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Originated Department	Medical Management

Ambulatory Insulin Pumps and Closed-Loop Insulin Delivery Systems

Audience
Providers, Members, Brokers, MHC

Purpose

Medical policies provide general support for applying Mountain Health Co-Op member policy document coverage decisions, and the member-specific benefit plan document must be referenced. The terms of the member-specific Policy document may differ from the standard benefit plan based on this medical policy. If there is a conflict between a member-specific policy document and the Mountain Health Co-Op medical policy, the document supersedes this policy. Any person(s) applying this medical policy must identify member eligibility, the member-specific policy document, and related policies or guidelines before applying this medical policy, including the existence of any state or federal guidance. Mountain Health Co-Op medical policies are designed for informational purposes only and are not an authorization, explanation of benefits, or contract. Receipt of benefits is subject to the satisfaction of all terms and conditions of the member-specific policy document coverage. Mountain Health Co-Op reserves the sole discretionary right to modify all policies and guidelines at any time.

Definition

As of 2018, 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 Centers for Disease Control (CDC) reported in 2018 that the U.S. had approximately 26.9 million people (of all ages), or 8.2% of the population, diagnosed with diabetes. In that same year, an estimated 88 million people age 18 and older had prediabetes, of which 7.3 million were not aware of having it or didn't report it.

Closed-loop insulin delivery systems combine the technology of a continuous glucose monitor (CGM) and an insulin pump, helping eliminate the need for patients or providers to intervene in the management of blood sugar trends in real time.

Policy/Procedure

Mountain Health Co-Op covers insulin pumps for all Type 1 diabetics, regardless of the adequacy of their current insulin regimen.

1. **Mountain Health Co-Op covers ambulatory insulin pumps for Type 2 diabetics if the following criteria are met:**
   a) Insulin pump criteria:
      a) Diabetes members with at least one year of subcutaneous multidose insulin therapy.
      b) Documentation through log books of a treatment regimen consisting of three or more injections of insulin per day, including both long-acting insulin analogs (insulin glargine, insulin determir, 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.
      c) 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.
      d) Documentation of members or caregivers' ability to perform carbohydrate counting and insulin dose calculation.
      e) Documentation of a diabetes specialist's assessment of the clinical therapeutic value of an insulin pump and ability to train members on appropriate insulin pump use.
      f) Documentation of at least 2 visits with a diabetes specialist during the six months prior to initiation.
      g) Meets one or more of the following criteria while on multiple daily injections of insulin (a - e):
         i. Glycosylated hemoglobin levels (HbA1c) greater than 8%;
         ii. Recent history (within the last six months) of significant, recurring hypoglycemia (less than 60mg per deciliter or requiring assistance);
         iii. Wide fluctuations (well above and below set glycemic targets) in blood glucose before and after meal times, despite appropriate adjustment of doses;
         iv. At least one documented incidence of hyperglycemic hyperosmotic syndrome or diabetic ketoacidosis within the previous six months;
   b) Covered Products:
      a) Medtronic
      i. Minimed 530G
      ii. Minimed 630G
      iii. Minimed 670G – Hybrid closed-loop insulin delivery system
      iv. Minimed 770G

b) Omnipod (Omnipod DASH and Omnipod 5 are NOT covered under the medical benefit but may be covered under the pharmacy benefit)

c) Tandem Diabetes
- **i.** t:flex
- **ii.** t:slim X2

d) Pump systems eligible for supplies only, NOT new service
- **i.** Animas Vibe
- **ii.** Animas One Touch Ping
- **iii.** Roche Accu-Chek Combo

c) <u>Renewals:</u>
- **a)** Patients must have had at least 2 visits with a diabetes specialist within the previous 12 months.
- **b)** Documentation must show that the member is adhering to the treatment plan outlined by a diabetes specialist.
- **c)** Patients who are continuing insulin pump therapy and requesting a new insulin pump must provide documentation that the current pump's warranty has expired.

d) <u>Exemptions:</u>
- **a)** Patients with gestational diabetes or diabetes during pregnancy are exempted from previous management provisions of this policy.

2. Mountain Health Co-Op may cover closed-loop insulin delivery systems when the following criteria are met (2.1, 2.2, and 2.3):

a) Member is age 8 or over

b) Member falls into one of the following categories:
- **a)** Patient had Type 1 diabetes or
- **b)** Insulin pump therapy is being used as an adjunct to kidney transplant or
- **c)** Member is pregnant, whether Type 1 or Type 2.

c) Type 2 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 have ONE of the following:
- **a)** Hemoglobin A1C ≥ 7.5; or
- **b)** Recurrent hypoglycemic events as listed below*; or
- **c)** Wide glucose excursions (daily 200mg/dL fluctuations or more).

** For recurrent hypoglycemic events:*

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

a) *At least 1 ER visit specifically for hypoglycemic conditions.*

b) *At least 1 hospitalization for hypoglycemic complications*

c) *Clinical documentation supporting significant or frequent hypoglycemic issues.*

4. Mountain Health Co-Op s will only cover replacements if ALL of the following criteria are met:

a) The device is out of warranty or 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.

5. Clinical Rationale

5.1 *Standard Insulin Pumps*

a) 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 to slow the development of long-term complications of poorly controlled diabetes.

b) 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 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.

c) In addition, the 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 more physiologically matches nutrient absorption, thereby reducing the risk of hypoglycemic complications.

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

e) The perceived advantages of the OmniPod insulin pump may lead members to desire this pump over standard insulin therapy. A Hayes review of this technology completed in 2020 and updated in December 2021 identified 5 studies that met the inclusion criteria and evaluated the efficacy and safety of the OmniPod system for managing DM. The review concluded that the overall very low-quality body of evidence did not allow for conclusions to be drawn regarding the safety and efficacy of therapy with the OmniPod system. Evidence across studies was inconsistent in evaluations of the effect of the OmniPod system on HbA1c level reductions, with some studies showing a clinically and statistically significant reduction, some studies demonstrating no clinically significant reduction, and 1 study demonstrating a clinically important increase in HbA1c levels at 3 years of follow-up. Reductions in insulin use were similarly inconsistent. It is not clear from the current evidence base whether using the OmniPod system results in a clinically significant improvement in HbA1c levels or insulin use in patients with type 1 DM over the long term. Overall quality was based on the balance of benefits and harms and was assessed taking

into consideration the quality of individual studies, the precision, directness, and consistency of data, and the applicability of the data to general practice. Limitations of individual studies include small sample size, retrospective study design, lack of long-term data, and lack of power analyses.

f) 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 users' 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 over other devices in many instances. The study concluded that reduced therapeutic complexity, in part, can be derived from improved device usability, which may, in turn, lead to increased patient adherence. This study also demonstrated the durability of this device in routine use.

g) A 2016 overview (McAdams et al) reported remarkable advances in replicating the natural pancreas function with continuous subcutaneous insulin, or the insulin pump, which 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 developing actively. Fine-tuned "pancreas replacement" promises to be one of the many avenues that offer hope for individuals suffering from diabetes.

h) Lastly, current standard manufacturers are continuing to evolve their devices. They have developed devices with continuous glucose monitoring capabilities and 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.

5.2 Closed Loop System

a) 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 before 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. Around 18 closed-loop APD

systemsare progressing through the early stages of clinical development. Only a few of these are currently in phase 3 trials and in settings that replicate real life.

b) In the 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 assessed dual-hormone and single-hormone (insulin only), and 20 assessed single-hormone closed-loop insulin delivery systems. Time in the target was 12.59% higher with closed-loop insulin delivery systems (95% CI 9.02-16.16; p

5.3 Hybrid Closed Loop Systems

a) UpToDate's review of hybrid closed-loop systems, last updated in September 2023, noted the two partially automated (hybrid) closed-loop systems of insulin delivery commercially available in the United States (T-Slim X2 and Medtronic 670G). Additional models (Omnipod-5, and Medtronic 770G) have since entered the US market. When using these insulin pump/CGM systems in the "auto" or "automatic" mode, instead of infusing basal insulin in mini-boluses every five minutes according to the programmed basal rates ("manual" mode), the system automatically gives a mini-bolus (or no bolus) of rapidly acting insulin every five minutes determined by an algorithm that is dependent on CGM results, target glucose, and the amount of active insulin on board.

b) With these "hybrid" closed-loop devices, the patient must still determine and administer pre-meal insulin boluses, facilitated by an individualized insulin-to-carbohydrate ratio set in the pump's bolus calculator. Some systems require periodic finger stick capillary glucose measurements for calibration and to address high or low values, and some have limited choices for the target glucose. Each available device can transmit insulin dosing data (display of basal and bolus insulin delivery), CGM and SMBG data, and pump and CGM settings to cloud-based systems. These data can be retrieved and reviewed on demand.

c) The few available small reports on the first commercial hybrid closed-loop system in the United States indicate that discontinuation rates in the real world are high. To stay in "auto mode," the patient must receive substantial education and support and exercise considerable diligence regarding self-care tasks; improvements are anticipated in future models.

d) In a meta-analysis of trials comparing the use of any hybrid closed-loop system with any insulin-based treatment in nonpregnant patients with type 1 diabetes, the proportion of time spent near normoglycemia (70 to 180 mg/dL [3.9 to 10 mmol/L]) over 24 hours was modest, albeit significantly, higher with the hybrid closed-loop system (weighted mean difference 9.62 percent, 95% CI 7.54-11 percent). Overall, the incidence of severe hypoglycemia was low in both groups. Most of the trials examined short-term (one to three days) control. Only a few trials have examined the utility of these devices in the outpatient setting, during eating and usual daily activities, over a more extended period.

e) The Hayes review noted in a crossover, random-order trial, 33 adults (mean A1C 8.5 percent [69.4 mmol/mol]) were assigned to either 12 weeks of partially automated

(hybrid), closed-loop insulin delivery (intervention) followed by 12 weeks of sensor-augmented pump therapy (control), or to the opposite order (sensor-augmented pump therapy followed by hybrid, closed-loop insulin delivery). Patients performed their usual daily activities and were not monitored remotely by study staff. Compared with the sensor-augmented pump, the use of the hybrid closed-loop system resulted in a greater proportion of time spent in the target range of 70 to 180 mg/dL (3.9 to 10 mmol/L; 67.7 versus 56.8 percent, mean difference of 11 percentage points, 95% CI 8.1-13.8). The mean glucose level (157 versus 168 mg/dL) and the mean A1C level (7.3 versus 7.6 percent) were also lower during the closed-loop phase of insulin delivery. Hypoglycemia, as measured by the area under the curve when glucose was <65 md/dL (3.5 mmol/L), was lower during the closed-loop system than during the control period (169 versus 198 [mg/dL x min]). In this study, in children and adolescents using the same device but delivering insulin only overnight, 25 patients (mean A1C 8.1 percent [65 mmol/mol]) used the hybrid closed-loop insulin delivery system overnight and discontinued it before breakfast. Compared with the sensor-augmented insulin pump, the use of the hybrid closed-loop system resulted in a more significant proportion of nocturnal time spent with glucose levels in the target range of 70 to 145 mg/dL (3.9 to 8 mmol/L; 59.7 versus 34.4 percent, mean difference 24.7 percentage points, 95% CI 20.6-28.7). The mean overnight glucose level was lower with the closed-loop system (146 versus 176 mg/dL)—the proportion of time spent with a blood glucose level.

f) The review also cited a subsequent six-month trial comparing a hybrid closed-loop system with a sensor-augmented insulin pump in 168 patients ≥14 years of age, the percentage of time in the target range (70 to 180 mg/dL [3.9 to 10 mmol/L]) as measured with CGM was higher in the closed-loop group (71 versus 59 percent, risk-adjusted difference 11 percent, 95% CI 9-14). A1C levels improved in patients using the closed-loop system (7.4 to 7.06 percent) but did not change in controls (7.4 to 7.39 percent). Although there were no hypoglycemic severe events in either group, the percentage of time spent in hypoglycemia was lower in patients assigned to the closed-loop system (e.g., <54 mg/dL, 0.29 versus 0.35 percent, risk-adjusted difference -0.10, 95% Cl -0.19 to - 0.02). There were, however, more hyperglycemic adverse reactions, including one episode of ketoacidosis, in the closed-loop group (14 versus 2 patients), primarily due to infusion set failures. In a similarly designed 16-week trial in children 6 to 13 years of age, the percentage of time in target range was higher with the closed-loop system (67 versus 55 percent, mean adjusted difference 11 percentage points, 95% CI 7-14).

5.4 Implantable Insulin Pumps

a) 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, and no mechanical defects were 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.

b) 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 the clinical safety and efficacy of this device or its cost-effectiveness in comparison to insulin pumps currently in use.

c) 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 techniques 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. Method 1 used a pipette, digital microscope, and imaging software 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 highly 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 a 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 at 1 U, and 6.03 +/- U at 6 U. In method 2, at a target bolus dose of 0.5 ml, the mean delivered dose for both OmniPods was 0.505 +/- 0.014. In conclusion, both methods confirmed high accuracy for the OmniPod insulin pump. These techniques can be used to estimate delivery volume in other infusion pumps as well.

d) 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 micro-weighing 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 tested in 13 patients with type 1 diabetes simultaneously with their pump for two 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 more accessible to wear than conventional pumps. The JP is more precise over a short period, more sensitive to catheter occlusion, well accepted by

patients, and consequently, of potential interest for a closed-loop insulin delivery system.

e) In January 2016, the Animas Corporation received FDA approval for using the Animas Vibe® Insulin Pump and Continuous Glucose Monitoring (CGM) System for managing 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, 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
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units
S1035	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

Vendors

- **Personify**
- **HPS**

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Review/Revision/Approval History	
Date	Description
06/01/02024	**New Policy**
3/16/2026	**Revised by Mountain Health CO-OP Policy Committee**

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