

Ambulatory Insulin Pumps and Closed-Loop Insulin Delivery Systems

Policy MP-007

Origination Date: 6/21/18

Reviewed/Revised Date: 9/16/19

Next Review Date: 9/16/20

Current Effective Date: 9/16/19

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for U of U Health Plans Commercial, and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.

Description:

As of 2015, diabetes remained the 7th leading cause of death in the United States. There are an estimated 1.5 million new cases of Americans (age 18 and older) diagnosed with diabetes every year. The American Diabetes Association (ADA) reported that the U.S. had 30.3 million people, in all age groups, with diabetes in 2015. Of those people, 23.1 million were diagnosed and 7.2 million were undiagnosed, equivalent to 9.4% of the population. In that same year, 84.1 million people age 18 and older had prediabetes, of which 7.2 million were not aware of having it or they didn't report it.

Continuous subcutaneous insulin infusions (insulin pump therapy) have been used to treat diabetes since the late 1970's and are now available in several forms. The most common type is an external insulin infusion pump which is a programmable, battery-powered mechanical syringe/reservoir device controlled by a micro-computer to provide continuous subcutaneous insulin infusion (CSII) in individuals with diabetes mellitus. Typically, the syringe has a 2-3 day insulin capacity and is connected to an infusion set attached to a small needle or cannula which the individual inserts into the subcutaneous tissue. The syringe is activated by a battery operated pump programmed to deliver a steady "basal" amount of insulin and release a "bolus" dose at meals and at programmed intervals. The pump is about the size of a deck of cards, weighs about 3 ounces, and can be worn on a belt or in a pocket.

Closed-loop insulin delivery systems combine the technology of a continuous glucose monitor (CGM) and an insulin pump, these help eliminate the need for patients or providers to intervene in the management of blood sugar trends in real-time. These "closed-loop" systems contain computer-controlled algorithms that connects the CGM and insulin infusion pump to allow continuous communication between the two devices. They allow people with diabetes to

receive insulin through a pump continuously throughout the day and night based on glucose measurements provided every five minutes by the CGM.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans covers insulin pumps for all Type 1 diabetics, regardless of the adequacy of their current insulin regimen. (Criterion “C” addresses pump renewals)

U of U Health Plans covers ambulatory insulin pumps for Type 2 diabetics if the following criteria are met:

A. Insulin pump criteria:

- i. Request is from a treating endocrinologist or diabetes specialist.
- ii. Diabetes members with at least one year of subcutaneous insulin therapy.
- iii. Documentation through log books of treatment regimen consisting of three or more injections of insulin per day including both long-acting insulin analogs (insulin glargine, insulin detemir or insulin degludec) plus a short-acting insulin analog (insulin aspart, insulin lispro or insulin glulisine) for at least two months prior to initiation of insulin pump. Must have at least 80% compliance over two months.
- iv. Has documented logs of glucose self-testing at least 4 times per day for two months prior to initiation of the insulin pump. Must have 80% compliance over two months.
- v. Documentation of members or caregivers ability to perform carbohydrate counting and insulin dose calculation.
- vi. Documentation of diabetes specialist’s assessment of clinical therapeutic value of an insulin pump and ability to train member on appropriate use of insulin pump.
- vii. Documentation of at least 2 visits with a diabetes specialist during the six months prior to initiation.
- viii. Meets one or more of the following criteria while on a multiple daily injection insulin:
 - a. Glycosylated hemoglobin levels (HbA1c) greater than 8%;
 - b. Recent history (within the last six months) of significant, recurring hypoglycemia (less than 60mg per deciliter or requiring assistance);

- c. Wide fluctuations (well above and below set glycemic targets) in blood glucose before and after meal times, despite appropriate adjustment of doses;
- d. At least one documented incidence of hyperglycemic hyperosmotic syndrome or diabetic ketoacidosis within the previous six months;
- e. Type I diabetes mellitus.

B. Covered Products:

- i. Medtronic
 - a. Minimed 530G
 - b. Minimed 630G
 - c. Minimed 670G – Hybrid closed-loop insulin delivery system
- ii. Omnipod and Ominpod DASH
- iii. Tandem Diabetes
 - a. t:flex
 - b. t:slim X2
- iv. Pump systems eligible for supplies only, **NOT** new service
 - a. Animas Vibe
 - b. Animas One Touch Ping
 - c. Roche Accu-Chek Combo

C. Renewals:

- i. Patients must have had at least 2 visits with a diabetes specialist within the previous 12 months.
- ii. Documentation must show that the member is adhering to the treatment plan outlined by a diabetes specialist.
- iii. Patients who are continuing insulin pump therapy and requesting a new insulin pump must provide documentation that current pump's warranty has expired.

D. Exemptions:

- i. Patients with gestational diabetes or diabetes during pregnancy are exempted from previous management provisions of this policy.

U of U Health Plans may cover closed-loop insulin delivery systems when the following criteria are met (A, B, and C):

- A. Member is age 8 and over.
- B. Member falls into one of the following categories:
 - i. Patient had Type 1 diabetes; or
 - ii. Insulin pump therapy is being used as an adjunct to kidney transplant; or
 - iii. Member is pregnant whether Type 1 or Type 2.
- C. Type 1 diabetic patients who have performed self-monitored blood glucose (SMBG) testing averaging ≥ 4 readings with 80% compliance for 30 consecutive days within a previous 3 month period and has **ONE** of the following:
 - i. Hemoglobin A1C ≥ 7.5 ; or
 - ii. Recurrent hypoglycemic events as listed below*; or
 - iii. Wide glucose excursions (daily fluctuations of 200mg/dL or more).

**For recurrent hypoglycemic events:*

*The Member has demonstrated significant hypoglycemic unawareness as manifested by any **ONE** of the following within the 6 months prior to the request:*

- 1) At least 1 ER visit specifically for a hypoglycemic conditions.*
- 2) At least 1 hospitalization for hypoglycemic complications.*
- 3) Clinical documentation supporting significant or frequent hypoglycemic issues.*

U of U Health Plans will only cover replacements if ALL of the following criteria are met:

- A. The device is out of warranty and the device is malfunctioning; and
- B. Malfunction or damage was not due to patient neglect or abuse; and
- C. Member must have attended 2 diabetic medical provider visits within the last 12 months at least one of which must be with a prescribing provider and demonstrated compliance with therapeutic regimen.

U of U Health Plans considers use of a hybrid closed loop insulin delivery system as an artificial pancreas device system investigational.

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at

<http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Clinical Rationale

Standard Insulin Pumps

Since the completion of the Diabetes Control and Complications Trial (DCCT) in 1993 and the introduction of Lispro (Humalog) insulin in 1996, children and adolescents with diabetes have increasingly turned to insulin pump therapy to maximize their diabetic control in an effort to slow the development of long term complications of poorly controlled diabetes.

The theoretical advantage of insulin pump therapy is its ability to mimic physiological insulin release and meet physiological insulin needs in people with insulin diabetes mellitus. The basal and bolus functions of the pump allow separate determination and adjustment of both these insulin requirements and also allow flexibility in timing and amounts of nutritional intake and physical activity, allowing wide variation in lifestyles. This flexibility allows for improved patient compliance and adherence to their diabetic regimen allowing for improved diabetic control.

In addition, use of the newer short-acting (Novalog or Humalog) or ultra-short acting insulins makes coverage of the early morning glucose rise ("Dawn phenomenon") easier, eases sick day management and matches nutrient absorption more physiologically, thereby reducing the risk of hypoglycemic complications.

Prior studies of pump users show a high degree of satisfaction and most show a decreased risk of severe hypoglycemia. Recent studies, additionally, have demonstrated improved effectiveness of diabetic control even in patients who have achieved good control (HgbA1C) using standard therapies.

The perceived advantages to the OmniPod insulin pump may lead members to desire this pump over standard insulin therapy. However, currently there seems to be little local support for use of this pump given the character of requests coming from local providers. As OmniPod development and research is emanating out of Massachusetts (the source of the only patient requesting an OmniPod to date also), as the technology diffuses throughout the US requests may increase.

An additional factor which may mitigate rapid increase uptake and demand for the OmniPod by providers and patients will be the considerable marketing resources that standard insulin pump manufacturers may apply to providers to counter the perceived advantages of this technology. Given the fact that the inertia for provider change is often slow and can be significantly impacted by manufacturer marketing and that patients tend to defer medical decisions to providers, additional impediments would seem to be present which will likely lead to slow uptake of this technology.

With regard to the t:slim insulin delivery system, a technology review was completed in August of 2013. This review noted there is a lack of high-quality peer-reviewed evidence demonstrating the safety, efficacy and improvement in patient clinical outcomes associated with the t:slim insulin delivery device especially as it compares to currently alternative insulin pumps (Grade 2C). However, a multi-centered and prospective study by Schaeffer et al. which was sponsored by the manufacturer aimed at assessing real-world user's perceptions of the t:slim pump demonstrated this technology to have performance

characteristics equivalent or in some instances superior to alternative insulin pumps currently available to patients. This study also demonstrated user preference in many instances over other devices. The study concluded that reduced therapeutic complexity, in part, can be derived from improved device usability which may in turn lead to increase patient adherence. This study also demonstrated durability of this device in routine use.

A 2016 overview (McAdams et al), reported remarkable advances in replicating the natural pancreas function with continuous subcutaneous insulin, or the insulin pump, has gained popularity and sophistication as a near-physiologic programmable method of insulin delivery that is flexible and lifestyle-friendly. The introduction of continuous monitoring with glucose sensors provides unprecedented access to, and prediction of, a patient's blood glucose levels. Efforts are underway to integrate the two technologies, from "sensor-augmented" and "sensor-driven" pumps to a fully-automated and independent sensing-and-delivery system. Implantable pumps and an early-phase "bionic pancreas" are also in active development. Fine-tuned "pancreas replacement" promises to be one of the many avenues that offers hope for individuals suffering from diabetes.

Lastly, current standard manufacturers are continuing to evolve their devices. They have developed devices with continuous glucose monitoring capabilities along with other "bells and whistles". By the time the OmniPod technology diffuses throughout the country and requests begin to increase, the manufacturers of the current standard technology may have evolved their devices to the point that this current OmniPod will not be perceived to have significant or any clinical advantages over their devices.

Closed Loop Systems

Trevitt, et al (2016) identified eighteen closed-loop APD systems that were identified and classified into subtypes according to their level of automation; the hormonal and glycemic control approaches used, and their research setting. All were being tested in clinical trials prior to potential commercialization. Six were being studied in the home setting, 5 in outpatient settings, and 7 in inpatient settings. It is estimated that 2 systems may become commercially available in the EU by the end of 2016, 1 during 2017, and 2 more in 2018. There are around 18 closed-loop APD systems progressing through early stages of clinical development. Only a few of these are currently in phase 3 trials and in settings that replicate real life.

In 2017 systematic review (Weisman, et al), 984 reports were identified; after exclusions, 27 comparisons from 24 studies including a total of 585 participants (219 in adult studies, 265 in pediatric studies, and 101 in combined studies) were eligible for analysis. Five comparisons assessed dual-hormone (insulin and glucagon), two comparisons assessed both dual-hormone and single-hormone (insulin only), and 20 comparisons assessed single-hormone closed-loop insulin delivery systems. Time in target was 12.59% higher with closed-loop insulin delivery systems (95% CI 9.02-16.16; $p < 0.0001$), from a weighted mean of 58.21% for conventional pump therapy ($I(2)=84\%$). Dual-hormone closed-loop insulin delivery systems were associated with a greater improvement in time in target range compared with single-hormone systems (19.52% [95% CI 15.12-23.91] vs 11.06% [6.94 to 15.18]; $p=0.006$), although six of seven comparisons compared dual-hormone systems to CSII with blinded CGM, whereas 21 of 22 single-hormone comparisons had SAP as the comparator. Single-hormone studies had higher heterogeneity than dual-hormone studies ($I(2)$ 79% vs 66%). Bias assessment characteristics were incompletely reported in 12 of 24 studies, no studies masked participants to the intervention assignment, and masking of outcome assessment was not done in 12 studies and was unclear in 12 studies.

Hybrid Closed Loop Systems

A recent UpToDate article (May 2018) cited a meta-analysis of trials in adults, adolescents or children with type 1 diabetes for the use of any artificial pancreas (including the fully or partially automated hybrid closed-loop system) with any insulin based treatment. The proportion of time spent near normoglycemia (70 to 180 mg/dL [3.9 to 10 mmol/L]) over 24 hours was significantly higher with the artificial pancreas. Only a few of the trials examined the utility of these devices in the outpatient setting, during eating and usual daily activities, over a longer period. Although these preliminary results are promising, additional trials are needed.

Implantable Insulin Pumps

A 2011 Medical Technology Assessment focused on the V-Go™ disposable insulin delivery system identified only 1 peer-reviewed article. In a proof of concept study, Kapitza et al. applied V-Go to the lower abdomen of 6 subjects once daily for 7 days. The device operated as the investigators expected with no mechanical defects reported. The group concluded that V-Go improved both glycemic control and glycemic variability. Glycemic variability decreased the margin of error by 5 mg/dl for both inpatient and outpatient populations. The study was thorough in that it studied clinical functionality, safety and pharmacodynamics. However, only 6 patients were followed over 1 week. No patient demographic information is given other than that all participants had Type 2 diabetes.

Due to the lack of randomized, prospective trials it is difficult to make any reasonable claim that V-Go improves patient outcomes over-and-above the standard of care. It is also impossible to assess clinical safety and efficacy of this device or to assess cost effectiveness of the device in comparison to insulin pumps currently in use.

A 2011 article (Zisser et al), describes two novel and easy approaches for assessing the accuracy of insulin pumps as implemented within the artificial pancreas system. The approaches are illustrated by data testing the OmniPod Insulin Management System at its lowest delivery volume (0.05 U) and at doses of 0.1, 0.2, 1, and 6U. In method 1, a pipette, digital microscope, and imaging software were used to measure average bolus delivery on a linear scale for multiple volumes. In method 2, a digital microscope and imaging software were used to measure the volume of a spherical bolus of 0.05 U of insulin. Bench testing results using the two novel methods demonstrated that the OmniPod is extremely accurate, with a relative error ranging from -0.90% to +0.96% for all measured doses (0.05, 0.1, 0.2, 1, and 6 U). In method 1, at target bolus dose of 0.05 U, the mean delivered dose (+/- standard deviation) was 0.0497 +/- 0.003 U, 0.099 +/- 0.005 U at 0.1 U, 0.2 +/- <1e-5 U at 0.2 U, 1.001 +/- 0.018 U at 1 U, and 6.03 +/- 0.04 U at 6 U. In method 2, at target bolus dose of 0.5 ml, the mean delivered dose for both OmniPods was 0.505 +/- 0.014. In conclusion, both methods confirmed a high degree of accuracy for the OmniPod insulin pump. These techniques can be used to estimate delivery volume in other infusion pumps as well.

A 2014 study (Borot et al), aimed to evaluate the infusion accuracy of the JewelPUMP (JP), a new patch pump based on a microelectromechanical system that operates without any plunger, in vitro and in vivo. For the in vitro studies, commercially available pumps meeting the ISO standard were compared to the JP: the MiniMed(R) Paradigm(R) 712 (MP), Accu-Chek(R) Combo (AC), OmniPod(R) (OP), Animas(R) Vibe (AN). Pump accuracy was measured over 24 hours using a continuous microweighing method, at 0.1 and 1 IU/h basal rates. The occlusion alarm threshold was measured after a catheter occlusion. The JP, filled with physiological serum, was then tested in 13 patients with type 1 diabetes simultaneously with their own pump for 2 days. The weight difference was used to calculate the infused insulin volume. The JP showed reduced absolute median error rate in vitro over a 15-minute observation window compared to other pumps (1 IU/h): +/-1.02% (JP) vs +/-1.60% (AN), +/-1.66% (AC), +/-2.22% (MP), and +/-4.63% (OP), P < .0001. But there was no difference over 24 hours. At 0.5 IU/h, the JP was able to detect an occlusion

earlier than other pumps: 21 (19; 25) minutes vs 90 (85; 95), 58 (42; 74), and 143 (132; 218) minutes (AN, AC, MP), $P < .05$ vs AN and MP. In patients, the 24-hour flow error was not significantly different between the JP and usual pumps (-2.2 +/- 5.6% vs -0.37 +/- 4.0%, $P = .25$). The JP was found to be easier to wear than conventional pumps. The JP is more precise over a short time period, more sensitive to catheter occlusion, well accepted by patients, and consequently, of potential interest for a closed-loop insulin delivery system.

In January 2016 the Animas Corporation received FDA approval for the use of the Animas Vibe® Insulin Pump and Continuous Glucose Monitoring (CGM) System for the management of diabetes in children and adolescents, ages 2 to 17. The Animas Vibe System was the first integrated system featuring Dexcom G4® PLATINUM CGM technology, and is the only such system available in the U.S. for pediatric patients as young as age two. The Animas® Vibe® System allows patients and their caregivers to view glucose data and administer insulin right from the pump, making it easy to fine tune insulin delivery to help manage their diabetes.

Applicable Coding

CPT Codes

No applicable codes identified

HCPCS Codes

- A4224** Supplies for maintenance of insulin infusion catheter, per week
- A4225** Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
- A4230** Infusion set for external insulin pump, nonneedle 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
- J1817** Insulin for administration through DME (i.e., insulin pump) per 50 units
- S1034** Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
- S1035** Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
- S1036** Transmitter; external, for use with artificial pancreas device system
- S1037** Receiver (monitor); external, for use with artificial pancreas device system
- S5550** Insulin, rapid onset, 5 units
- S5551** Insulin, most rapid onset (Lispro or Aspart); 5 units
- S5552** Insulin, intermediate acting (NPH or LENTE); 5 units

S5553	Insulin, long acting; 5 units
S5565	Insulin cartridge for use in insulin delivery device other than pump; 150 units
S5566	Insulin cartridge for use in insulin delivery device other than pump; 300 units
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)
S9353	Home infusion therapy, continuous insulin infusion therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

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