Clinical Policy Title: Insulin infusion therapy

Clinical Policy Number: CCP.1065

Effective Date:	**March 1, 2014**
Initial Review Date:	November 20, 2013
Most Recent Review Date:	June 4, 2019
Next Review Date:	June 2020

Policy contains:

- Continuous subcutaneous insulin infusion:
  - Disposable.
  - Non-disposable.
- Implantable intraperitoneal insulin infusion.

Related policies:

CCP.1015	Outpatient diabetes self-management training
CCP.1202	Pancreas transplantation
CCP.1205	Artificial pancreas device system
CCP.1366	Continuous glucose monitoring

ABOUT THIS POLICY: *AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' 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 AmeriHealth Caritas 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. AmeriHealth Caritas' 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. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.*

Coverage policy

AmeriHealth Caritas considers the use of U.S. Food and Drug Administration-approved, non-disposable continuous subcutaneous insulin infusion pumps to be medically necessary durable medical equipment for the treatment of diabetes mellitus when all of the following criteria are met (American Diabetes Association, 2019; Farrar, 2016; Grunberger, 2018; Yeh, 2012):

- Patient has type 1 diabetes mellitus, type 2 diabetes mellitus, or gestational diabetes mellitus.
- A team of specialists in diabetes care determines if both of the following conditions 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 demonstrate(s) appropriate pump usage, monitoring of glucose levels, and use of the data to manage diabetes.
- Either of the following criteria:
  - The member receives multiple daily injections of insulin (i.e., at least three injections per day), has had 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, and both of the following criteria.
    - The member has completed a comprehensive diabetes education program.
    - The member meets at least one of the following criteria while on multiple daily injections of insulin:
      - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL.
      - Elevated glycosylated hemoglobin level (A1C) > 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).
  - The member has been on an insulin pump prior to enrollment in AmeriHealth Caritas, and has documented frequency of glucose self-testing on average at least four times per day during the month prior to enrollment.

AmeriHealth Caritas considers the use of programmable, *disposable* continuous subcutaneous insulin pumps (e.g., OmniPod® Insulin Management System [Insulet Corp., Bedford, Massachusetts]) to be clinically proven and, therefore, an acceptable alternative to a nondisposable continuous subcutaneous insulin pump for persons who meet medical necessity criteria for external insulin infusion pumps.

AmeriHealth Caritas considers the use of *implantable* intraperitoneal insulin pumps to be investigational and, therefore, not medically necessary, as none have received U.S. Food and Drug Administration (2019a) approval for use outside of clinical trials.

Limitations:

All other uses of non-disposable continuous subcutaneous insulin infusion pumps are not medically necessary.

Continued coverage of continuous subcutaneous insulin infusion requires the patient to 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 continuous subcutaneous insulin infusion and works closely with a team including nurses, diabetes educators and dietitians knowledgeable in the use of continuous subcutaneous insulin infusion.

Some continuous subcutaneous insulin infusion pumps 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 continuous subcutaneous insulin infusion pump and blood glucose monitor.

Repair and maintenance of a non-disposable continuous subcutaneous insulin infusion 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.

Replacement of a non-disposable continuous subcutaneous insulin infusion pump is medically necessary* either:

- For children who require a larger insulin reservoir.
- If the infusion pump is out of warranty, or is malfunctioning and cannot be refurbished.

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.

*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.

Alternative covered services:

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

Background

Diabetes can cause serious health complications, including heart disease, blindness, renal failure, and lower-extremity amputations (Centers for Disease Control and Prevention, 2019). Clinical presentation

and disease progression can vary considerably. Diabetes is usually diagnosed according to one of the following criteria (American Diabetes Association, 2019):

- Fasting plasma glucose ≥ 126 mg/dL (7.0 mmol/L).
- Two-hour plasma glucose ≥ 200 mg/dL (11.1 mmol/L) after a 75-g oral glucose tolerance test.
- A1C ≥ 6.5 percent (48 mmol/mol).
- Random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

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, ongoing diabetes support, blood glucose monitoring, and insulin replacement therapy (American Diabetes Association, 2019).

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. These advances include continuous subcutaneous insulin infusion (or insulin pumps), intraperitoneal insulin pumps, real-time continuous glucose monitoring (real-time continuous glucose monitoring), and sensor-augmented pumps that combine real-time continuous glucose monitoring 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 real-time continuous glucose monitoring sensors (sensor-augmented pumps). 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 pumps have received U.S. Food and Drug Administration (2019a) 510(k) premarket approval as Class II devices. Presently, no continuous implantable insulin pumps have received premarket approval outside of clinical trials.

As of this writing, there are two external, disposable subcutaneous insulin infusion devices without visible tubing commercially available in the United States. They are (U.S. Food and Drug Administration, 2019a):

- OmniPod 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 to control the insulin pump. The unit is worn for up to three days before requiring replacement. OmniPod originally received 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 Personal Diabetes Manager and smaller and more lightweight models (Insulet, 2019).
- V-Go™ Disposable Insulin Delivery Device (Valeritas Inc., Shrewsbury, Massachusetts) is a fully disposable, non-electronic, self-contained, sterile, patient-fillable, single-use, insulin infusion device with an integrated stainless steel subcutaneous needle indicated for adult patients with type 2 diabetes mellitus requiring insulin (Valeritas, 2019). 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, 2019).

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- The Cochrane Library.

We conducted searches on April 16, 2019. 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

AmeriHealth Caritas identified one systematic review, two evidence-based guidelines, and two economic analyses for this policy. The systematic review evaluated the safety and efficacy of non-disposable subcutaneous (Yeh, 2012). Both economic studies were cost-effectiveness analyses of insulin pump therapy in adults with type 1 diabetes mellitus from the United States perspective. One cost-effectiveness analysis compared the use of continuous subcutaneous insulin infusion injection versus multiple daily injections (St. Charles, 2009), and the other compared sensor-augmented pump to multiple daily injections (Kamble, 2012). Guidelines from the American Diabetes Association (2014) and the American Association of Clinical Endocrinologists Consensus Panel on Insulin Pump Management (Grunberger, 2010) are included.

No systematic reviews or economic analyses of either the OmniPod or V-Go disposable insulin pumps were identified. One 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 continuous subcutaneous insulin infusion for persons with diabetes mellitus who require intensive insulin therapy (i.e., ≥ three injections per day of insulin). Results of randomized controlled trials found multiple daily injections and rapid-analogue-based continuous subcutaneous insulin infusion were similarly effective in lowering A1C levels with similar rates of hypoglycemia in persons ages ≥ 4 with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus, including pregnant women (Yeh, 2012). In adults with type 1 diabetes mellitus, A1C levels decreased more with continuous subcutaneous insulin infusion than with multiple daily injections, but one study heavily influenced these results. Adolescents and adults with type 1 diabetes mellitus reported better overall quality of life with continuous subcutaneous insulin infusion than with multiple daily injections.

Sensor-augmented pump use was associated with a significantly greater reduction in A1C compared with multiple daily injections/self-monitoring of blood glucose (self-monitoring of blood glucose) in non-pregnant adults with type 1 diabetes mellitus based primarily on the results of the Sensor-Augmented Pump Therapy for A1C Reduction-3 randomized controlled trial (Bergenstal, 2010). The ability to

improve glycemic control and lower the incidence of diabetes complications may make continuous subcutaneous insulin infusion 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 quality of life.

According to evidence-based guidelines, the ideal candidate for continuous subcutaneous insulin infusion pump therapy is a motivated and diabetes-educated person whose type 1 diabetes mellitus or insulinopenic type 2 diabetes mellitus is inadequately controlled with multiple daily injections (i.e., performs ≥ three insulin injections and ≥ three self-monitoring of blood glucose measurements daily) and who is willing and intellectually and physically able to undergo the rigors of insulin pump therapy initiation and maintenance (American Diabetes Association, 2014; Grunberger, 2010).

Eligible candidates should be capable of self-management through frequent self-monitoring of blood glucose measurements (at least initially) 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 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 intraperitoneal insulin pumps compared to multiple daily injections or intensive subcutaneous administration in adults with type 1 diabetes mellitus and type 2 diabetes mellitus, along with high patient satisfaction and quality of life 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 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 had 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 U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience database (2017b).

For the Omnipod, results of low-quality, single clinical studies suggest it may offer comparable short-term glycemic control to that of traditional continuous subcutaneous insulin infusion pumps in young adults and children with type 1 diabetes mellitus and in adults with uncontrolled type 2 diabetes mellitus with severe insulin resistance (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 continuous subcutaneous insulin infusion 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 continuous subcutaneous insulin infusion pump in relation to its tubing.

The Omnipod 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 the U.S. Food and Drug Administration's (2017b) Manufacturer and User Facility Device Experience database since its approval, the existing research evidence of the OmniPod is insufficient to permit conclusions regarding its safety and effectiveness.

Evidence gaps:

The relative efficacy of continuous subcutaneous insulin infusion versus multiple daily injections 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 continuous subcutaneous insulin infusion compared to multiple daily injections, 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 (American Diabetes Association, 2015; Lajara, 2016). The cost-effectiveness analysis found progression to intensive insulin therapy administered with both V-Go and multiple daily injections resulted in significant glycemic improvement. V-Go was associated with a greater reduction in A1C, required less insulin and was more cost effective than intensive insulin therapy administered with multiple daily injections. However, optimal patient selection criteria and consideration of adverse events in the analysis were unclear. The American Diabetes Association Standards of Care (2015) made no mention of disposable insulin pumps.

A search of the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience database (2016b) 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. We found no additional studies of intraperitoneal insulin pumps.

We included a Cochrane review comparing pregnancy outcomes using continuous subcutaneous insulin infusion and multiple daily injections (Farrar, 2016), and an update of the American Diabetes Association Standards of Medical Care in Diabetes (2017). Farrar (2016) found insufficient evidence to recommend one particular form of insulin administration over another for pregnant women with diabetes, as both produced comparable health outcomes. The new information is consistent with previous findings. Therefore, no policy changes are warranted.

In 2018, we added an updated guideline from the American Diabetes Association (2018). A request from diabetes specialists prompted reconsideration of the medical necessity of the Omnipod based on positive clinical experience with the device and no major safety concerns. The Omnipod is a popular choice among practitioners, parents, and children (especially the very young) for its discrete size, ability to bolus remotely, and absence of tubing, while improving glycemic control and quality of life. For these reasons, the policy statement for Omnipod was changed to medically necessary, and the lower age limit criterion for nondisposable insulin pumps was removed.

In 2019, we updated two guidelines (American Diabetes Association Standards of Medical Care in Diabetes, 2019; Grunberger, 2018, replaces 2010). In children with type 1 diabetes, one randomized controlled trial (Blair, 2018, 2019; Current Controlled Trials ISRCTN29255275) and a meta-analysis (Qin, 2018) provided conflicting results of the benefits of insulin pumps over multiple daily injections during the first year. Both authors agreed that longer-term benefits (12 months and older) of glycemic control and beyond A1C reduction were unknown, and the impact of study designs, age, and other participant attributes were needed to clarify such benefits. One observational study (Rachmiel, 2019) of 113 children with type 1 diabetes found the Medtronic, Omnipod, and Animas insulin pump devices were comparable regarding glycemic control, weight gain, and patient satisfaction. The new information is consistent with the current policy, and no policy changes are warranted. The policy ID was changed from CP# 06.02.05 to CCP.1065.

References

Professional society guidelines/other:

21CFR201. Subpart B--Labeling requirements for prescription drugs and/or insulin.

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Peer-reviewed references:

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Centers for Medicare & Medicaid Services National Coverage Determinations:

60-14 Coverage issues. Durable medical equipment. Infusion pumps.
280.14 Infusion Pumps.

Local Coverage Determinations:

A52507 External Infusion Pumps - Policy Article.
L33794 External Infusion Pumps.

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.

CPT Code	Description	Comments
96521	Refilling and maintenance of portable pump	

ICD-10 Code	Description	Comments
E10.10-E10.9	Type 1 diabetes mellitus	
E11.00-E11.9	Type 2 diabetes mellitus	
O24.011-O24.93	Diabetes mellitus in pregnancy, childbirth, and the puerperium	
Z79.4	Long term (current) use of insulin	
Z96.41	Presence of insulin pump (external) (internal)	

HCPCS Level II Code	Description	Comments
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each	
A4230	Infusion set for external insulin pump, non-needle cannula type	
A4231	Infusion set for external insulin pump, needle type	
A4232	Syringe with needle for external insulin pump, sterile, 3 cc	
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories	
E0784	External ambulatory infusion pump, insulin	
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)	