Clinical UM Guideline

Subject: Automated Insulin Delivery Systems

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Description

This document addresses automated insulin delivery systems for the management of diabetes mellitus. Automated insulin delivery systems combine insulin pumps and continuous interstitial glucose monitors (CGMs). These devices allow management of blood glucose with little to no input by the user. Such devices come in several configurations, including open-loop, hybrid closed-loop, and fully closed-loop systems.

Note: This document does not address supplies related to the use of automated insulin delivery devices.

Note: For requests for insulin pumps alone (continuous glucose monitor not requested or in use), please see:

- CG-DME-51 External Insulin Pumps

Note: For additional information regarding diabetes care, please see:

- CG-DME-42 Continuous Glucose Monitoring Devices
- CG-SURG-79 Implantable Infusion Pumps

Clinical Indications

Medically Necessary:

Use of an open-loop or hybrid closed-loop automated insulin delivery system is considered **medically necessary** for individuals who meet the following criteria:

A. Type 1 diabetes mellitus; **and**
B. Age used in accordance with FDA approval or authorization (for example, age 2 years or older); **and**
C. Meets the following criteria below for personal long-term use of continuous interstitial glucose monitoring devices:
    1. Insulin injections are required multiple times daily or an insulin pump is used for maintenance of blood sugar control; **and**
    2. Both of the following (a and b):
        a. The individual or caregiver(s) demonstrates the following:
            i. An understanding of the technology, including use of the device to recognize alerts and alarms; **and**
            ii. Motivation to use the device correctly and consistently; **and**
            iii. Continued participation in a comprehensive diabetes treatment plan;
            and
        b. *Any* of the following are present, despite ongoing management using self-monitoring and insulin administration regimens to optimize care:
            i. Inadequate glycemic control, demonstrated by HbA1c measurements above target; **or**
            ii. Persistent fasting hyperglycemia; **or**
            iii. Recurring episodes of hypoglycemia (blood glucose less than 54 mg/dL); **or**
            iv. Hypoglycemia unawareness that puts the individual or others at risk; **or**
            v. In children and adolescents with type 1 diabetes who have achieved HbA1c levels below 7.0%, when treatment is intended to maintain target HbA1c levels and limit the risk of hypoglycemia.

Use of a fully closed-loop device automated insulin delivery system is considered **medically necessary** for individuals who meet the following criteria:

A. Type 1 diabetes mellitus; **and**
B. Age used in accordance with FDA approval or authorization (for example, age 6 years or older); **and**
C. Presence of diabetes for at least 12 months; **and**
D. Diabetes managed using the same regimen (either pump or multiple daily injections, with or without continuous glucose monitoring) for 3 months or longer; **and**
E. Meets the following criteria below for personal long-term use of continuous interstitial glucose monitoring devices:
    1. Insulin injections are required multiple times daily or an insulin pump is used for maintenance of blood sugar control; **and**
    2. Both of the following (a and b):
        a. The individual or caregiver(s) demonstrates the following:
            i. An understanding of the technology, including use of the device to recognize alerts and alarms; **and**
            ii. Motivation to use the device correctly and consistently; **and**
            iii. Continued participation in a comprehensive diabetes treatment plan;
            and
        b. *Any* of the following are present, despite ongoing management using self-monitoring and insulin administration regimens to optimize care:
            i. Inadequate glycemic control, demonstrated by HbA1c measurements above target; **or**
            ii. Persistent fasting hyperglycemia; **or**
            iii. Recurring episodes of hypoglycemia (blood glucose less than 54 mg/dL); **or**
            iv. Hypoglycemia unawareness that puts the individual or others at risk; **or**
            v. In children and adolescents with type 1 diabetes who have achieved HbA1c levels below 7.0%, when treatment is intended to maintain target HbA1c levels and limit the risk of hypoglycemia.

Continued use of an open-loop, hybrid closed-loop, or fully closed-loop automated insulin delivery system is considered **medically necessary** when there is documentation that the device has resulted in clinical benefit (for example, improved or stabilized HbA1c control or fewer episodes of symptomatic hypoglycemia or hyperglycemia).

Replacement of a previously approved open-loop, hybrid closed-loop, or fully closed-loop automated insulin delivery system is considered **medically necessary** when the medically necessary criteria above have previously been met *and* all of the criteria below have been met:

A. The device is out of warranty; **and**
B. The device is malfunctioning; **and**

C. The device cannot be refurbished.

Not Medically Necessary:

Use of an open-loop, hybrid closed-loop, or fully closed-loop automated insulin delivery system is considered **not medically necessary** when the criteria above have not been met.

Continued use of an open-loop, hybrid closed-loop, or fully-closed loop automated insulin delivery system is considered **not medically necessary** when continued use criteria above have not been met.

Replacement of currently functional and warrantied open-loop, hybrid closed-loop, or fully closed-loop automated insulin delivery system is considered **not medically necessary** when the replacement criteria above have not been met.

Use of a *non-FDA-approved* open-loop, hybrid closed-loop, or fully closed-loop automated insulin delivery system is considered **not medically necessary** under all circumstances.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:
For the following codes, or when the code(s) describes an automated insulin delivery system:

HCPCS	
E0784	External ambulatory infusion pump, insulin [**when specified as a component of an automated insulin delivery system** in conjunction with a continuous glucose monitoring device]
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
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

ICD-10 Diagnosis	
E08.00-E13.9	Diabetes mellitus
O24.011-O24.93	Diabetes mellitus in pregnancy, childbirth and the puerperium
P70.2	Neonatal diabetes mellitus

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure, device or situation designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Diabetes and Diabetes Management

Approximately 37 million Americans have been diagnosed with diabetes and another 8.5 million are believed to have undiagnosed disease. (American Diabetes Association (ADA, 2025). Diabetes mellitus, the fourth leading cause of death in the U.S., is a chronic condition, marked by impaired metabolism of carbohydrate, protein and fat from resistance to or absence of insulin. Management of diabetes mellitus involves normalization of blood sugar.

The most common forms of diabetes are referred to as Type 1 and Type 2. Type 1 can occur at any age, but is most commonly diagnosed from infancy to late 30s. In type 1 the pancreas produces little to no insulin, and the body's immune system destroys the insulin-producing cells in the pancreas. Type 2 typically develops after age 40, but has recently begun to appear with more frequency in children. In type 2, the pancreas produces insulin, but the body does not produce enough or is not able to use it effectively.

Adequate glycemic control is critical for directing therapy in individuals with diabetes. Ideal blood sugar concentration range is between 70 mg/dL to 180 mg/dL. Hyperglycemia, defined as blood glucose concentrations above 200 mg/dL 1 to 2 hours following a meal is associated with headaches, thirst, fatigue, blurred vision, hunger, difficulty concentrating, and coma. Long-term exposure to hyperglycemia has been associated with organ damage (including loss of function of the kidney, liver, heart, and eyes), peripheral nerve damage, and high blood pressure. Hypoglycemia is defined as an episodes of an abnormally low plasma glucose concentration (with or without symptoms) that expose the individual to harm. A blood glucose concentration between 54 mg/dL and 69 mg/dL, considered mild hypoglycemia, may include hunger or nausea, elevated heart rate, fatigue, difficulty concentrating, and tingling of the oral area. Serious hypoglycemia, defined as a blood glucose concentration < 54 mg/dL, has been associated with confusion, loss of coordination, blurry vision, loss of consciousness and seizures. As noted by the Endocrine Society (2023), blood glucose concentrations < 54 mg/dL is associated with increased risk for cognitive dysfunction and mortality. Individuals with persistent fasting hyperglycemia, hypoglycemia unawareness that puts the individual or others at risk, or recurrent episodes of serious hypoglycemia (< 54 mg/dL) may benefit from use of continuous interstitial glucose monitoring devices and automated insulin delivery devices if ongoing management using self-monitoring and insulin administration regimens to optimize care has not resulted in adequate glycemic control.

A common clinical indicator of adequate blood sugar control is glycosylated hemoglobin, also known as hemoglobin A1c, or HbA1c. The ADA (2025) has stated that an appropriate target for HbA1c concentrations for many nonpregnant adults with diabetes is 7% or lower. They also state that more stringent HbA1c goals (such as < 6.5% [< 48 mmol/mol]) may be appropriate "for selected individuals if they can be achieved without significant hypoglycemia, excessive weight gain, negative impacts on well-being, or undue burden of care or in those who have nonglycemic factors that decrease A1C (e.g., lower erythrocyte life span)." They also add, "Lower goals may also be appropriate during the honeymoon phase." For children with type 2 diabetes and a low risk of hypoglycemia, they state that an HbA1c goal of 6.5% (< 48 mmol/mol) should be considered. For those with a higher risk of hypoglycemia HbA1c goals should be individualized. Similarly, a goal of 6.5% (< 48 mmol/mol) is ideal in pregnant individuals when safe to achieve.

When the use of multiple daily insulin injection therapy does not provide adequate control of blood sugar levels, an insulin pump may be recommended. These devices are worn externally with insulin infused subcutaneously through a catheter placed under the skin of the abdomen. The pumps can administer insulin at a set (basal) rate and provide injections (bolus) as needed. The pump typically has a syringe reservoir that has a 2- to 3-day insulin capacity. The purpose of the insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve intensive glucose control.

Whether an individual with diabetes uses injection therapy or an insulin pump, the individual needs to check blood glucose concentrations multiple times a day to make sure they are staying within normal blood glucose range. As with injection therapy, self-monitoring blood glucose management may be insufficient. In such circumstances, the use of a CGM may be warranted. These devices measure glucose concentrations in the fluid in between the body's cells, also known as interstitial fluid. They are designed to provide real-time glucose measurements, which have been found to accurately reflect blood glucose levels.

Automated Insulin Delivery Devices

Automated insulin delivery systems combine an insulin pump and CGM, either as separate devices or as a device that incorporates both functions. These devices may be called "open-loop," "hybrid closed-loop," or "closed-loop." These terms refer to how the devices interact with each other, as well as how the individual interacts with them.

Open-loop Devices

Open-loop devices require the intervention of the individual being treated to manage the insulin administration by setting a basal rate and initiating prandial bolus dosing. Most open-loop devices require self-monitoring of blood glucose concentrations as well. Open-loop devices may include a low glucose suspend feature that temporarily stops insulin delivery for a set period of time when the CGM device detects that glucose concentrations have reached a pre-set lower threshold. Some open-loop devices may go a step further and involve a "predictive" low glucose suspend feature, also known as a "threshold suspend" feature. This feature uses a predictive algorithm to determine when glucose concentrations are headed towards a pre-set lower threshold and then decreases or suspends insulin delivery before the threshold is reached.

Multiple well-designed and conducted studies addressing the use of open-loop threshold suspend-type devices have been published and demonstrated a significant benefit to individuals who utilized threshold suspend-type devices, with significant reduction in severe hypoglycemic events (Agrawal, 2015; Bergenstal, 2013; Forlenza, 2019; Gómez, 2017; Ly, 2013.

Hybrid Closed-Loop Devices

Hybrid closed-loop devices eliminate the requirement of routine manual adjustment of pump administration rates, with the insulin pump and CGM devices working together to predict and calculate insulin dose requirements. However, these types of devices still require manual calculation and administration of pre-meal insulin bolus doses, hence the "hybrid" moniker. Self-monitoring of blood glucose concentrations is not typically requires with these types of devices.

Hybrid closed-loop systems can increase, decrease, or stop insulin delivery automatically beyond pre-set infusion rates in response glucose concentration measurements from a paired CGM device. Most available devices have two modes, Manual and Automatic. In Manual mode, the device operates in a similar fashion to a low glucose suspend threshold device, stopping insulin delivery in response to low glucose measurements by the CGM. In Automatic mode, the device can automatically adjust basal insulin infusion rates to increase, decrease, or suspend delivery based on CGM data. In either mode, the user must manually deliver prandial insulin. The critical difference between threshold suspend-type devices and the hybrid closed-loop system is the ability to automatically vary basal insulin infusion rates based on CGM data.

Similar to open-loop devices, there have been multiple high quality studies demonstrating significant clinical outcomes benefit from the use of hybrid closed-loop devices (Bergenstal, 2016; Breton, 2020 and 2021; Brown, 2019 and 2021; Collyns, 2021; Edd, 2023; Ekhlaspour, 2019; Forlenza, 2018; Garg, 2017; Isganaitis, 2021; Kanapka, 2021; Kudva, 2024; McAuley, 2020; Messer, 2018 and 2021; Nimri, 2017; Pihoker, 2023; Renard, 2023; Sherr, 2020; van Beers, 2017). These studies demonstrate a significant incremental benefit of automated hybrid closed-loop control of insulin administration compared to other treatment methods. Additionally, expert clinical opinion supports the use of these devices in light of the potential significant benefits available to the most at-risk individuals with type 1 diabetes.

Pasquel (2025) published the results of a prospective cohort study involving the use of the Omnipod 5 hybrid closed-loop device for the treatment of insulin-dependent individuals with type 2 diabetes and a HbA1c between 7% and 12%. Concomitant use of antihyperglycemic and weight loss medications we allowed. The study involved 203 adults, 289 of which completed the 13-week trial period. There was no control group and no blinding or investigators or participants. The authors reported that HbA1c decreased by mean of 0.8 percentage points, from 8.2% at baseline to 7.4% at treatment phase end ($p<0.001$ for noninferiority and superiority). A greater decrease in HbA1c was associated with a higher baseline HbA1c level. TIR increased from a mean of 45% at baseline to 66% at 13 weeks, or an additional 4.8 h/d in target range ($p<0.001$). No significant differences in time in hypo- or hyperglycemic ranges were found. There were no serious adverse device effects reported. Given the lack of a control group, blinding, and other factors the generalizability of these results is limited. Furthermore, given the additional attention the received by participants due to study procedures the relatively modest change in A1C may have been as much a result of that attention as opposed to due to the use of the CGM.

Closed-Loop Devices

Finally, "closed-loop" systems are available that require no intervention by the treated individual when under normal operating conditions. On May 23, 2023, the FDA granted the first 510K clearance to a fully closed-loop device, the Beta Bionics iLet ACE Pump and Dosing Decision Software for people 6 years of age and older with type 1 diabetes. The Bionic Pancreas Research Group published a series of articles in 2022 from the Clinical Trial Registry NCT04200313 reporting on the clinical outcomes of the iLet system in both pediatric and adult populations with type 1 diabetes. The study populations reported in these publications may have overlap.

Their first publication (Russell, 2022) described the results of a randomized controlled trial (RCT) enrolling subjects with type 1 diabetes aged 6 to 79 years and using insulin for at least 1 year. Subjects who were 18 years of age or older were randomly assigned in a 2:2:1 fashion to use the iLet system with insulin aspart or insulin lispro (bionic-pancreas group), the iLet system with fast-acting insulin aspart, or standard-care insulin delivery plus use of the unblinded Dexcom G6 CGM (standard care group). Subjects 6 to 17 years of age were randomly assigned in a 2:1 fashion to the bionic-pancreas group or the standard-care group. Overall, 219 subjects were included in the bionic-pancreas group and 107 in the standard care group. Baseline HbA1c levels ranged from 5.5 to 13.1%. The trial period was 13 weeks. The primary outcome measure, mean HbA1c at 13 weeks, was reported to have decreased from 7.9% at baseline to 7.3% in the bionic-pancreas group at 13 weeks. No change was reported in the standard-care group (7.7% at both time points, $p<0.001$ between groups). The percentage of time glucose levels were below 54 mg/dL was found to be noninferior in the bionic-pancreas group vs. the standard-care group. The between-group difference in the percentage of time spent in target range was 11 percentage points better in the bionic-pancreas group ($p<0.001$). Percentage of time spent below 70 mg/dL did not differ significantly between the two groups ($p=0.51$). Mean adjusted difference in HbA1c levels at 13 weeks was similar in the adult and pediatric cohorts. A total of 244 adverse events were reported in 126 subjects in the bionic-pancreas group and 10 in 8 subjects in the standard-care group. These included 214 episodes of hyperglycemia with or without ketosis in the bionic-pancreas group and 2 episodes in the standard-care group. Nearly all the events in the bionic-pancreas group were attributed to infusion-set failure. Two children in the bionic-pancreas group received insulin glargine due to prolonged periods of hyperglycemia despite the bionic pancreas administering the maximum amount of insulin allowed by its algorithms. The authors reported that the use of the bionic pancreas was associated with a greater reduction in HbA1c vs. standard care in this study cohort.

Lynch (2022) reported the results of an extension study involving 90 of the 107 standard care group subjects from the Russell study who used the iLet system for 13 weeks following the end of the previous trial. There were 42 subjects in the adult cohort and 48 in the pediatric cohort. Ninety-three percent of subjects completed the study. HbA1c was reported to have decreased from 7.7% to 7.1% (p<0.001) and similar in the adult and pediatric cohorts. Improvement in HbA1c of > 0.5% was achieved by 46% of participants. The percentage achieving an HbA1c level < 7.0% increased from 26% to 39% (p=0.02) and < 7.5 from 38% to 72% (p<0.001). Mean time in range increased from 53% to 65% (p<0.001). Two severe hypoglycemia events were reported in 1 adult subject who also experienced two such events during the RCT while using multiple daily injection therapy. Neither event was related to a device malfunction. A single pediatric participant developed diabetic ketoacidosis associated with infusion set failure. This study demonstrated significant improvement in diabetes-related outcomes in this cohort with the use of the iLet system.

Messer (2022) reported the results of an RCT involving 165 subjects with type 1 diabetes aged 6-17 years and using insulin for at least 1 year who were randomly assigned in a 2:1 fashion to using the iLet system (n=112) or their standard treatment regimen plus a CGM device, if not already used (n=53). Mean HbA1c decreased from 8.1 to 7.5% at 13 weeks in the iLet group and was unchanged at 7.8% in the standard care group (p<0.001). Fifty-one percent of the iLet group vs. 8% of the standard care group had improved HbA1c by > 0.5% (p<0.001). In the subgroup of subjects with baseline HbA1c > 9%, the treatment effect more significant, with mean measures in the iLet group decreasing from 9.7% at baseline to 7.9% at 13 weeks vs. 9.7% to 9.8% in the standard care group. Over 13 weeks, mean time in range was increased by 10% and mean CGM-measured glucose concentrations were reduced by 15 mg/dL on average in the iLet group vs. the standard care group (p<0.001). Statistically significant differences favoring the iLet group also were reported with regard to time > 180 mg/dL, time > 250 mg/dL, and mean glucose SD (p<0.001 for all). No between-group differences were reported with regard to the incidence of hypoglycemia (p=0.24). However, baseline rates of hypoglycemia were low (0.2% in the iLet group and 0.22% in the standard group). Mean total daily insulin dose was not significantly different between groups. Three severe hypoglycemia events were reported in the iLet group (2.7% of 112 participants) and one in the standard care group (1.9% of 53 participants). No cases of diabetic ketoacidosis were reported. Most adverse events were related to hyperglycemia with or without ketosis and were attributable to infusion set failure.

Kruger (2022) reported the results of an RCT involving 161 adult subjects with type 1 diabetes and using insulin for at least 1 year randomized in a 2:1 fashion to use the iLet system with insulin aspart or insulin lispro (n=107) or their standard care (n=54) and followed for 13 weeks. The study was completed by 104 (97%) iLet-group subjects and all of the standard-care group subjects. Mean HbA1c decreased from 7.6% to 7.1% in the iLet group and from 7.6% to 7.5% in the standard care group (p<0.001 between groups). HbA1c improved by > 0.5% in 43% of the iLet-group subjects vs. 17% of the standard-care group subjects (p<0.001) and by > 1.0% in 23% vs. 4% of subjects, respectively (p=0.009). For subjects with baseline HbA1c > 8.0% (n=55), mean HbA1c decreased from 8.9% to 7.4% at 13 weeks in the iLet group vs. from 8.8% to 8.3% in the standard-care group (p<0.001). Mean time in range was increased by 11% and mean CGM-assessed glucose was reduced by 16 mg/dL in the iLet group vs. the standard-care group (p<0.001). Mean time > 180 mg/dL and > 250 ng/dL were all significantly better in the iLet group vs. standard-care group (p<0.001 for both). No significant differences between groups were reported for time < 70 mg/dL or < 54 Mg/dL (p=0.51 and p=0.33, respectively). A total of 7 severe hypoglycemia events occurred in 7 iLet group subjects (6.5%) and 2 events in 1 subject in the standard-care group (1.9%). The rates of severe hypoglycemia were 25.5 and 14.2 per 100 person-years, respectively (p=0.40).

Beck (2022) reported on an RCT involving 275 adults with type 1 diabetes and using insulin for at least 1 year who were randomized on a 2:2:1 basis to treatment with the iLet system with fast acting insulin aspart (n=114), the iLet system with standard insulin (n=107), or standard care (n=54). Mean HbA1c decreased from 7.8% to 7.1% at 13 weeks in the fast-insulin group vs. 7.6% to 7.5% in the standard-care group (p<0.001). Mean time in range, time > 180 mg/dL, and time > 250 mg/dL were significantly in favor of the fast-insulin group (p<0.001 for all). No difference was noted with regard to time < 70 mg/dL. No significant differences were noted between the fast and standard glucose groups with regard to mean glucose concentration or time < 70 mg/dL. However, time in range was significantly better in the fast-insulin group (p=0.0005). There were three severe hypoglycemia events in 3 fast-insulin group subjects (2.6%), two events in 1 participant in the standard-care group (1.9%), and seven events in 7 standard-insulin group subjects (6.5%), with no significant differences noted between groups (p=0.83 fast insulin vs. standard of care and fast insulin vs. standard insulin p=0.20). Two fast-insulin subjects experienced one diabetic ketoacidosis event caused by an infusion set failure. There were no such events in the standard insulin or standard care groups.

The body of evidence to-date for the iLet closed-loop automated insulin dosing system demonstrates significant improvements in HbA1c measures, as well as time in range and time below < 180 mg/dL when compared to other methods of glucose control, including multiple daily injections, sensor-augmented pump therapy and use of hybrid closed-loop devices.

Other closed-loop systems are under investigation, but have not yet received FDA approval or clearance.

Forlenza (2016) published the results of a small RCT involving 14 subjects randomized to treatment with either closed-loop treatment with the Medtronic ePID (external physiological insulin delivery) 2.0 controller vs. MDI therapy with blinded CGM (n=7 in each group) for a 72-hour period. The results indicated that mean serum glucose values were significantly lower in the closed-loop group vs. the controls (111 mg/dL vs. 130 mg/dL, p=0.003). This was achieved without increased risk of hypoglycemia, as demonstrated by the percentage of time < 70 mg/dL being lower in the closed-loop group vs. controls (1.9% vs. 4.8%, p=0.46). While the authors concluded that their results suggest that closed-loop therapy is superior to conventional therapy in maintaining euglycemia without increased hypoglycemia, additional investigation is warranted in larger studies.

Thabit (2017) reported on an RCT involving 40 adult subjects with type 2 diabetes assigned to a 72-hour treatment period with the closed-loop Florence D2W-T2 automated system or standard of care with subcutaneous insulin therapy. The Florence D2W-T2 is composed of a tablet computer-based control algorithm linked to an Abbott Freestyle Navigator II CGM and a Sooil DANA R Diabecare insulin pump. In this study, the proportion of time spent in target range was significantly higher in the closed-loop group vs. the control group (59.8% vs. 38.1%, p=0.004). The proportion of time spent with glucose concentrations > 10.0 mmol/L was significantly lower in the closed-loop group vs. controls (30.1 vs. 49.1, p=0.011). No significant differences between groups were reported for mean glucose concentrations or time spent with glucose concentrations below target range. Glucose variability was significantly reduced in the Florence group vs. controls (coefficient of variation [CV], 27.9 vs. 33.4, p=0.042), and nocturnal time spent within range was significantly greater in the Florence group as well (68.9% vs. 48.8%, p=0.007). No episodes of severe hypo- or hyperglycemia with ketonemia occurred in either group. As with the previously described study, these results are promising, but additional investigation involving larger studies is needed.

Brown (2017) reported on the results of a randomized crossover study involving 40 subjects with type 1 diabetes comparing the use of a hybrid closed-loop device (Roche Accu-Chek Spirit Combo connected to either a DexCom G4 Platinum or AP Share CGM) vs. a closed-loop system (Diabetes Assistant [DiAs] portable artificial pancreas platform, which connected the pumps and CGM devices wirelessly to a smartphone running the DiAs algorithm) to evaluate performance in controlling overnight glycemic control. Subjects were evaluated in 5 consecutive day periods wearing either device. The closed-loop evaluations were conducted at either a hotel or study center and the control trials were done at the subjects' usual environment. The primary endpoint of time in the target range improved in closed-loop trials vs. the pump trials (mean=78.3% vs. 71.4%; p=0.003) when measured for 24 hours during the study period. The time in the target range was also improved in the overnight hours (23:00 to 07:00) in closed-loop trials vs. the pump trials (85.7% vs. 67.6%; p<0.001). Mean overnight glucose concentrations were significantly lower during the closed-loop trials vs. the pump trials (137.2 vs 154.9 mg/dL; p<0.001). Mean glucose concentrations upon awakening were closer to the algorithm target of 120 mg/dL in the closed-loop trials vs. pump trials (123.7 vs. 145.3 mg/dL; p<0.001). The time spent in range during both overnight and during the 24-hour observation periods was significantly better in the closed-loop trials vs. the pump trials (p=0.002 and p<0.001, respectively), likewise, the time spent in the hyperglycemic range (< 180 mg/dL) was significantly less in the closed-loop trials (p<0.001). No instances of ketoacidosis or hypoglycemia requiring outside intervention were reported. The DiAs system is not currently approved or cleared by the FDA and not commercially available in the U.S., and No rigorously designed and conducted studies of the DiAs system outside the investigational setting have been published.

An RCT involving 136 hospitalized subjects with type 2 diabetes aged 18 years and older in noncritical care was described by Bally in 2018. Subjects were assigned to either standard care with manual blood glucose monitoring and conventional subcutaneous insulin therapy (n=66) or treatment with an experimental closed-loop system (n=70). The system used a Dana Diabecare insulin pump, Abbott Freestyle Navigator II CGM, and a proprietary control algorithm run on a tablet computer. The mean percentage of time that the sensor glucose measurement was in the target range of 100-180 mg/dL was reported to be 65.8% in the closed-loop group vs. 41.5% in the control group (p<0.001). Values above the target range were reported in 23.6% and 49.5% of subjects, respectively (p<0.001). The mean glucose level was 154 mg/dL in the closed-loop group vs. 188 mg/dL (p<0.001). No significant between-group differences were reported with regard to the duration of hypoglycemia or daily insulin usage. Finally, no episode of severe hypoglycemia or clinically significant hyperglycemia with ketonemia occurred in either group. As with the DiAs system, this system is not currently approved or cleared by the FDA and not commercially available in the U.S. and no rigorously designed and conducted studies outside the investigational setting have been published.

The results of the studies addressing the *non-iLet* devices demonstrate significant benefits. However, the utility of other closed-loop devices remain unclear. Until these devices have received FDA approval or clearance and are available on the market in the U.S. their use is limited to the research setting.

*FDA Authorized/Approved/Cleared Devices**

Device Name	Type	Notes	FDA Links
Beta Bionics iLet®	Closed-loop	Adults and children ages 6 years and older	https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220916.pdf
CamDiab CamAPS FX	Closed-loop mobile application for use with compatible devices	Adults and children age two years and older with type 1 diabetes. Works with mylife YpsoPump, DANA Diabecare RS, and DANA-i insulin pumps; and the Dexcom G6 and FreeStyle Libre 3 CGMs	https://www.accessdata.fda.gov/cdrh_docs/reviews/K232603.pdf
DEKA Loop	Hybrid closed-loop interoperable automated glycemic controller software for use with compatible devices	Type 1 diabetes in individuals six years and older. Works with the DEKA ACE Pump and Dexcom G6 and FreeStyle Libre 2 CGM devices	https://www.accessdata.fda.gov/cdrh_docs/pdf23/K234055.pdf
Insulet SmartAdjust Technology	Hybrid closed-loop interoperable automated glycemic controller software for	Type 1 diabetes in individuals two years and older and type 2 diabetes in	https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203774.pdf

	use with compatible devices	individuals 18 years and older. Works with the Omnipod 5 pump and Dexcom G6 and FreeStyle Libre 2 CGM devices	
Medtronic MiniMed Paradigm Real Time System	Open-loop device with a threshold suspend feature	Adults and children ages 7 years and older	https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150019A.pdf
Medtronic MiniMed 530G	Open-loop device with a threshold suspend feature	Adults and children ages 16 years and older *May also be used as a stand-alone insulin pump* device when not paired with CGM sensor and transmitter devices	https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120010A.pdf
Medtronic MiniMed 630G	Open-loop device with a threshold suspend feature	Adults and children ages 16 years and older May also be used as a stand-alone insulin pump device when not paired with CGM sensor and transmitter devices	https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150001A.pdf
Medtronic MiniMed 670G	Hybrid closed-loop system	Adults and children ages 14 years and older	https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017A.pdf
MiniMed 770G	Hybrid closed-loop system	Adults and children ages 2 years and older	https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017S076A.pdf
MiniMed 780G	Hybrid closed-loop system	Adults and children ages 7 years and older	https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017S091A.pdf
Tandem t:slim X2	Hybrid closed-loop	Adults and children	https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180008A.pdf

	system	ages 2 years and older	
Tidepool Loop (also known as the Twiist AID System)	Hybrid closed-loop interoperable automated glycemic controller software for use with compatible devices	Type 1 diabetes in individuals six years and older. Works with the Tidepool Twiist pump and Dexcom G6 CGM device	https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203689.pdf

* This may not be an all-inclusive list. Additional CGM devices may be FDA approved and available in the U.S.

Other Information

There are other automated insulin delivery devices under development which attempt to more fully mimic the action of the pancreas through the administration of both insulin and glucagon. Such devices have been referred to as a *bionic pancreases* or *dual-hormone artificial pancreases.* To date, no devices of this type have received FDA approval or clearance, and they are not addressed in this document.

Specialty Medical Society Recommendations

The ADA Standards of Medical Care in Diabetes-2025 has recommendations regarding the use of continuous glucose monitoring. These recommendations state:

> 6.3a An A1C goal of <7% (<53 mmol/mol) is appropriate for many nonpregnant adults without severe hypoglycemia or frequent hypoglycemia affecting health or quality of life. **A**
> 7.3 The type(s) and selection of devices should be individualized based on a person's specific needs, preferences, and skill level. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., a young child or a person with cognitive impairment or dexterity, psychosocial, and/or physical limitations), the caregiver's skills and preferences are integral to the decision-making process. **E**
> 7.4 When prescribing a device, ensure that people with diabetes and caregivers receive initial and ongoing education and training, either in person or remotely, and ongoing evaluation of technique, results, and the ability to utilize data, including uploading/sharing data (if applicable), to monitor and adjust therapy. **C**
> 7.6 People with diabetes who have been using CGM, continuous subcutaneous insulin infusion (CSII), and/or automated insulin delivery (AID) for diabetes management should have continued access across third-party payers, regardless of age or A1C levels. **E**
> 7.8 Recommend early initiation, including at diagnosis, of CGM, CSII, and AID depending on a person's or caregiver's needs and preferences. **C**
> 7.26 AID systems should be the preferred insulin delivery method to improve glycemic outcomes and reduce hypoglycemia and disparities in youth and adults with type 1 diabetes **A** and other types of insulin-deficient diabetes **E** who are capable of using the device (either by themselves or with a caregiver). Choice of an AID system should be made based on the individual's circumstances, preferences, and needs. **A**
> 14.7 Advise frequent glucose monitoring before, during, and after exercise, via blood glucose meter or continuous glucose monitoring (CGM), to prevent, detect, and treat hypoglycemia and hyperglycemia associated with exercise. **C**
> 14.20 Automated insulin delivery (AID) systems should be offered for diabetes management to youth with type 1 diabetes who are capable of using the device safely (either by themselves or with caregivers). The choice of device should be made based on the individual's and family's circumstances, desires, and needs. **A**
> 14.23 A1C goals must be individualized and reassessed over time. An A1C of <7% (<53 mmol/mol) is appropriate for many children and adolescents. **B**
> 14.24 Less stringent A1C goals (such as <7.5% [<58 mmol/mol]) may be appropriate for youth who cannot articulate symptoms of hypoglycemia; have hypoglycemia unawareness; lack advanced insulin delivery technology and/or CGM; cannot check blood glucose regularly; or have nonglycemic factors that increase A1C (e.g., high glycators). **B**
> 14.25 Even less stringent A1C goals (such as <8% [<64 mmol/mol]) may be appropriate for individuals with a history of severe hypoglycemia, limited life expectancy, or where the harms of treatment are greater than the benefits. **B**
> 14.26 Health care professionals may reasonably suggest more stringent A1C goals (such as <6.5% [<48 mmol/mol]) for selected individuals if they can be achieved without significant hypoglycemia, excessive weight gain, negative impacts on well-being, or undue burden of care or in those who have nonglycemic factors that decrease A1C (e.g., lower erythrocyte life span). Lower goals may also be appropriate during the honeymoon phase. **B**

In 2022, the American Association of Clinical Endocrinology (AACE) published clinical practice guidelines addressing the use of advanced technology in the management of persons with diabetes mellitus (Grunberger, 2021). Their recommendations in that document include the following:

> R2.2.1 The AGP may be utilized to assess glycemic status in persons with diabetes. Grade B; Low Strength of Evidence; BEL 1
> R2.2.2 When using the AGP, a systematic approach to interpret CGM data is recommended:
>
> 1. Review overall glycemic status (eg, GMI, average glucose)
> 2. Check TBR, TIR, and TAR statistics, focusing on hypoglycemia (TBR) first. If the TBR statistics are above the cut-point for the clinical scenario (ie, for most with T1D >4% <70 mg/dL; >1% <54 mg/dL), the visit should focus on this issue. Otherwise, move on to the TIR and TAR statistics.
> 3. Review the 24-hour glucose profile to identify the time(s) and magnitude(s) of the problem identified.
> 4. Review treatment regimen and adjust as needed.
>   Grade B; Low Strength of Evidence; BEL 1
>
> R2.9.2 AID systems are strongly recommended for all persons with T1D, since their use has been shown to increase TIR, especially in the overnight period, without causing an increased risk of hypoglycemia. Given the improvement in TIR and the reduction in hyperglycemia with AID, this method of insulin delivery is preferred above other modalities. For persons with diabetes with suboptimal glycemia, significant glycemic variability, impaired hypoglycemia awareness, or who allow for permissive hyperglycemia due to the fear of hypoglycemia, such AID systems should be considered. Grade A; High Strength of Evidence; BEL 1

Definitions

Automated insulin delivery systems: A device that combines the functions of an external insulin pump and a CGM device to create a device that attempts to mimic normal physiological functioning, but requires some intervention by the user. Such devices control the majority of insulin administration tasks, such as measuring blood glucose concentrations and calculation and management of insulin administration. As noted above, there are several categories of this type of device: open-loop systems and hybrid closed-loop systems.

Automated insulin dosing system: Devices similar to automated insulin delivery systems, but do not require daily intervention by the user. See closed-loop systems below.

Closed-loop systems: A type of automated insulin delivery device consisting of an external insulin infusion pump device, a CGM device, and possibly a third device that acts as a controller for the system. This type of system is able to increase, decrease or stop insulin delivery automatically beyond pre-set infusion rates in response to glucose concentration measurements taken by the CGM. Individuals using this type of device do not need to calculate and adjust infusion rates to compensate for prandial boluses, and little to no input is needed by the individual during normal functioning.

Continuous interstitial glucose monitoring (CGM) device: A device applied to the skin that contains a sensor implanted into the skin to measure glucose concentrations in the interstitial fluid. Such devices may be used to create a record of glucose concentrations over time to allow analysis by a medical professional. They may also measure and provide real-time glucose concentration data to allow an individual or automated insulin delivery system to adjust insulin delivery rates to provide better control of blood glucose concentrations.

External insulin infusion pumps: A device that is worn externally and attached to a temporary subcutaneous insulin catheter. An integrated computer controls a pump mechanism that administers insulin at a set rate or provide bolus injections as needed.

Flash CGM: A type of CGM device that requires the use of a device access glucose data from a sensor on a per-need basis. Glucose concentration data is not continuously visible with this type of device.

Glycemic: Having to do with blood sugar (glucose) levels.

Glycemic control: The ability of an individual’s body to control blood glucose concentrations within a specific physiologic range, either on its own or with the assistance of medical therapy.

Glycosylated hemoglobin (HbA1c) test: A laboratory test that provides the percentage of a specific type of modified hemoglobin in the blood. This test ascertains the level of diabetic blood glucose control over the past three to four months.

Hybrid closed-loop systems: A type of automated insulin delivery device consisting of an external insulin infusion pump device and a CGM device. This type of system is able to increase, decrease or stop insulin delivery automatically beyond pre-set infusion rates in response glucose concentration measurements taken by the CGM. Individuals using this type of device need to calculate and adjust infusion rates for prandial boluses.

Hyperglycemia: A condition characterized by excessively high blood glucose concentrations, generally considered greater than 200 mg/dL one to two hours following a meal in individuals with diabetes.

Hypoglycemia: In patients with diabetes, defined as an episode of an abnormally low plasma glucose concentration (with or without symptoms) that expose the individual to harm. Serious hypoglycemia is generally considered a blood glucose level less than 54 mg/dL.

Interstitial glucose: Glucose present in the fluid present in spaces between the tissue cells of the body.

Low glucose suspend feature: A function of an automated insulin delivery system that uses the data from a CGM to detect when blood glucose concentrations pass below a pre-set threshold. When that occurs, the pump function temporarily stops insulin delivery with the goal of avoiding or shortening hypoglycemic events.

Open-loop system: A type of automated insulin delivery system that integrates an external insulin pump and CGM device. This type of device requires manual adjustment of insulin administration rates based on CGM data, as well as manual calculation and administration of pre-meal insulin bolus doses. These types of devices require self-adjustment of the basal insulin infusion rate and most require a blood glucose measurement to confirm CGM data.

Predictive low glucose management (PLGM): A feature of some CGM systems that uses a computer algorithm to monitor blood glucose concentration trend data to predict when concentrations will be approaching the preset low threshold and decrease or stop insulin administration to avoid hypoglycemic events.

Real time CGM: A type of CGM device that provides real-time, continuously visible glucose concentration data to the user.

Type 1 diabetes: A condition characterized by the impaired or inability of the pancreas to produce insulin. Sometimes known as ‘juvenile diabetes.’

Type 2 diabetes: A condition characterized by a person’s body losing the ability to use insulin properly, a problem referred to as insulin resistance.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	02/20/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised “<” symbol to “less than” in MN statement. Revised Discussion, References, and Websites sections.

Reviewed	08/08/2024	MPTAC review. Revised Discussion, References, and Websites sections.
	04/30/2024	Added note to Description section regarding requests for insulin pumps alone.
Revised	02/15/2024	MPTAC review. Removed criteria related to HbA1c range. Revised criteria related to blood glucose concentrations and self-monitoring. Revised Discussion, Definitions, References, and Websites sections.
New	11/09/2023	MPTAC review. Initial document development. Moved content related to automated insulin delivery system from CG-DME-42 Continuous Glucose Monitoring Devices and External Insulin Infusion Pumps.