Artificial pancreas device system

Clinical Policy ID: CCP.1205

Recent review date: 2/2024

Next review date: 6/2025

Policy contains: Continuous glucose monitoring; continuous subcutaneous insulin infusion; nocturnal hypoglycemia; Type 1 diabetes.

Coverage policy

The artificial pancreas device system is clinically proven and, therefore, may be medically necessary in carefully selected members with Type 1 diabetes mellitus when used in accordance with U.S. Food and Drug Administration (2013, 2016a, 2016b) requirements and all of the following criteria are met (American Diabetes Association, 2022; Handelsman, 2015):

- Member requires continuous subcutaneous insulin infusion (insulin pump therapy) and continuous monitoring and trending of their interstitial glucose levels.
- Member has used insulin pump therapy for more than six months.
- Member is at risk of hypoglycemia (e.g., at least two documented events of nocturnal hypoglycemia or hypoglycemia unawareness in a two-week period).
- Member is motivated and knowledgeable in diabetes self-care, including insulin adjustment.
- One of the following U.S. Food and Drug Administration-approved devices is available in states where the device is on the fee schedule:
- MiniMed® 530G with Enlite® Sensor (Medtronic Inc., Northridge, California) for members ages 16 years and older.
- MiniMed® 630G Insulin Pump System with SmartGuard™ technology (Medtronic Inc., Northridge, California) for members ages 16 years and older.

- MiniMed® 670G System with SmartGuard® Hybrid Closed Loop technology (Medtronic Inc., Northridge, California) for members ages 14 years and older.

Limitations

All other uses of an artificial pancreas device system are not medically necessary.

An artificial pancreas device system not U.S. Food and Drug Administration-approved for commercial use is not medically necessary.

The Medtronic MiniMed 670G System is not medically necessary for members under the age of seven years or who require less than a total daily insulin dose of eight units per day because the device requires a minimum of eight units per day to operate safely (U.S. Food and Drug Administration, 2016b).

An artificial pancreas device system is not medically necessary for members with any of the following criteria, including, but not limited to (American Diabetes Association, 2022; Handelsman, 2015; U.S. Food and Drug Administration, 2013, 2016a, 2016b):

- Unwilling or unable to perform a minimum of four blood glucose tests per day.
- Unwilling or unable to maintain contact with their health care professional.
- Pregnancy.
- Vision or hearing does not allow recognition of pump signals and alarms.
- Receiving dialysis.
- In the previous six months, documentation of one or more of the following:
  - Experienced more than one episode of severe hypoglycemia, defined as a hypoglycemic event requiring assistance of another person to actively administer carbohydrates or glucagon, or to take other corrective actions.
  - Hospitalization or a hospital emergency room visit for uncontrolled diabetes.
  - Diabetic ketoacidosis.

Alternative covered services

- Multiple daily injections of insulin.
- Non-disposable external continuous infusion insulin pumps.
- Real-time continuous glucose monitoring.
- Blood glucose self-monitoring (finger stick).

Background

Intensive insulin therapy is an aggressive treatment approach for persons with diabetes who require close monitoring of blood glucose levels and frequent doses of insulin. Innovations in insulin delivery and glucose monitoring are designed to improve glycemic control and quality of life while limiting adverse effects, such as hypoglycemia and weight gain (Seaquist, 2013). These advances include continuous subcutaneous insulin infusion, real-time continuous glucose monitoring and sensor-augmented pumps, which combine real-time continuous glucose monitoring with continuous subcutaneous insulin infusion. Intensive insulin therapy consists of continuous subcutaneous insulin infusion using rapid-acting insulin or multiple daily injections (at least three) along with glucose monitoring. Audible and/or vibratory alarms may be helpful in avoiding severe hypoglycemic events, particularly at night.

Despite these developments, a substantial proportion of individuals with insulin-dependent diabetes cannot achieve adequate glycemic control. Nocturnal hypoglycemia, in particular, may impact one's sense of well-being on the following day because of its impact on sleep quantity and quality (Seaquist, 2013).

An artificial pancreas device system combines a continuous glucose monitoring system, an insulin pump, and a control algorithm to closely mimic the glucose-regulating function of a healthy pancreas. The ideal system would monitor glucose levels in the body and automatically adjust the delivery of insulin to reduce hyperglycemia and minimize hypoglycemia with little or no input from the patient. The U.S. Food and Drug Administration (2018) classifies artificial pancreas device systems as follows:

- The threshold suspend system, also called the low glucose suspend system (product code OZO), reduces the severity of or reverses hypoglycemia by temporarily suspending insulin delivery when the glucose level falls or approaches a low glucose threshold. This system serves as a potential backup when a patient is unable to respond to a hypoglycemic event. Approved devices are the MiniMed 530G and the MiniMed 630G systems (U.S. Food and Drug Administration, 2013, 2016a).
- Insulin-only system (product code OZP) achieves a target glucose level by automatically increasing or decreasing the amount of insulin infused based on specified thresholds of measured glucose levels. The only U.S. Food and Drug Administration-approved system is the MiniMed® 670G Hybrid Closed Loop system (U.S. Food and Drug Administration, 2016b).
- Bi-hormonal control system (product code OZQ) achieves a target glucose level by using two algorithms to instruct an infusion pump to deliver insulin to lower glucose levels and another (e.g., glucagon) to increase blood glucose levels. The bi-hormonal system mimics the glucose-regulating function of a healthy pancreas more closely than an insulin-only system. As of this writing, no products have been approved for commercial use.

The U.S. Food and Drug Administration issued premarket approvals for the MiniMed 530G (P120010) and the MiniMed 630G (P150001) for individuals ages 16 years and older who require insulin as well as continuous monitoring and trending of their interstitial glucose levels. It is intended for continuous delivery of basal insulin (at user-selectable rates) and administration of insulin boluses (in user-selectable amounts). Neither system is intended to be used directly for preventing or treating hypoglycemia; they are intended to suspend insulin delivery when the user is unable to respond to the threshold suspend alarm and indicate when a finger stick may be required.

The U.S. Food and Drug Administration (2016b) approved the MiniMed 670G (P160017) for continuous delivery of basal insulin (at user-selectable rates) and administration of insulin boluses (in user-selectable amounts) for the management of Type 1 diabetes mellitus in persons ages 14 years and older requiring intensive insulin therapy and continuous monitoring and trending of glucose levels in subcutaneous fluid. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by these devices.

Findings

We identified one systematic review, one additional comparative study, two evidence-based guidelines, and no economic analyses for this policy. The evidence is limited to two studies reporting results from the Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial (Bergenstal, 2013; ClinicalTrials.gov identifier NCT01497938; Weiss, 2015). ASPIRE is a multicenter, in-home, randomized study comparing the effect of the Paradigm Veo® pump (marketed in the United States as the MiniMed 530G) with a threshold suspend feature and continuous glucose monitoring to the Paradigm® Revel™ 2.0 pump (Medtronic Inc., Northridge, California) with a continuous glucose monitoring device in persons with Type 1 diabetes. The primary safety outcome was change in glycated hemoglobin levels from the beginning to the end of the trial. The primary outcome measure was the area under the sensor glucose concentration time curve for nocturnal hypoglycemic events.

Compared with a sensor-augmented pump only, preliminary results suggest the threshold suspend feature reduces both the frequency and overall burden of hypoglycemia without raising glycated hemoglobin and nocturnal hypoglycemia when patients fail to respond (Bergenstal, 2013; Weiss, 2015). However, a critical appraisal of the studies found several limitations (Blue Cross Blue Shield Association Technology Evaluation Center, 2014):

- The studies included only patients with Type 1 diabetes who were hypoglycemia-prone with two hypoglycemic episodes in the two-week run-in phase but not too ill (i.e., not recently hospitalized or treated in emergency department), thus limiting the generalizability of the results.
- The study had a short follow-up and was underpowered to detect differences in clinical hypoglycemic events, such as severe hypoglycemia.
- Although the threshold suspend was initially set at 70 mg/dL, it could have been changed subsequently to be set between 70 mg/dL and 90 mg/dL. The investigators did not mention whether such differences in thresholds were taken into account in the analyses. The impact of the artificial pancreas with threshold suspend feature would also vary with the percentage of time it is worn.
- There was only a 5 mg/dL difference between initiation of the threshold suspend and reaching a hypoglycemic level (70 mg/dL versus 65 mg/dL). It is unclear how the threshold suspend feature would reduce hypoglycemic episodes.
- It is unclear whether subjects consumed food or glucose during the four hours after suspending insulin delivery.
- The area under the sensor glucose concentration time curve used to measure nocturnal hypoglycemia events combines the duration of hypoglycemia and its severity. This measure is not an indicator used in clinical practice, and it may magnify the effect of an individual dimension used in its calculation (e.g., duration and glucose levels). This study reported differences between study arms in glucose levels below 70 mg/dL, but it did not directly compare the time in hypoglycemia between the two groups.

A search of the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database (2023) retrieved more than 500 adverse events associated with the MiniMed 530G system and 46 adverse events associated with the MiniMed 530G with the Enlite Sensor. In its approval of the MiniMed 530G system, the U.S. Food and Drug Administration (2013) listed several contraindications to use:

- Persons unwilling or unable to perform a minimum of four blood glucose tests per day.
- Persons unwilling or unable to maintain contact with their health care professional.
- Persons whose vision or hearing does not allow recognition of pump signals and alarms.
- The Enlite Serter should not be used on products other than the Enlite Sensor. Medtronic cannot guarantee this product's safety or efficacy if used on other products.

The American Association of Clinical Endocrinologists/American College of Endocrinology recommends sensor-augmented continuous subcutaneous insulin infusion, including those with a threshold suspend function, for patients with Type 1 diabetes and patients with Type 2 diabetes who are insulin dependent and at risk of hypoglycemia (Handelsman, 2015). The American Diabetes Association (2022) recommends a sensor-augmented, low glucose threshold suspend pump for patients with frequent nocturnal hypoglycemia and/or hypoglycemia unawareness. Both organizations base their recommendations on the results of the ASPIRE trial and recognize that the threshold suspend feature is an important advancement toward an automatic or semiautomatic closed-loop insulin delivery device.

Adding the threshold suspend feature is a small but important incremental step toward developing a full artificial pancreas device system. Although the results of this single trial are generally favorable, the study has limitations. Medtronic Inc. is conducting a post-approval trial (ClinicalTrials.gov identifier NCT02003898) and a trial of the MiniMed 530G in pediatric populations ages 7 to 15 years (ClinicalTrials.gov identifier NCT02120794). While the results of these studies are needed to confirm the device's safety and efficacy before widespread clinical use, it may benefit some persons who are insulin dependent with frequent nocturnal hypoglycemia and/or hypoglycemia unawareness.

In 2017, the U.S. Food and Drug Administration issued premarket approval to two Medtronic devices: the Medtronic MiniMed 670G System and the MiniMed 630G System. As with the MiniMed 530G, the continuous glucose monitoring component is intended to indicate when a finger stick measurement should be taken, and is not the basis of manual insulin therapy adjustments. Both systems require a prescription (U.S. Food and Drug Administration, 2016a, 2016b).

Greater reliance on automation of blood glucose measurement and insulin delivery, particularly in pediatric populations, requires clearly established safety and efficacy data before incorporating this device into advanced diabetes care. Studies of the MiniMed 670G in children ages 7 to 15 years (ClinicalTrials.gov identifier: NCT02660827) and in persons ages 7 to 75 years (ClinicalTrials.gov identifier: NCT02748018) are ongoing. Therefore, no policy changes are warranted at this time.

In 2018, we identified one new systematic review (Weisman, 2017), one guideline update (from the American Diabetes Association), one small study of the MiniMed 670G in pregnant women (Stewart, 2016), and three trial publications of the MiniMed 670G from the same investigator group (Bergenstal, 2016; Cordero, 2017; Garg, 2017) for this policy. The MiniMed 670G is a safe alternative to conventional pump therapy, improves time in target glycemic range, and reduces glycated hemoglobin, hyperglycemia, and hypoglycemia in adolescent and adult populations with Type 1 diabetes.

Individuals with and without continuous glucose monitoring experience can benefit from this device. Closed-loop systems may have advantages over sensor-augmented pump therapy in specific populations, such as pregnant women with Type 1 diabetes and those with a history of nocturnal hypoglycemia (American Diabetes Association, 2022; Stewart, 2016). However, the U.S. Food and Drug Administration has not approved any of these devices for use in pregnant women. Consequently, the policy is revised to include the MiniMed 630G and 670G as medically necessary in carefully selected non-pregnant patients with Type 1 diabetes.

In 2019, we updated the latest guideline from the American Diabetes Association and added a systematic review and meta-analysis (Bekiari, 2018), with no changes to the policy. The policy ID was changed from CP# 08.02.07 to CCP.1205.

In 2020, we updated the latest guideline from the American Diabetes Association. We also added two studies of the Medtronic MiniMed 670G in participants with Type 1 diabetes that demonstrated the feasibility and safety of a new algorithmic enhancement (de Bock, 2018) and cost effectiveness (Jendle, 2019) compared to continuous subcutaneous insulin infusion from the Swedish perspective at a willingness-to-pay threshold of SEK 300,000 per quality-adjusted life year gained. We added one systematic review (Munoz-Velandia, 2019) of eight quantitative and 11 qualitative studies of patient values and preferences of continuous subcutaneous insulin infusion or artificial pancreas treatment that may inform choice of delivery system in adults with Type 1 diabetes. The key driver of patients' preferences was glycemic control, followed by reductions in glycemic variability, hypoglycemic episodes, and chronic complications, and components of treatment burden (e.g., device size, appearance, and cost, ease of use, and the embarrassment of public use). The new findings warrant no changes to the policy.

In 2021, we updated the American Diabetes Association's latest guideline and added one systematic review (Asarani, 2021) to the policy. Both references address the increasing use of "do-it-yourself" artificial pancreas systems among individuals with Type 1 diabetes. These systems automate insulin delivery with existing, commercially-available pumps and real-time continuous glucose monitoring combined with open-source algorithms. The results of a systematic review (Asarani, 2021) of 10 low-quality studies (n = 730 participants) suggest improvements in time in range, HbA1c, hypoglycemia, and quality of life with the use of do-it-yourself systems, but the results need to be confirmed in well-designed randomized trials. The U.S. Food and Drug Administration has not yet approved these systems. No policy changes are warranted.

In 2022, we updated the American Diabetes Association's latest guideline (2021). We also added a systematic review/meta-analysis of six randomized controlled trials that compared time in range between fully closed-loop systems and standard of care during physical exercise in 266 people with type 1 diabetes. Time in range was higher in favor of closed-loop systems, especially among children and adolescents (Eckstein, 2021). We also included a randomized trial (n = 36) that found closed-loop automated insulin delivery (artificial pancreas) improves glucose control compared with sensor-augmented pump therapy, confirming the conclusions of eight other trials since 2015 (Haidar, 2021).

In 2023, we updated the American Diabetes Association's latest guideline (2022). We also added

- A systematic review/meta-analysis of 12 randomized trials found closed-loop insulin delivery was superior in blood glucose control than insulin sensor-augmented pump delivery. Metrics included average blood glucose value ($P = .003$); time in range ($P < .00001$); low blood glucose index ($P < .00001$), high blood glucose index ($P < .00001$), and adverse effects ($P = .001$) (Fang, 2022).
- A systematic review/meta-analysis of 25 studies (n = 504), compared closed-loop artificial pancreas systems with continuous subcutaneous insulin infusion in persons with diabetes <18 years of age. Results in the closed loop group were superior (higher percent of time spent in the target glycemic range, lower percent of time in hyperglycemia/hypoglycemia, and lower mean glucose (Karageorgiou, 2019).
- A review of 123,355 users of the MIniMed 670G system in 2017-2020, > 7 years, with >10 days of treatment, found significant improvements (versus pre-auto mode initiation), including a decrease in mean glucose management indicator ($P < .001$), an increase in time spent in target range ($P < .001$), and decreases in time spent above or below target range ($P < .001$, $P = .002$) (Arunachalum, 2023).

In 2024, we added a guideline that supported use of closed-loop systems for persons with type 1 diabetes (National Institute for Health and Care Excellence, 2023). We also added large reviews of persons with type 1 diabetes, including:

- A systematic review/meta-analysis of 41 studies of outpatients documented superior outcomes after treatment with artificial pancreas versus conventional insulin therapy, for higher time in the target range in overnight use and lower time in the hypoglycemic range ($P < .00001$) (Kang, 2022).
- A meta-analysis of 11 studies (n = 570) of adolescents showed superior control of blood glucose for closed-loop systems, compared to sensor-augmented pumps (Jabari, 2023).
- A systematic review of 30 papers on children, adolescents, and young adults concluded the MiniMed 670G system improved metrics up to one year after treatment, but improvements are not as great as in advanced hybrid closed loop systems (Mameli, 2023).
- A systematic review/meta-analysis of 26 randomized trials of children and adolescents (n = 915) found automated insulin delivery systems were superior to controls (insulin pump therapy, sensor-augmented pumps, and multiple daily injections) in proportion of time in the target glucose range ($P < .00001$), hypoglycemia ($P = .003$), and mean proportion of HbA1C ($P = .0007$) (Michou, 2023).

References

On November 3, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "pancreas, artificial" (MeSH), "Islets of Langerhans Transplantation" (MeSH), and the free-text terms "bionic pancreas" and "artificial pancreas. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

11/2015: initial review date and clinical policy effective date: 4/2016

2/2017: Policy references updated.

2/2018: Policy references updated. Policy coverage modified.

2/2019: Policy references updated. Policy ID changed.

2/2020: Policy references updated.

2/2021: Policy references updated.

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