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MEDICAL POLICY – 1.01.30

Artificial Pancreas Device Systems

BCBSA Ref. Policy:	1.01.30	
Effective Date:	Oct. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Sept. 9, 2024	7.03.02 Allogeneic Pancreas Transplant
Replaces:	N/A	7.03.12 Islet Transplantation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

An artificial pancreas device system combines a glucose monitor and an insulin infusion pump. The goal is to try to match how a normal pancreas would work. The pancreas releases insulin based on changing levels of glucose in the blood. In this system, insulin is either withheld or released based on the blood glucose level shown on the monitor. For those with type 1 diabetes, these systems may help improve overall glycemic control. They can be especially helpful in controlling episodes of very low blood sugar at night. This policy discusses when an artificial pancreas device system may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Medical Necessity
Artificial pancreas device system with low glucose suspend feature	**Use of a US Food and Drug Administration (FDA) cleared or approved automated insulin delivery system (artificial pancreas device system) with a low glucose suspend feature may be considered medically necessary in individuals with type 1 diabetes who meet ALL of the following criteria:** • An individual aged 6 years and older • Glycated hemoglobin (hemoglobin A1c) level between 5.8% and 10.0% • Used insulin pump therapy for more than 6 months • At least two documented nocturnal hypoglycemic events in a two-week period (see **definition** below)
Hybrid closed loop insulin delivery system with low glucose suspend and suspend before low features	**Use of an FDA cleared or approved automated insulin delivery system (artificial pancreas device system) designated as a hybrid closed-loop insulin delivery system (with low glucose suspend and suspend before low features) may be considered medically necessary in individuals with type 1 diabetes who meet ALL of the following criteria:** • An individual aged 6 years and older • Glycated hemoglobin (hemoglobin A1c) level between 5.8% and 10.0% • Used insulin pump therapy for more than 6 months • At least two documented nocturnal hypoglycemic events in a two-week period **OR** • Individuals aged 2 to 6 years • Clinical diagnosis of type 1 diabetes for 3 months or more • Used insulin pump therapy for more than 3 months • Glycated hemoglobin (hemoglobin A1c) level < 10.0% • Minimum daily insulin requirement (total daily dose) of ≥ to 8 units.
Closed-loop insulin delivery system	**Use of an FDA cleared or approved automated insulin delivery system (artificial pancreas device system) designated as a closed-loop insulin delivery system may be considered medically necessary in individuals with type 1 diabetes who meet all of the following criteria:** • An individual aged 6 years and older • Clinical diagnosis of type 1 diabetes for 12 months or more

Device	Medical Necessity
	• Using insulin for at least 12 months • Diabetes managed using the same regimen (either insulin pump or multiple daily injection, with or without continuous glucose monitoring) for 3 months or longer.

Device	Investigational
Automated insulin delivery system	**Use of an automated insulin delivery system (artificial pancreas device system) is considered investigational for individuals who do not meet the above criteria.** **Use of an automated insulin delivery system (artificial pancreas device system) not cleared or approved by the FDA is considered investigational.**

Documentation Requirements
The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of: • Diagnosis/condition and age • History and physical examination documenting the severity of the condition • Hemoglobin A1c (glycated hemoglobin) results • History of insulin pump usage • Documentation of nighttime hypoglycemia events • Total daily dose of insulin, if applicable

Coding

Code	Description
HCPCS	
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system, 1 unit = 1 day supply

Code	Description
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Consideration of Age

The ages stated in this policy for which the artificial pancreas system may be considered medically necessary are based on the US Food and Drug Administration approved indications for the device.

Evidence Review

Description

Automated insulin delivery systems, also known as artificial pancreas device systems, link a glucose monitor to an insulin infusion pump that automatically takes action (e.g., suspends or adjusts insulin infusion) based on the glucose monitor reading. These devices are proposed to improve glycemic control in individuals with insulin-dependent diabetes, in particular, reduction of nocturnal hypoglycemia.

Background

Diabetes and Glycemic Control

Tight glucose control in individuals with diabetes has been associated with improved health outcomes. The American Diabetes Association (ADA) has recommended a glycated hemoglobin level below 7% for most individuals. However, hypoglycemia may place a limit on the ability to

achieve tighter glycemic control. Hypoglycemic events in adults range from mild to severe based on a number of factors including the glucose nadir, the presence of symptoms, and whether the episode can be self-treated or requires help for recovery. Children and adolescents represent a population of individuals with type 1 diabetes who have challenges in controlling hyperglycemia and avoiding hypoglycemia. Hypoglycemia is the most common acute complication of type 1 diabetes (T1D).

Table 1 is a summary of selected clinical outcomes in T1D clinical management and research.

Table 1. Outcome Measures for Type 1 Diabetes

Measure	Definition	Guideline type	Organization	Date
Hypoglycemia		Stakeholder survey, expert opinion with evidence review	Type 1 Diabetes Outcome Program[a1]	2017
Level 1 Level 2 Level 3	Glucose <70mg/ dL but≥54 mg/ dL Glucose <54 mg/ dL Event characterized by altered mental/physical status requiring assistance			
Hypoglycemia	Same as Type 1 Diabetes Outcome Program[a]	Professional Practice Committee with systematic literature review	ADA[2]	2019
Hypoglycemia Clinical alert for evaluation and/or treatment Clinically important or serious Severe hypoglycemia	 Glucose <70mg/dL Glucose <54 mg/dL Severe cognitive impairment requiring external assistance by another person to take corrective action	Clinical Practice Consensus	ISPAD[3]	2018
Hyperglycemia Level 1	 Glucose >180 mg/dL and ≤250 mg/dL		Type 1 Diabetes Outcome Program[a4]	2017

Measure	Definition	Guideline type	Organization	Date
Level 2	Glucose >250 mg/dL			
Time in Range[b]	Percentage of glucose readings in the range of 70 to 180 mg/dL per unit of time		Type 1 Diabetes Outcome Program[a]	2017
Diabetic ketoacidosis (DKA)	Elevated serum or urine ketones > ULN Serum bicarbonate <15 mEq/L Blood pH <7.3		Type 1 Diabetes Outcome Program[a2]	2017

ADA: American Diabetes Association, ISPAD: International Society for Pediatric and Adolescent Diabetes; ULN: upper limit of normal.

[a] Steering Committee: representatives from American Association of Clinical Endocrinologists (AACE), American Association Diabetes Educators, the American Diabetes Association (ADA), the Endocrine Society, Juvenile Diabetes Research Foundation (JDRF) International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, T1D Exchange.

[b] Time in range: has also been adopted by researchers evaluating the precision and effectiveness of emerging glucose monitoring and automated insulin delivery technologies.

Hypoglycemia

Persons with type 1 diabetes are especially prone to develop hypoglycemia. Alterations in the counterregulatory hormonal responses inherent in the disease, variable patient adherence, and iatrogenic hypoglycemia caused by aggressive prevention of hyperglycemia are responsible for this propensity. Hypoglycemia affects many aspects of cognitive function, including attention, memory, psychomotor and spatial ability. Severe hypoglycemia can cause serious morbidity affecting the central nervous system (e.g., coma, seizure, transient ischemic attack, stroke), heart (e.g., cardiac arrhythmia, myocardial ischemia, infarction), eye (e.g., vitreous hemorrhage, worsening of retinopathy), as well as cause hypothermia and accidents that may lead to injury. Fear of having hypoglycemia symptoms can also cause decreased motivation to adhere strictly to intensive insulin treatment regimens.

The definition of a hypoglycemic episode is not standardized. In the pivotal Automation to Simulate Pancreatic Insulin Response randomized controlled trial, a nocturnal hypoglycemic episode was defined as a sensor glucose value of 65 mg/dL or less between 10 PM and 8 AM for more than 20 consecutive minutes in the absence of a pump interaction within 20 minutes. In 2017, the ADA defined serious, clinically significant hypoglycemia as glucose levels <54 mg/dL, and a glucose alert value as a glucose ≤70 mg/dL. These definitions were based on recommendations from the International Hypoglycaemia Study Group.[1]

Treatment

Type 1 diabetes is caused by the destruction of the pancreatic beta cells which produce insulin, and the necessary mainstay of treatment is insulin injections. Multiple studies have shown that intensive insulin treatment, aimed at tightly controlling blood glucose, reduces the risk of long-term complications of diabetes, such as retinopathy and renal disease. Optimal glycemic control, as assessed by glycated hemoglobin, and avoidance of hyper- and hypoglycemic excursions have been shown to prevent diabetes-related complications. Currently, insulin treatment strategies include either multiple daily insulin injections or continuous subcutaneous insulin infusion with an insulin pump.

Restoration of pancreatic function is potentially available through islet cell or allogeneic pancreas transplantation. (See **Related Policies**)

The US Food and Drug Administration (FDA) describes the basic design of an artificial pancreas device system (APDS) as a continuous glucose monitoring (CGM) linked to an insulin pump with the capability to automatically stop, reduce, or increase insulin infusion based on specified thresholds of measured interstitial glucose.[5]

The APDS components are designed to communicate with each other to automate the process of maintaining blood glucose concentrations at or near a specified range or target and to minimize the incidence and severity of hypoglycemic and hyperglycemic events. An APDS control algorithm is embedded in software in an external processor or controller that receives information from the CGM and performs a series of mathematical calculations. Based on these calculations, the controller sends dosing instructions to the infusion pump.

Threshold Suspend Device System

Different APDS types are currently available for clinical use. Sensor augmented pump therapy (SAPT) with low glucose suspend (LGS) (suspend on low) may reduce the likelihood or severity of a hypoglycemic event by suspending insulin delivery temporarily when the sensor value reaches (reactive) a predetermined lower threshold of measured interstitial glucose. LGS automatically suspends basal insulin delivery for up to two hours in response to sensor-detected hypoglycemia.

A sensor augmented pump therapy with predictive low glucose management (PLGM) (suspend before low) suspends basal insulin infusion with the prediction of hypoglycemia. Basal insulin infusion is suspended when sensor glucose is at or within 70 mg/dL above the patient-set low

limit and is predicted to be 20 mg/dL above this low limit in 30 minutes. In the absence of an individual response, the insulin infusion resumes after a maximum suspend period of two hours. In certain circumstances, auto-resumption parameters may be used.

When a sensor value is above or predicted to remain above the threshold, the infusion pump will not take any action based on CGM readings. Individuals using this system still need to monitor their blood glucose concentration, set appropriate basal rates for their insulin pump, and give premeal bolus insulin to control their glucose levels.

Control-to-Range System

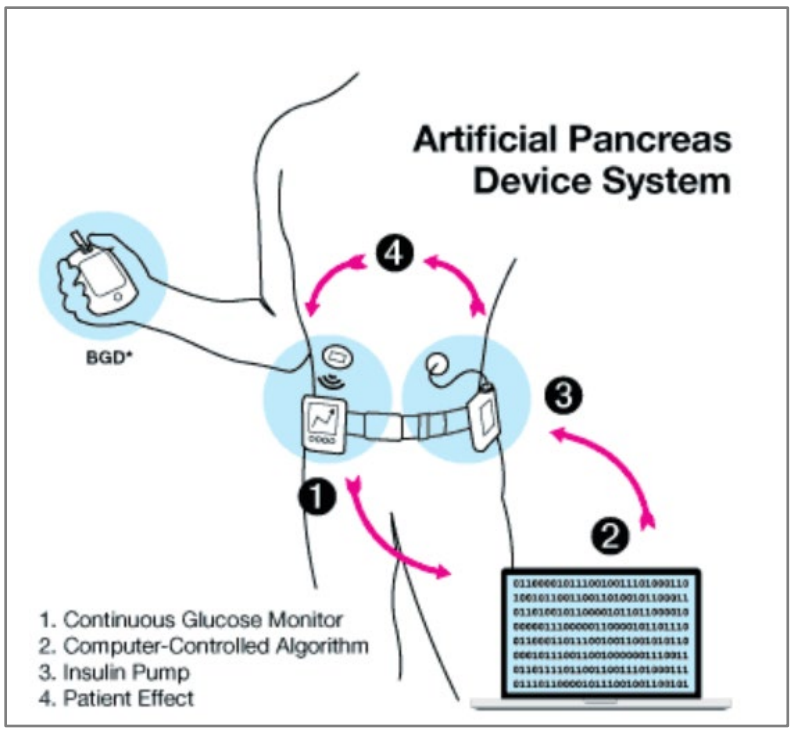
A control-to-range system reduces the likelihood or severity of a hypoglycemic or hyperglycemic event by adjusting insulin dosing only if a person's glucose levels reach or approach predetermined higher and lower thresholds. When an individual's glucose concentration is within the specified range, the infusion pump will not take any action based upon CGM readings. Individuals using this system still need to monitor their blood glucose concentration, set appropriate basal rates for their insulin pump, and give premeal bolus insulin to control their glucose levels.

Control-to-Target System

A control-to-target system sets target glucose levels and tries to maintain these levels at all times. This system is fully automated and requires no interaction from the user (except for calibration of the CGM). There are two subtypes of control-to-target systems: insulin-only and bihormonal (e.g., glucagon). There are no systems administering glucagon marketed in the United States.

An APDS may also be referred to as a “closed-loop” system. A closed-loop system has automated insulin delivery and continuous glucose sensing and insulin delivery without individual intervention. The systems utilize a control algorithm that autonomously and continually increases and decreases the subcutaneous insulin delivery based on real-time sensor glucose levels.

A hybrid closed-loop system also uses automated insulin delivery with continuous basal insulin delivery adjustments. However, at mealtime, the individual enters the number of carbohydrates they are eating in order for the insulin pump to determine the bolus meal dose of insulin. A hybrid system option with the individual administration of a premeal or partial premeal insulin bolus can be used in either control-to-range or control-to-target systems.



Source: **https://www.fda.gov/medical-devices/artificial-pancreas-device-system/what-pancreas-what-artificial-pancreas-device-system** Accessed August 16, 2024.

These systems are regulated by the FDA as class III device systems.

Summary of Evidence

Low-Glucose Suspend Device

For individuals who have T1D who receive an artificial pancreas device system with a low glucose suspend feature, the evidence includes three randomized controlled trials (RCTs) conducted in home settings. The relevant outcomes are symptoms, change in disease status, morbid events, resource utilization and treatment-related morbidity. Primary eligibility criteria of the key RCT, the Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial, were ages 16-to-70 years old, T1D, glycated hemoglobin levels between 5.8% and 10.0%, and at least two nocturnal hypoglycemic events (≤65 mg/dL) lasting more than 20 minutes during a 2-week run-in phase. Both trials required at least six months of insulin pump use. Both RCTs reported significantly less hypoglycemia in the treatment group than in the control group. In both trials, primary outcomes were favorable for the group using an artificial pancreas system; however, findings from one trial were limited by nonstandard reporting of hypoglycemic episodes, and findings from the other trial were no longer statistically significant when two outliers (children)

were excluded from analysis. The RCT limited to adults showed an improvement in the primary outcome (area under the curve for nocturnal hypoglycemic events). The area under the curve is not used for assessment in clinical practice but the current technology does allow user and provider review of similar trend data with CGM. Results from the ASPIRE study suggested that there were increased risks of hyperglycemia and potential diabetic ketoacidosis in subjects using the threshold suspend feature. This finding may be related to whether or not actions are taken by the user to assess glycemic status, the etiology of the low glucose reading (activity, diet or medication) or to resume insulin infusion. Both retrospective and prospective observational studies have reported reductions in rates and severity of hypoglycemic episodes in automated insulin delivery system users. The evidence suggests that the magnitude of reduction for hypoglycemic events in the T1D population is likely to be clinically significant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Hybrid Closed-Loop Insulin Delivery System

For individuals who have T1D who receive an artificial pancreas device system with a hybrid closed-loop insulin delivery system, the evidence includes multicenter pivotal trials using devices cleared by the US Food and Drug Administration, supplemental data and analysis for expanded indications, and more recent studies focused on children and adolescents. Three crossover RCTs using a similar first-generation device approved outside the US have been reported. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Of these three crossover RCTs, two found significantly better outcomes (i.e., time spent in nocturnal hypoglycemia and time spent in preferred glycemic range) with the device than with standard care. The third study had mixed findings (significant difference in time spent in nocturnal hypoglycemia and no significant difference in time spent in preferred glycemic range). Additional evidence from device performance studies and clinical studies all demonstrated reductions in time spent in various levels of hypoglycemia, improved time in range (70-180mg/dl), rare diabetic ketoacidosis and few device-related adverse events. The evidence suggests that the magnitude of reduction for hypoglycemic events in the T1D population is likely to be clinically significant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have T1D who receive an artificial pancreas device system with a closed-loop insulin delivery system, the evidence includes a 13-week multicenter RCT of the iLet Bionic Pancreas System compared to usual care in 326 individuals ages 6 to 79 years with T1D. Comparator group participants continued their pre-study subcutaneous insulin delivery (either

multiple daily injections, an insulin pump without automation of insulin delivery, an insulin pump with predictive low glucose suspend feature, or an insulin pump as part of an HCL system) plus real-time CGM. The glycated hemoglobin level decreased from 7.9% to 7.3% in the closed-loop insulin delivery system group and did not change (7.7% at both time points) in the standard-care group (mean adjusted difference at 13 weeks, −0.5%; 95%CI −0.6 to −0.3; p <0.001). The rate of severe hypoglycemia was 17.7 events per 100 participant-years in the closed-loop insulin delivery system group and 10.8 events per 100 participant-years in the standard-care group (p = 0.39). No episodes of diabetic ketoacidosis occurred in either group. The trial's results for the subgroups of adults (ages 18 and older) and youth (ages 6 to 17 years) have additionally been reported and were similar to the main results for the full cohort. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 2**.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02748018[a]	Multi-center, Randomized, Parallel, Adaptive, Controlled Trial in Adult and Pediatric Patients With Type 1 Diabetes Using Hybrid Closed Loop System and Control (CSII, MDI, and SAP) at Home	280	Sep 2024
Unpublished			
NCT03774186	Pregnancy Intervention With a Closed-Loop System (PICLS) Study	24	Mar 2022
NCT04269668[a]	An Open-label, Two-center, Randomized, Cross-over Study to Evaluate the Safety and Efficacy of Glycemic Control Using Hybrid-closed Loop vs. Advanced Hybrid Closed-loop in Young Subjects With Type 1 Diabetes	28	Mar 2021
NCT03739099	Assessment of the Efficacy of Closed-loop Insulin Therapy (Artificial Pancreas) on the Control of Type 1 Diabetes in	122	May 2023

	Prepubertal Child in Free-life: Comparison Between Nocturnal and 24-hour Use on 18 Weeks, Followed by an Extension on 18 Weeks		

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2019 Input

Clinical input supported that the outcome of hypoglycemia prevention provides a clinically meaningful improvement in net health outcome, and this use is consistent with generally accepted medical practice. Clinical input also supported that the use of hybrid closed loop artificial pancreas device systems provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Reduction in the experience of hypoglycemia and inappropriate awareness of hypoglycemia and glycemic excursions were identified as important acute clinical outcomes in children, adolescents, and adults and are related to the future risk for end-organ complications.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Clinical Endocrinologists et al

In 2021, the American Association of Clinical Endocrinologists published a clinical practice guideline for the use of advanced technology in the management of individuals with diabetes.[37] The guideline included the following statements:

"Low-glucose suspend (LGS) is strongly recommended for all persons with T1D to reduce the severity and duration of hypoglycemia, whereas predictive low glucose suspend (PLGS) is strongly recommended for all persons with T1D to mitigate hypoglycemia. Both systems do not lead to a rise in mean glucose, and lead to increased confidence and trust in the technology, more flexibility around mealtimes, and reduced diabetes distress for both persons with diabetes and caregivers. Therefore, anyone with frequent hypoglycemia, impaired hypoglycemia awareness, and those who fear hypoglycemia leading to permissive hyperglycemia should be considered for this method of insulin delivery." Grade A; High Strength of Evidence.

"AID [Automated insulin delivery] systems are strongly recommended for all persons with T1D, since their use has been shown to increase time in target range (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..

American Diabetes Association

The American Diabetes Association (ADA) has released multiple publications on controlling type 1 diabetes (see **Table 3**).

Table 3. American Diabetes Association Recommendations on Controlling Type 1 Diabetes

Date	Title	Publication Type	Recommendation (LOE)
2024	Diabetes Technology:	Guideline standard[38]	Automated insulin delivery systems should be offered for diabetes management to youth and adults with type 1

Date	Title	Publication Type	Recommendation (LOE)
	Standards of Care in Diabetes - 2024		diabetes (A) and other types of insulin deficient diabetes (E) who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs. Insulin pump therapy alone with or without sensor-augmented pump low glucose suspend feature and/or automated insulin delivery systems should be offered for diabetes management to youth and adults on multiple daily injections with type 1 diabetes (A) or other types of insulin-deficient diabetes (E) who are capable of using the device safely (either by themselves or with a caregiver) and are not able to use or do not choose an automated insulin delivery system. The choice of device should be made based on the individual's circumstances, preferences, and needs. (A)
2017	Standardizing Clinically Meaningful Outcome Measures Beyond HbA1c for Type 1 Diabetes	Consensus report[39,a]	Developed definitions for hypoglycemia, hyperglycemia, time in range, and diabetic ketoacidosis in type 1 diabetes (N/A)

HbA1c: hemoglobin A1c; N/A: not applicable.

[a] Jointly published with the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the Endocrine Society, Juvenile Diabetes Research Foundation (JDRF) International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Table 4 summarizes the FDA cleared or approved automated insulin delivery systems.

Table 4. US Food and Drug Administration -Approved Automated Insulin Delivery Systems (Artificial Pancreas Device Systems)

Device	Age Indication	Manufacturer	Date Approved	PMA No./ Device Code
MiniMed 530G System[a] (open-loop, LGS)	≥16 y	Medtronic	Jul 2013	P120010/OZO
MiniMed 630G System with SmartGuard[b] (open-loop, LGS)	≥16 y ≥14 y	Medtronic	Aug 2016 Jun 2017	P150001/OZO P150001/S008
MiniMed 670G System[c] (HCL, LGS or PLGM)	≥14 y ≥7-13 y	Medtronic	Sep 2016 Jul 2018	P160017/OZP P160017/S031
MiniMed 770G System[d] (HCL)[6]	≥2y	Medtronic	Aug 2020	P160017/S076
MiniMed 780G System (HCL)[7]	≥7y	Medtronic	May 2023	P160017/S091
t:slim X2 Insulin Pump with Basal-IQ Technology (LGS)[7]	≥6 y	Tandem	Jun 2018	P180008/OZO, PQF
t:slim X2 Insulin Pump with Control-IQ Technology (HCL)	≥6y	Tandem	Dec 2019	DEN180058/QFG
Omnipod 5 (HCL)	≥6 y	Insulet	Jan 2022	K203768 K203772
iLet Bionic Pancreas (CL)[9]	≥6 y	Beta Bionics	May 2023	K220916 K223846

CL: closed-loop; HCL: hybrid closed-loop; LGS: low glucose suspend; OZO: Artificial Pancreas Device System, threshold suspend; OZP: Automated Insulin Dosing Device System, Single Hormonal Control; PMA: premarket approval; PLGM: predictive low glucose management.

[a]MiniMed 530G System consists of the following devices that can be used in combination or individually: MiniMed 530G Insulin Pump, Enlite Sensor, Enlite Serter, the MiniLink Real-Time System, the Bayer Contour NextLink glucose meter, CareLink Professional Therapy Management Software for Diabetes, and CareLink Personal Therapy Management Software for Diabetes (at time of approval).

[b] MiniMed 630G System with SmartGuard consists of the following devices: MiniMed 630G Insulin Pump, Enlite Sensor, One-Press Serter, Guardian Link Transmitter System, CareLink USB, Bayer's CONTOUR NEXT LINK 2.4 Wireless Meter, and Bayer's CONTOUR NEXT Test Strips (at time of approval).

[c] MiniMed 670G System consists of the following devices: MiniMed 670G Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, and the Contour NEXT Link 2.4 Glucose Meter (at time of approval).

[d]MiniMed 770G System consists of the following devices: MiniMed 770G Insulin Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, the Accu-Chek Guide Link blood glucose meter, and the Accu-Chek Guide Test Strips.

eMiniMed 780G System consists of the following devices: MiniMed 780G Insulin Pump, the Guardian 4 Transmitter, the Guardian 4 Sensor (3), One-Press Serter, the Accu-Chek Guide Link blood glucose meter, and the Accu-Chek Guide Test Strips

The MiniMed 530G System includes a threshold suspend or LGS feature.[10] The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is at or below a preset threshold within the 60- to 90-mg/dL range. When the glucose value reaches this threshold, an alarm sounds. If patients respond to the alarm, they can choose to continue or cancel the insulin suspend feature. If patients fail to respond, the pump automatically suspends action for two hours, and then insulin therapy resumes.

The MiniMed 630G System with SmartGuard, which is similar to the 530G, includes updates to the system components including waterproofing.[11] The threshold suspend feature can be programmed to temporarily suspend delivery of insulin for up to two hours when the sensor glucose value falls below a predefined threshold value. The MiniMed 630G System with SmartGuard is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on the values provided by the MiniMed 630G system. The device is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the SmartGuard Suspend on Low alarm to take measures to prevent or treat hypoglycemia themselves.

The MiniMed 670G System is a hybrid closed-loop insulin delivery system consisting of an insulin pump, a glucose meter, and a transmitter, linked by a proprietary algorithm and the SmartGuard Hybrid Closed Loop.[12] The system includes an LGS feature that suspends insulin delivery; this feature either suspends delivery on low-glucose levels or suspends delivery before low-glucose levels, and has an optional alarm (manual mode). Additionally, the system allows semiautomatic basal insulin-level adjustment (decrease or increase) to preset targets (automatic mode). As a hybrid system; basal insulin levels are automatically adjusted, but the patient needs to administer premeal insulin boluses. The CGM component of the MiniMed 670G System is not intended to be used directly for making manual insulin therapy adjustments; rather it is to provide an indication of when a glucose measurement should be taken. The MiniMed 670G System was originally approved for marketing in the United States on September 28, 2016 (P160017) and received approval for marketing with a pediatric indication (ages 7 to 13 years) on June 21, 2018 (P160017/S031).

The MiniMed 770G System is an iteration of the MiniMed 670G System. In July 2020, the device was approved for use in children ages 2 to 6 years. In addition to the clinical studies that established the safety and effectiveness of the MiniMed 670G System in users ages 7 years and older, the sponsor performed clinical studies of the 670G System in pediatric subjects ages 2 to 6 years. FDA concluded that these studies establish a reasonable assurance of the safety and

effectiveness of the MiniMed 770G System because the underlying therapy in the 670G system, and the associated Guardian Sensor (3), are identical to that of the 770G System.[6]

On June 21, 2018, the FDA approved the t:slim X2 Insulin Pump with Basal-IQ Technology (PMA P180008) for individuals who are six years of age and older.[13] The System consists of the t:slim X2 Insulin Pump paired with the Dexcom G5 Mobile CGM, as well as the Basal-IQ Technology. The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the System as the receiver for a therapeutic CGM. The t:slim X2 Insulin Pump running the Basal-IQ Technology can be used to suspend insulin delivery based on CGM sensor readings.

In December 2019, FDA approved the t:slim X2 Insulin Pump with Control-IQ Technology through the De Novo process.[14] The device uses the same pump hardware as the insulin pump component of the systems approved in t:slim X2 Insulin Pump with Basal-IQ Technology (P180008) and P140015. A custom disposable cartridge is motor-driven to deliver patient programmed basal rates and boluses through an infusion set into subcutaneous tissue.

In 2022, FDA approved the Omnipod 5 ACE Pump for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

In May 2023, FDA approved the first closed-loop system through the 510(k) premarket clearance pathway.[9] Currently, the iLet Bionic Pancreas (Beta Bionics) is the only closed-loop insulin delivery system commercially available in the US The system differs from hybrid closed-loop systems in that it is initialized only with a user's body weight and doses insulin autonomously without carbohydrate counting.[33] The closed-loop insulin delivery system requires only that the user make a qualitative estimate of carbohydrate content that is relative to what is usual for the user ("Usual For Me", "More", or "Less") compared to a typical meal of that type ("Breakfast", "Lunch", or "Dinner"). In response to qualitative meal announcements to the system by the user, the system delivers approximately 75% of the autonomously estimated insulin immediately and then autonomously adjusts insulin dosing post-prandially as needed. Additionally, the device includes a feature which enables continued insulin delivery when CGM information is not available, based on a basal insulin profile autonomously determined and continually updated. Use of this feature, however, is intended to be temporary, with the goal to resume CGM-guided insulin dosing as soon as possible.

The system was developed as both an insulin-only system and a bihormonal system that administers both insulin and glucagon. Currently, only the insulin-only system has FDA clearance.

References

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History

Date	Comments
03/10/15	New Policy. Policy created with information on this topic previously addressed in Policy No. 1.01.522 and a literature review through December 20, 2014. FDA-approved artificial pancreas device system with low glucose suspend feature may be considered medically necessary for patients with type 1 diabetes who meet criteria; otherwise artificial pancreas device systems are considered investigational.
01/12/16	Annual Review. Added Related Policy 1.01.522 Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid. Policy updated with literature review through October 1, 2015; references added. Policy statements unchanged.
04/12/16	Minor update. Removal of related policy 1.01.522, policy was archived on April 30, 2016.
11/08/16	Minor update. Language added to support that this policy applies only to those age 16 and older as indicated by FDA approval for the use of the device.
02/01/17	Annual Review, approved January 10, 2017. Policy updated with literature review through October 4, 2016; references added. Policy statements unchanged.

Date	Comments
04/11/17	Policy moved into new format; no change to policy statements. Evidence Review section reformatted.
02/01/18	Annual Review, approved January 16, 2018. Policy updated with literature review through October 2017; references updated. Policy statement added that use of hybrid closed loop insulin delivery system as an artificial pancreas device system (age 14 and older) is considered investigational.
9/01/18	Minor update. Re-added language supporting that this policy applies to those age 16 and older; it was inadvertently removed in a previous update.
03/01/19	Minor update, added Documentation Requirements section.
07/01/19	Annual Review, approved June 11, 2019. Policy updated with literature review through March 2019, references 1, 3-7, 13, 17, 18, and 20-24 added. Policy statements changed: the age criterion changed in the first medically necessary statement; medically necessary statement added on FDA-approved automated insulin delivery system (artificial pancreas device system) designated as hybrid closed loop insulin delivery system in patients with type 1 diabetes who meet specified criteria; and investigational statement added on use of an automated insulin delivery system (artificial pancreas device system) for individuals who have not met specified criteria.
02/01/20	Annual Review, approved January 9, 2020. Policy updated with literature review through September 2019; references added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
07/02/20	Delete policy.
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. Policy updated with literature review through March 2020; references added Policy statements revised to lower age cutoff to 6 years.
07/01/21	Annual Review, approved June 8, 2021. Policy updated with literature review through March 4, 2021; references added. Added use of an FDA-approved hybrid closed loop system in children ages 2 to 6 years as medically necessary.
09/01/22	Annual Review, approved August 22, 2022. Policy updated with literature review through June 10, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
10/01/23	Annual Review, approved September 12, 2023. Changed the wording from "patient" to "individual" throughout the policy for standardization. Policy updated with literature review through June 7, 2023; references added. New indication and medically necessary policy statement with criteria added for the artificial pancreas device system with a closed-loop insulin delivery system (bionic pancreas) for individuals with type 1 diabetes.
10/01/24	Annual Review, approved September 9, 2024. Policy updated with literature review through May 30, 2024; no references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.