapy and the potential for improved glycemic control secondary to the additional features of the replacement pump.

B. Arbor Health Plan considers the use of disposable CSII pumps (e.g., OmniPod®, V-Go™) to be investigational and, therefore, not medically necessary.

C. Arbor Health Plan considers the use of *implantable* intraperitoneal insulin pumps to be investigational and, therefore, not medically necessary.
Limitations:

- All other uses of non-disposable CSII pumps are **not** medically necessary.
- Continued coverage of CSII requires the patient be seen and evaluated by the treating physician at least every three months.
- The pump must be ordered by, and follow-up care of the patient must be managed by, a physician who manages multiple patients with CSII and works closely with a team including nurses, diabetes educators and dietitians knowledgeable in the use of CSII.
- Some CSII pumps (e.g., Paradigm® REAL-Time Insulin Pump and Continuous Glucose Monitoring System, Animas® OneTouch® PING™) are able to take results of the blood glucose reading, calculate the appropriate insulin infusion rate, wirelessly transmit the results from the blood glucose monitor to the pump and automatically adjust the insulin infusion rate, saving the member some extra steps. These insulin pump features, when present, are considered integral to the CSII pump and blood glucose monitor.
- Replacement of a functioning insulin pump with an insulin pump with wireless communication to a glucose monitor is **not** medically necessary, as such wireless communication has not been shown to improve clinical outcomes.

Alternative covered services:

- Multiple daily injections of insulin.
- Diabetes education and counseling.

**Background**

Insulin is a naturally occurring hormone secreted by the pancreas. Diabetes mellitus (or diabetes) is a chronic metabolic disorder characterized by the presence of hyperglycemia due to defective insulin secretion (Type 1 [T1DM]), defective insulin action (Type 2 [T2DM]) or both. Certain types of diabetes may be characterized more specifically based on etiology and clinical presentation, e.g., Type 2 gestational diabetes or diabetes resulting from genetic defects or drug treatment (American Diabetes Association [ADA], 2014). Diabetes can cause serious health complications, including heart disease, blindness, renal failure and lower-extremity amputations, and is the seventh leading cause of death in the United States (CDC, 2015).

Clinical presentation and disease progression can vary considerably. Diabetes is usually diagnosed according to one of the following criteria (ADA, 2014):

- Fasting plasma glucose (FPG) ≥ 126 mg/dL (7.0 mmol/L).
- Two-hour PG ≥ 200 mg/dL (11.1 mmol/L) after a 75-g oral glucose tolerance test.
- HbA1C (A1C) ≥ 6.5%.
- Random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

A variety of strategies and techniques exist to manage diabetes. Critical to the management plan is glycemic control as a means of reducing the risk of acute hypoglycemic or hyperglycemic episodes and ketoacidosis, thereby delaying the onset and progression of late-stage vascular complications. Components of the diabetes care plan include diabetes self-management education (DSME), ongoing diabetes support, blood glucose monitoring and insulin replacement therapy (ADA, 2014).
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 (QOL) while limiting adverse effects, such as hypoglycemia and weight gain. These advances include continuous subcutaneous insulin infusion (CSII or insulin pumps), implantable continuous intraperitoneal insulin infusion, real-time continuous glucose monitoring (rt-CGM) and sensor-augmented pumps that combine rt-CGM with insulin pumps.

**Insulin pumps:**

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 rt-CGM sensors (sensor-augmented pumps or SAPs). Insulin doses are separated into:

- 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 (Anhalt, 2010). With insulin pumps, the tubing can kink or disconnect and compromise convenient and discreet use. As a result, a number of external insulin infusion “patch” 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. Some require a separate wireless controller device, and others include all necessary control components (Anhalt, 2010).

**Regulation:**

Hormones such as insulin are regulated as drugs under the Federal Food, Drug and Cosmetic Act (21CFR201). More than 70 insulin infusion pumps have received FDA 510(k) premarket approval as Class II devices (product code LZG) (FDA, 2016a). Presently, no continuous implantable insulin infusion pumps have received FDA 510(k) premarket approval (product code LKK) outside of clinical trials (FDA, 2016a).

As of this writing, there are two external, disposable subcutaneous insulin infusion devices without visible tubing commercially available in the United States. They are (FDA, 2016a):

- **The OmniPod® Insulin Management System (Insulet Corp., Bedford, MA)** is a single-use, disposable device that consolidates the pump, tubing and subcutaneous needle into one compact unit (pod) and uses wireless remote technology called the Personal Diabetes Manager (PDM) to control the insulin pump. The unit is worn up to three days before requiring replacement. OmniPod originally received FDA 510(k) clearance under the name of iXL™-II Diabetes Management System in 2003. Since then, several clearances have been granted that address modifications to the system, most notably integration of *in vitro* blood glucose measurement into the PDM and smaller and more lightweight models (Insulet, 2016).

- **The V-Go™ Disposable Insulin Delivery Device (Valeritas Inc., Shrewsbury, MA)** is a fully disposable, non-electronic, self-contained, sterile, patient-fillable, single-use disposable, subcutaneous insulin infusion device with an integrated stainless steel subcutaneous needle indicated for adult patients with T2DM requiring insulin (Valeritas, 2016). Three device models (delivering 20, 30 and 40 units/day) provide a continuous preset basal rate of insulin, allow for
on-demand bolus dosing around mealtimes and must be replaced daily. The manufacturer’s website notes that if regular adjustments or modifications to the preset basal rate of insulin are required in a 24-hour period, or if the amount of insulin used at meals requires adjustments of less than 2-unit increments, use of the V-Go may result in hypoglycemia (Valeritas, 2016).

**Searches**

Arbor Health Plan searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on March 22, 2016. Search terms were: “Insulin Infusion Systems” [MeSH] and free text terms “OmniPod” and “V-Go.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Arbor Health Plan identified two systematic reviews, two evidence-based guidelines and two economic analyses for this policy. Both systematic reviews evaluated the safety and efficacy of non-disposable subcutaneous (Yeh, 2012) and intraperitoneal insulin pumps (Hayes, 2011 [updated 2014]). Both economic studies were cost-effectiveness analyses of insulin pump therapy in adults with T1DM from the United States perspective. One cost-effectiveness analysis compared the use of CSII injection versus MDI (St. Charles, 2009), and the other compared SAP to MDI (Kamble, 2012). Guidelines from the ADA and the American Association of Clinical Endocrinologists (AACE) Consensus Panel on Insulin Pump Management are included (ADA, 2014; Grunberger, 2010).

No systematic reviews or economic analyses of either the OmniPod or V-Go disposable insulin infusion pumps were identified; existing evidence for disposable pumps consists of small, observational studies of patients with diabetes who are experienced in the use of traditional CSII (Hayes, 2013a; Hayes, 2013b). One additional study investigated single-dose and averaged-dose accuracy of incremental basal deliveries for the OmniPod and three durable models of insulin pumps (Jahn, 2013).

The evidence is sufficient to support the use of CSII for persons with diabetes mellitus who require intensive insulin therapy (i.e., ≥ three injections per day of insulin). Results of randomized controlled trials (RCTs) found MDI and rapid-analogue-based CSII were similarly effective in lowering HbA1C levels with similar rates of hypoglycemia in persons ≥ age 4 with T1DM and in adults with T2DM, including pregnant women (Yeh, 2012). In adults with T1DM, HbA1C levels decreased more with CSII than with MDI, but one study heavily influenced these results. Adolescents and adults with T1DM reported better overall QOL with
CSII than with MDI. Sensor-augmented pump use was associated with a significantly greater reduction in HbA1C compared with MDI/self-monitoring of blood glucose (SMBG) in non-pregnant adults with T1DM based primarily on the results of the Sensor-Augmented Pump Therapy for A1C Reduction (STAR) 3 RCT (Bergenstal, 2010). The ability to improve glycemic control and lower the incidence of diabetes complications may make CSII a more cost-effective option over the long term, but much will depend on future technological advancements and how patients’ fears about hypoglycemia are handled in the analysis. These data suggest that intensive insulin therapies designed to optimize glycemic control can be individualized to maximize treatment satisfaction and QOL.

According to evidence-based guidelines, the ideal candidate for CSII pump therapy is a motivated and diabetes-educated person whose T1DM or insulinopenic T2DM is inadequately controlled with MDI (i.e., performs ≥ three insulin injections and ≥ three SMBG measurements daily) and who is willing and intellectually and physically able to undergo the rigors of insulin pump therapy initiation and maintenance (ADA, 2014; Grunberger, 2010). Eligible candidates should be capable of self-management through frequent SMBG measurements (at least initially) and/or the use of a continuous glucose sensor device. Candidates must be able to master carbohydrate counting, insulin correction and adjustment formulas and troubleshoot problems related to pump operation and blood glucose levels. Finally, patients should be emotionally mature, with a stable life situation, and willing to maintain frequent contact with members of their health care team, in particular their pump-supervising physician (Grunberger, 2010).

Diabetes experts determined patients with the following specific characteristics are not good candidates for insulin pump use (Grunberger, 2010):

- Unable or unwilling to perform multiple daily insulin injections (≥ three to four daily), frequent blood glucose monitoring (≥ four to six daily) and carbohydrate counting.
- Lacking motivation to achieve tighter glucose control and/or having a history of non-adherence to insulin injection protocols.
- Having a history of serious psychologic or psychiatric conditions (e.g., psychosis, severe anxiety or depression).
- Having reservations about pump usage interfering with lifestyle (e.g., contact sports or sexual activity).
- Having unrealistic expectations of pump therapy (e.g., belief that it eliminates the need to be responsible for diabetes management).

The evidence is insufficient to support the use of implantable intraperitoneal insulin pumps. There is a growing body of evidence suggesting comparable or superior clinical outcomes with IIP compared to MDI or intensive subcutaneous administration in adults with T1DM and T2DM, along with high patient satisfaction and QOL scores. However, high rates of device malfunction due to catheter obstruction or breakage or premature battery failure are associated with this device, and at present no devices have been FDA approved for use in the United States outside of clinical trials.

The evidence is insufficient to support the use of external disposable subcutaneous insulin pumps for persons with diabetes. For the V-Go Disposable Insulin Delivery device, two small, low-quality studies were found with insufficient reporting on patient selection criteria or health outcomes to permit conclusions on its safety or impact on health outcomes. Multiple adverse effects and safety issues have been reported to FDA’s Manufacturer and User Facility Device Experience (MAUDE) database (FDA, 2016b). Therefore, the existing research evidence of the V-Go Disposable Insulin Delivery device is insufficient to permit conclusions regarding its safety and effectiveness.
For the Omnipod, results of low-quality, single clinical studies suggest it may offer comparable short-term glycemic control to that of traditional CSII pumps in young adults and children with T1DM and in adults with uncontrolled T2DM with severe insulin resistance (Hayes, 2013b; Jahn, 2013). The newer, lighter OmniPod models offer ease of use and may be preferred by those with active lifestyles. The OmniPod may not improve upon the technical limitations of traditional CSII using current insulin analogues that are not rapid enough to achieve desired peak pre-prandial insulin concentrations, catheter wear time that may affect insulin absorption or dose accuracy. However, insulin delivery with the OmniPod may be less susceptible to the siphon effect that might occur as a result of the position of the traditional CSII pump in relation to its tubing. These results have not been replicated in larger, higher-quality studies, nor has the impact on other health outcomes been determined. In light of more than 500 adverse effects and safety issues reported to FDA’s MAUDE database since its approval, the existing research evidence of the OmniPod is insufficient to permit conclusions regarding its safety and effectiveness (FDA, 2016b).

**Evidence gaps:**

The relative efficacy of CSII versus MDI in patients with poor glycemic control or a history of recurrent or severe hypoglycemia and hypoglycemic unawareness is unclear, as are the long-term impact of the slightly better glycemic control with CSII compared to MDI, pregnancy-related outcomes and outcomes in pediatric populations.

**Policy updates:**

We identified one new cost-effectiveness analysis and one new guideline for this policy update (Lajara, 2016; ADA, 2015). The cost-effectiveness analysis found progression to intensive insulin therapy administered with both V-Go and MDI resulted in significant glycemic improvement. V-Go was associated with a greater reduction in HbA1C, required less insulin and was more cost effective than IIT administered with MDI. However, optimal patient selection criteria and consideration of adverse events in the analysis were unclear. The ADA Standards of Care for 2015 made no mention of disposable insulin infusion pumps (ADA, 2015). A search of the MAUDE database from January 1, 2015, to February 29, 2016, revealed 13 records of adverse events associated with the V-Go device primarily related to nocturnal hypoglycemia and, to a lesser extent, diabetic ketoacidosis; more than 500 adverse events were associated with the Omnipod device during the same time period (FDA, 2016b). We found no additional studies of implantable intraperitoneal infusion pumps. These results do not change the original findings; therefore, no changes to the policy are warranted.
Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Non-disposable insulin pumps</strong></td>
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<tr>
<td>Yeh (2012)</td>
<td><em>Key points:</em></td>
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<tr>
<td>Agency for Healthcare Research and</td>
<td>• Systematic review of 19 RCTs in</td>
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<td>Quality Subcutaneous infusion</td>
<td>children or adults comparing</td>
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<td>continuous subcutaneous insulin</td>
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<td>infusion (CSII) with multiple</td>
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<td>daily injections (MDI).</td>
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<td></td>
<td>• Overall quality: low. Most</td>
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<td>studies were small, of short</td>
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<td>duration and limited to</td>
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<td>Caucasian adults with T1DM.</td>
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<td>• Children (≥ age 4) with T1DM:</td>
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<td>o No difference in combined mean</td>
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<td>between group difference in change</td>
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<td>in HbA1C level from baseline after</td>
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<td>≥ 16 weeks of follow-up;</td>
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<td>adolescents &gt; 12 years (-0.10%</td>
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<td>[95% CI, -0.48% to 0.27%]; I² = 0%</td>
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<td></td>
<td>and children ≤ 12 years or younger</td>
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<td>(-0.05% [CI, -1.01% to 0.96%]; I²</td>
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<td>= 0%).</td>
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<td>o No difference between devices in</td>
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<td>rate of severe hypoglycemia,</td>
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<td>daytime, nocturnal; mild</td>
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<td>hypoglycemia; weight gain; QOL;</td>
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<td>better satisfaction with CSII.</td>
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<td>• Adults with T1DM:</td>
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<td>o HbA1C levels decreased more</td>
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<td>with CSII than with MDI, but one</td>
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<td>study heavily influenced results</td>
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<td>(combined mean between-group</td>
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<td>difference, -0.30% [CI, -0.58%</td>
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<td></td>
<td>to -0.02%]; I² = 64.5%).</td>
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<td>o Similar effects on severe</td>
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<td>glycemic events and weight gain</td>
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<td>between devices. QOL favored CSII.</td>
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<td>• Adults with T2DM:</td>
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<td>o No difference in combined mean</td>
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<td>between-group difference between</td>
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<td>CSII and MDI in mean decrease of</td>
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<td>HbA1C levels (-0.18% [CI, -0.43%</td>
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<td>to 0.08%]; I² = 0.0%; P = 0.84).</td>
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<td>o Insufficient evidence of effect</td>
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<td>on severe hypoglycemic events,</td>
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<td>weight gain or other glycemic</td>
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<td>outcomes.</td>
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<td>• Sensor-augmented pumps are</td>
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<td>superior to MDI/SMBG in lowering</td>
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<td>HbA1C. Insufficient evidence to</td>
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<td>draw definitive conclusions about</td>
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<td>severe hypoglycemia or QOL.</td>
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<tr>
<td>Hayes (2011; updated 2014)</td>
<td><em>Key points:</em></td>
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<tr>
<td>Intraperitoneal infusion (IIP)</td>
<td>• Systematic review of three RCTs</td>
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<td></td>
<td>comparing IIP with MDI injections,</td>
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<td>several uncontrolled prospective</td>
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<td>studies and registry data.</td>
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<td>• Overall quality: low to moderate.</td>
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<td>Generalizability of RCT results</td>
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<td>from specialized centers to more</td>
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<td>typical health care settings is</td>
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<td>unclear.</td>
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<td>• Safety: High incidence of device</td>
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<td>malfunction due to catheter</td>
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<td>obstruction or breakage or</td>
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<td>premature battery failure. Rates</td>
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<td>of catheter obstruction = 45% to</td>
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<td>86% over a three-year period. IIP</td>
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<td>site infection rate = 4%.</td>
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<td>Adverse event rate higher with islet</td>
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<td>cell transplantation than IIP.</td>
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<td>• Efficacy: IIP improved glycemic</td>
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<td>control, reduced hyperinsulinemia,</td>
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<td>decreased risk of hypoglycemic</td>
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<td>episodes and improved lipid profiles</td>
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<td>and liver function for adults with</td>
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<td>T1DM and T2DM. Comparable or</td>
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<td>superior results to intensive</td>
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<td>subcutaneous administration.</td>
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<td>• High patient satisfaction with IIP</td>
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<td>therapy and better QOL scores than</td>
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<td>those receiving MDI therapy.</td>
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<td>• Insufficient evidence of</td>
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<td>improvement in progression of</td>
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<td>late-stage diabetic complications</td>
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<td>treatment with an IIP.</td>
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</table>

**Disposable insulin pumps**

<p>| Hayes (2013a) V-GO                    | <em>Key points:</em>                      |
|                                       | • Searches retrieved six review    |
|                                       | articles, one cohort study (n = 6),|
|                                       | one retrospective cohort study (n =|
|                                       | 23); low quality.                  |
|                                       | • Seven adverse events associated  |
|                                       | with the V-Go system in MAUDE      |
|                                       | database, no recalls.              |</p>
<table>
<thead>
<tr>
<th>Citation</th>
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<tbody>
<tr>
<td>Hayes (2013b)</td>
<td>Key points:</td>
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<tr>
<td></td>
<td>- Searches retrieved five reviews, one multicenter comparison, cohort study (n = 6), three laboratory studies, one randomized crossover study (n = 29), one prospective study (n = 20), one comparison study (n = 20) and three conference abstracts; low quality.</td>
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<td></td>
<td>- 500 adverse events listed in MAUDE database associated with OmniPod since August 2012.</td>
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<td>- Results of single studies suggest Omnipod:</td>
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<td>- Is preferred to CSII among young adults with T1DM experienced with CSII and fit better into their lifestyles without compromising glycemic control.</td>
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<td>- Improved glycemic control and QOL better than MDI in children with T1DM.</td>
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<td>- Using U500 regular insulin was safe and effective at glycemic control in adults with uncontrolled T2DM and severe insulin resistance.</td>
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<td>- May not overcome technical limitations of traditional CSII with respect to inability to achieve desired pre-prandial peak insulin concentration due to the relatively slow pharmacokinetics of current insulin analogues and the effect of catheter wear time on insulin absorption.</td>
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<td></td>
<td>- May offer less variation in insulin delivery than traditional CSII that may be susceptible to the siphon effect in the tubing during low basal rates.</td>
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<tr>
<td>Jahn (2013)</td>
<td>Key points:</td>
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<td>- Technical in vitro evaluation of single-dose and averaged-dose accuracy of incremental basal deliveries for one-patch model and three durable models of insulin pumps.</td>
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<td>- Results: significant differences in single-dose and averaged-dose accuracy among the insulin pumps tested; differences were most evident between the OmniPod and the durable pump models.</td>
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<td>- Of the pumps studied, the Animas OneTouch Ping demonstrated the best single-dose and averaged-dose accuracy. Further research on the clinical relevance of these findings is warranted.</td>
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<td>Lajara (2016)</td>
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<td>V-Go versus MDI in person with T2DM</td>
<td>- Using electronic medical records data of patients transitioned to V-Go (n=56) or MDI added to prandial insulin when HbA1C &gt;7% on basal insulin therapy (n = 60). Primary endpoint = difference in HbA1C change using follow-up HbA1C results.</td>
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<td>- RESULTS: Both groups experienced significant glycemic improvement from similar mean baselines.</td>
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<td>- By 27 weeks, HbA1C least squares mean change from baseline: V-Go -1.98% (95% CI, -2.36 to -1.60) versus MDI -1.34% (95% CI -1.68 to -1.00); treatment difference -0.64% (95% CI-1.17 to -0.10; p = 0.020). Mean insulin usage ± one standard deviation: V-Go 56 ± 17 units/day versus MDI 78 ± 40 units/day (p &lt; 0.001).</td>
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<td>- Diabetes-related direct pharmacy costs were lower with V-Go and the cost inferential from baseline per 1% reduction in HbA1C was significantly less with V-Go ($118.84 +/- $158.55 per patient/month) versus MDI ($217.16 +/- $251.66 per patient/month) (p = 0.013).</td>
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<td>- CONCLUSION: Progression to intensive insulin therapy (IIT) resulted in significant glycemic improvement with V-Go, was associated with a greater reduction in HbA1C, required less insulin and was more cost effective than IIT administered with MDI.</td>
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<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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<td>Kamble (2012)</td>
<td><strong>Key points:</strong></td>
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| Sensor augmented pumps (SAP) versus MDI | - Using CORE diabetes simulation model, incremental cost effectiveness ratio (ICER) of SAP was an estimated $229,675 per quality-adjusted life year (QALY) with three-day sensors and $168,104 per QALY with six-day sensors from the perspective of the United States.  
- When considering the significant and ongoing costs associated with SAP relative to MDI and costs of long-term complications in relation to expected health benefits, SAP is not economically attractive over a number of scenarios for adults with T1DM.  
- Assumptions in explicit modeling of patients’ fears about hypoglycemia can dramatically impact cost-effectiveness ratios. |
| St. Charles (2009) | **Key points:**                   |
| CSII versus MDI  | - CSII was associated with an improvement in QALYs gained of 1.061 vs. MDI for adults and 0.799 vs. MDI for children and young adults.  
- ICERs were $16,992 and $27,195 per QALY gained for CSII vs. MDI in adults and children and young adults, respectively.  
- Improved glycemic control from CSII led to a lower incidence of diabetes complications, with the most significant reduction in proliferative diabetic retinopathy (PDR), end-stage renal disease (ESRD) and peripheral vascular disease (PVD).  
- The number needed to treat to avoid one case of PDR, ESRD or PVD was 9, 19 and 41, respectively.  
- CONCLUSIONS: At a willingness to pay threshold of $50,000/QALY, CSII is a cost-effective option for patients with T1DM in the United States. |

**Glossary**

**Basal insulin** — A low level of insulin that covers the body’s need for insulin between meals and during the night.

**Bolus insulin** — The additional amounts of insulin needed in response to glucose taken in during a meal.

**Diabetes** — A metabolic disease in which the body’s inability to produce any or enough insulin causes elevated levels of glucose in the blood.

**Glucose** — Simple sugar found in the blood.

**Glycemia** — The concentration of glucose in the blood.

**Glycemic control** — Typical levels of blood glucose in a person with diabetes mellitus used as a "target" goal for treatment.

**Glycemic excursions** — Fluctuation of a person’s blood glucose levels during the course of a day.

**Glycosylated hemoglobin level** — The level of glucose attached to blood hemoglobin A that determines the average blood sugar concentrations for the preceding two to three months. Also called glycated hemoglobin, glycohemoglobin, glycyslated hemoglobin, HA1c or HbA1C.

**Hyperglycemia** — Abnormally high level of glucose in the blood. Fasting hyperglycemia is a blood glucose level above 130mg/dL after fasting for at least eight hours. Post-prandial hyperglycemia is a blood glucose level above 180mg/dL one to two hours after eating.
Hypoglycemia — A blood glucose level of less than 70mg/dL.

Hypoglycemic unawareness — An inability to know and recognize the symptoms of hypoglycemia while they are occurring; may require intervention from another person for resuscitative actions.

Insulin — Hormone released by the pancreas in response to increased levels of glucose in the blood.

Insulinopenia — Deficient secretion of insulin by the pancreas, resulting in hyperglycemia.

Intraperitoneal — Relating to the space located within the abdominal cavity wrapped in a serous membrane that forms the lining of the abdominal cavity called the peritoneum.

Prandial — During or relating to a meal.

Rapid-acting insulin — A type of insulin that starts to lower blood glucose within five to 10 minutes after injection and has its strongest effect 30 minutes to three hours after injection, depending on the type used.

Real time — The process of producing information without any delay.

Subcutaneous — Administration by injection under the skin.

Type 1 diabetes (T1DM) — A lifelong condition in which the pancreas stops making insulin. Previously known as “insulin-dependent diabetes mellitus (IDDM)” or “juvenile diabetes.”

Type 2 diabetes (T2DM) — A form of diabetes in which insulin is present but does not work adequately because the body either does not produce enough insulin or the cells ignore the insulin. Previously known as “adult-onset diabetes mellitus” or “noninsulin-dependent diabetes mellitus.”

References

Professional society guidelines/other:


Peer-reviewed references:

21CFR201. Subpart B--Labeling Requirements for Prescription Drugs and/or Insulin.


Clinical trials:

Searched clinicaltrials.gov on March 23, 2016 using terms V-Go or Omnipod | Open Studies. Three studies found, two relevant.


CMS National Coverage Determinations (NCDs):


Local Coverage Determinations (LCDs):


Commonly submitted codes

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

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<td>Z96.41</td>
<td>Presence of insulin pump (external) (internal)</td>
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<td>Infusion set for external insulin pump, needle type</td>
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<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
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<td>Infusion pump, implantable, nonprogrammable (includes all components, e.g., pump, catheter, connectors, etc.)</td>
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<td>E0783</td>
<td>Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)</td>
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<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
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