**Clinical Policy Title: Artificial pancreas device system**

Clinical Policy Number: 08.02.07

**Effective Date:** April 1, 2016  
**Initial Review Date:** November 18, 2015  
**Most Recent Review Date:** February 6, 2018  
**Next Review Date:** February 2019

**Related policies:**
- CP# 06.02.05 Insulin infusion therapy (insulin pumps)  
- CP# 06.02.02 Outpatient diabetes self-management training  
- CP# 06.02.03 Continuous interstitial glucose monitoring  
- CP# 08.02.06 Pancreas transplantation

**ABOUT THIS POLICY:** AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

**Coverage policy**

AmeriHealth Caritas considers artificial pancreas device systems to be clinically proven and, therefore, medically necessary in carefully selected members with type 1 diabetes mellitus when used in accordance with U.S. Food and Drug Administration (FDA) requirements and the following criteria are met (American Diabetes Association [ADA], 2018; FDA, 2016a and 2016b; Handelsman, 2015; FDA, 2013):

- 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 FDA-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 FDA-approved for commercial use is not medically necessary.

The Medtronic MiniMed 670G System is not medically necessary for members under the age of 7 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 (FDA, 2016b).

An artificial pancreas device system is not medically necessary for members with any of the following criteria, including, but not limited to (ADA, 2018; FDA, 2016a and 2016b; Handelsman, 2015; FDA, 2013):
  • 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.
• Nondisposable external continuous infusion insulin pumps.
• Real-time continuous glucose monitoring.
• Blood glucose self-monitoring (finger stick).

Background
In 2015, 23.1 million people had diagnosed diabetes (7.2 percent of the U.S. population) of whom approximately 1.15 million had diagnosed type 1 diabetes (Centers for Disease Control and Prevention [CDC], 2017). 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).

**Artificial pancreas device systems:**

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 FDA (2017) 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. FDA-approved devices are the MiniMed 530G and the MiniMed 630G systems (FDA, 2016a; FDA, 2013).
- **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 FDA-approved system is the MiniMed® 670G System (FDA, 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 FDA 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 FDA 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 (FDA, 2016b). All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by these devices.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on December 18, 2017. Search terms were: “pancreas, artificial” (MeSH), “Islets of Langerhans Transplantation” (MeSH), and the free-text terms “bionic pancreas” and “artificial pancreas.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

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 (clinicaltrials.gov identifier NCT01497938; Weiss, 2015; Bergenstal, 2013). 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 (Weiss, 2015; Bergenstal, 2013). 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 hypoglycemic-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 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 FDA Manufacturer and User Facility Device Experience database 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 FDA listed several contraindications to use (FDA, 2013):

- 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 (2015, updated 2018) 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.

Policy updates:

In 2016, the FDA 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 (FDA, 2016).

While the MiniMed 670G represents a technical refinement of the existing artificial pancreas device system, to date the published evidence is insufficient to support its clinical use (Hayes, 2016). 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 (ADA, 2018), 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 (Cordero, 2017; Garg, 2017; Bergenstal, 2016) 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 (ADA, 2018; Stewart, 2016). However, the FDA 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.

### Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Cordero (2017)</strong>&lt;br&gt;The effect of prior continuous glucose monitoring use on glycemic outcomes in the pivotal trial of the MiniMed 670G hybrid closed-loop system&lt;br&gt;Clinicaltrials.gov: NCT02463097</td>
<td><strong>Key points:</strong>&lt;br&gt;- A three-month pivotal trial comparing the outcomes using the MiniMed 670G in 78 individuals with prior continuous glucose monitoring experience to those of 46 with no prior experience.&lt;br&gt;- Compared to baseline, both experienced and naïve patients had increased sensor glucose values in target range (71 to 180 mg/dL), reduced glycated hemoglobin levels, and no events of diabetic ketoacidosis or severe hypoglycemia.&lt;br&gt;- There were no between-group differences with respect to outcomes.</td>
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<td><strong>Garg (2017) and Bergenstal (2016)</strong>&lt;br&gt;Glucose outcomes with the in-home use of a hybrid closed-loop insulin delivery system in adolescents and adults with type 1 diabetes&lt;br&gt;Clinicaltrials.gov identifier: NCT02463097</td>
<td><strong>Key points:</strong>&lt;br&gt;- Multicenter pivotal trial of 30 adolescents (ages 14 to 21 years) and 94 adults (ages 22 to 75 years) with type 1 diabetes using the MiniMed 670G system during a two-week run-in phase without hybrid closed loop control, or Auto Mode, enabled (Manual Mode) and, thereafter, with Auto Mode enabled during a three-month study phase. A supervised hotel stay (six days and five nights) that included a 24-hour frequent blood sample testing with a reference measurement (i-STAT) occurred during the study phase.&lt;br&gt;- MiniMed 670G therapy was safe during in-home use by adolescents and adults. There were no severe hypoglycemic or diabetic ketoacidosis events in either cohort; 28 device-related hyperglycemic events occurred that were resolved at home.&lt;br&gt;- Compared to baseline, the study phase demonstrated statistically significant increases in time in target and reductions in glycaated hemoglobin, hyperglycemia, and hypoglycemia (P &lt; 0.001).</td>
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<td><strong>Weisman (2017)</strong>&lt;br&gt;Effect of artificial pancreas systems on glycemic control in patients with type 1 diabetes</td>
<td><strong>Key points:</strong>&lt;br&gt;- Systematic review and meta-analysis of 27 comparisons from 24 randomized controlled trials comparing artificial pancreas systems (insulin only or insulin plus glucagon) with conventional pump therapy (continuous subcutaneous insulin infusion with blinded continuous glucose monitoring or unblended sensor-augmented pump therapy) in outpatient settings. Studies included 219 participants in adult studies, 265 in pediatric studies, and 101 in combined studies.&lt;br&gt;- Overall quality: low to moderate with unclear bias across most studies.&lt;br&gt;- Time of blood glucose in target range was significantly higher with dual hormone and artificial pancreas systems than conventional pump therapy and single hormone systems, despite heterogeneous clinical and technical factors.</td>
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<td><strong>Stewart (2016)</strong>&lt;br&gt;An open-label, randomized, crossover study of 16 pregnant women comparing overnight closed-loop therapy with sensor-augmented pump therapy for four weeks.</td>
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</table>
Closed-loop insulin delivery during pregnancy in women with type 1 diabetes

- The percentage of time that overnight glucose levels were in the target range was higher during closed-loop therapy than during control therapy (74.7% vs 59.5%; absolute difference, 15.2 percentage points; 95% confidence interval, 6.1 to 24.2; \( P = 0.002 \)).
- The overnight mean glucose level was lower during closed-loop therapy than during control therapy (119 vs 133 mg per deciliter [6.6 vs 7.4 mmol per liter], \( P = 0.009 \)).
- There were no significant differences between closed-loop and control therapy in the percentage of time in which glucose levels were below the target range (1.3% and 1.9%, respectively; \( P = 0.28 \)), in insulin doses, or in adverse-event rates.
- No episodes of severe hypoglycemia requiring third-party assistance occurred during either study phase.

Weiss (2015)

- Secondary analysis of ASPIRE trial

Key points:

- Effects of threshold suspend versus sensor-augmented pump only on nocturnal hypoglycemia in relation to baseline glycated hemoglobin and change in glycated hemoglobin during study.
- Threshold suspend feature significantly decreased the rate and severity (as measured by area under the sensor glucose concentration time curve) of nocturnal hypoglycemia events in many subjects, including those with low baseline glycated hemoglobin levels and those whose glycated hemoglobin values decreased during the study period.
- Threshold suspend feature may help protect against hypoglycemia in those wishing to intensify diabetes management to achieve target glucose levels.

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the services or items subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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### ICD-10 Code

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<td>S1036</td>
<td>Transmitter, external for use with APDS</td>
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<td>S1037</td>
<td>Receiver (monitor); external for use with APDS</td>
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