

## Corporate Medical Policy

### Artificial Pancreas Device Systems

**File Name:** artificial\_pancreas\_device\_systems  
**Origination:** 10/2015  
**Last Review:** 6/2024

#### Description of Procedure or Service

---

Tight glucose control in patients with diabetes has been associated with improved health outcomes. The American Diabetes Association recommends a glycated hemoglobin level below 7% for most patients. However, hypoglycemia may place a limit on the ability to achieve tighter glyceemic control. Hypoglycemic events in adults range from mild to severe, based on a number of factors including the glucose nadir, presence of symptoms, and whether the episode can be self-treated or requires help for recovery. Children and adolescents represent a population of type 1 diabetics who have challenges in controlling hyperglycemia and avoiding hypoglycemia. Hypoglycemia is the most common acute complication of type 1 diabetes.

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 glyceemic 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.

The Food and Drug Administration (FDA) describes the basic design of an artificial pancreas device system (APDS) as a 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.

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.

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. Low glucose suspension (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 a patient response, the insulin infusion resumes after a maximum suspend period of two hours. In certain circumstances, auto-resumption parameters may be used.

# Artificial Pancreas Device Systems

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. Patients 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.

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 a patient's glucose concentration is within the specified range, the infusion pump will not take any action based upon CGM readings. Patients 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.

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 (eg, 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 patient 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. There are no completely closed-loop insulin delivery systems marketed in the United States.

A hybrid closed-loop system also uses automated insulin delivery with continuous basal insulin delivery adjustments. However, at mealtime, the patient 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 patient administration of a premeal or partial premeal insulin bolus can be used in either control-to-range or control-to-target systems.

The MiniMed 530G System includes a threshold suspend or low glucose suspend feature. 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 2 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. The threshold suspend feature can be programmed to temporarily suspend delivery of insulin for up to 2 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. The system includes a low glucose suspend 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 continuous glucose monitoring component of the MiniMed 670G System is not intended to be used directly for making manual insulin therapy adjustments; rather

# Artificial Pancreas Device Systems

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.

On June 21, 2018, the FDA approved the t:slim X2 Insulin Pump with Basal-IQ Technology (PMA P180008) for individuals who are 6 years of age and older. The System consists of the t:slim X2 Insulin Pump paired with the Dexcom G5 Mobile Continuous Glucose Monitoring, 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 continuous glucose monitoring. The t:slim X2 Insulin Pump running the Basal-IQ Technology can be used to suspend insulin delivery based on continuous glucose monitoring sensor readings.

In December 2019, FDA approved the t:slim X2 Insulin Pump with Control-IQ Technology through the De Novo process. 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.

## **Related Policies:**

Continuous Monitoring of Glucose in the Interstitial Fluid  
Pancreas Transplant  
Islet Cell Transplantation

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## **Policy**

---

**BCBSNC will provide coverage for an Artificial Pancreas Device System when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.**

## **Benefits Application**

---

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

# Artificial Pancreas Device Systems

## When Artificial Pancreas Device Systems are covered

---

Use of an automated insulin delivery system with a low glucose suspend feature or artificial pancreas device system designated as hybrid closed-loop insulin delivery system (with low glucose suspend and suspend before low features) may be considered medically necessary in patients with type 1 diabetes who meet **ALL** of the following criteria:

- Device is age appropriate per FDA approved indications
- Glycated hemoglobin level above 5.8%
- Used insulin pump therapy for more than 3 months

Use of an 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:

- Age 6 years and older
- Clinical diagnosis of type 1 diabetes for 12 months or more;
- Using insulin for at least 12 months;
- Diabetes managed using the same regimen (either pump or multiple daily injections, with or without continuous glucose monitoring) for 3 months or longer.

## When Artificial Pancreas Device Systems are not covered

---

Use of an artificial pancreas device system is considered investigational in all other situations.

Use of an automated insulin delivery system (artificial pancreas device system) not approved by the FDA is investigational.

The use of d-Nav technology for automated, intermittent glucose monitoring and insulin titration is considered investigational.

## Policy Guidelines

---

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a low-glucose suspend feature, the evidence includes 3 randomized controlled trials (RCTs) conducted in home settings. 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, type 1 diabetes, glycated hemoglobin levels between 5.8% and 10.0%, and at least 2 nocturnal hypoglycemic events ( $\leq 65$  mg/dL) lasting more than 20 minutes during a 2-week run-in phase. Both trials required at least 6 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 1 trial were limited by nonstandard reporting of hypoglycemic episodes, and findings from the other trial were no longer statistically significant when 2 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 continuous glucose monitoring. 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

# Artificial Pancreas Device Systems

of hypoglycemic episodes in automated insulin delivery system users. The evidence suggests that the magnitude of reduction for hypoglycemic events in the type 1 diabetes 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 type 1 diabetes 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 U.S. 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 studied and approved outside the United States have been reported. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Of these 3 crossover RCTs 2 found significantly better outcomes (ie, 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 demonstrate reductions in time spent in various levels of hypoglycemia, improved time in range (70-180 mg/dL), rare diabetic ketoacidosis, and few device-related adverse events. The evidence suggests that the magnitude of reduction for hypoglycemic events in the type 1 diabetes 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 type 1 diabetes 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 type 1 diabetes. 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. 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. 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.

## **Billing/Coding/Physician Documentation Information**

---

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 95250, 95251, A4226, E0787, S1034, S1035, S1036, S1037, 0740T, 0741T*

*Requests for an upgraded device (hybrid closed loop system) must include physician documentation indicating rationale for necessity of the upgrade if the existing device is still under warranty.*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

# Artificial Pancreas Device Systems

## Scientific Background and Reference Sources

---

Food and Drug Administration (FDA). Types of Artificial Pancreas Device Systems. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ArtificialPancreas/ucm259555.htm> . Accessed June 29, 2015.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.30, 1/15/15

American Diabetes A. 7. Approaches to glycemic treatment. *Diabetes Care*. Jan 2016 vol.39 no. Supplement 1 S52-S59. [http://care.diabetesjournals.org/content/39/Supplement\\_1/S52.full](http://care.diabetesjournals.org/content/39/Supplement_1/S52.full). Accessed 12/23/2015.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.30, 11/12/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.30, 11/10/16

American Diabetes Association. 6. Glycemic Targets. *Diabetes Care*. Jan 2017;40(Suppl 1):S48-S56. PMID 27979893

Blue Cross and Blue Shield Technology Evaluation Center (TEC). Artificial Pancreas Device Systems. TEC Assessments. 2013;Volume 28:Tab 14

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.30, 1/11/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.30, 4/8/2019

Brown SA, Kovatchev BP, Raghinaru D et al. Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. *N. Engl. J. Med.* 2019 Oct;381(18). PMID 31618560

Agiostratidou G, Anhalt H, Ball D, et al. Standardizing clinically meaningful outcome measures beyond HbA1c for type 1 diabetes: A Consensus Report of the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange. *Diabetes Care*. Dec 2017;40(12):1622-1630. PMID 29162582

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.30, 4/16/2020

Specialty Matched Consultant Advisory Panel review 06/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.30, 4/8/2021

Specialty Matched Consultant Advisory Panel review 06/2021

Medical Director review 6/2021

Cobry EC, Kanapka LG, Cengiz E, et al. Health-Related Quality of Life and Treatment Satisfaction in Parents and Children with Type 1 Diabetes Using Closed-Loop Control. *Diabetes Technol Ther.* Jan 28 2021. PMID 33404325

Kanapka LG, Wadwa RP, Breton MD, et al. Extended Use of the Control-IQ Closed-Loop Control System in Children With Type 1 Diabetes. *Diabetes Care*. Feb 2021; 44(2): 473-478. PMID 33355258

# Artificial Pancreas Device Systems

Breton MD, Kanapka LG, Beck RW, et al. A Randomized Trial of Closed-Loop Control in Children with Type 1 Diabetes. *N Engl J Med.* Aug 27 2020; 383(9): 836-845. PMID 32846062

Specialty Matched Consultant Advisory Panel review 06/2022

Medical Director review 6/2022

Food & Drug Administration. MiniMed 770G System. Summary of Safety and Effectiveness Data. 2020. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/P160017S076B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017S076B.pdf).

Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 530G System. 2013; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120010>.

Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 630G System with Smartguard. 2016; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=320606>.

Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 670G System. 2016; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160017>.

Food and Drug Administration (FDA). t:slim X2 Insulin Pump with Basal-IQ Technology Premarket Approval (2018). [https://www.accessdata.fda.gov/cdrh\\_docs/pdf18/P180008A.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180008A.pdf).

Faulds ER, Zappe J, Dungan KM. REAL-WORLD IMPLICATIONS OF HYBRID CLOSE LOOP (HCL) INSULIN DELIVERY SYSTEM. *Endocr Pract.* May 2019; 25(5): 477-484. PMID 30865545

Specialty Matched Consultant Advisory Panel review 06/2023

Medical Director review 6/2023

Food and Drug Administration (FDA). Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems [draft]. 2012; <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259305.pdf>.

Food & Drug Administration. 2023. FDA Clears New Insulin Pump and Algorithm-Based Software to Support Enhanced Automatic Insulin Delivery. <https://www.fda.gov/news-events/press-announcements/fda-clears-new-insulin-pump-and-algorithm-based-software-support-enhanced-automatic-insulin-delivery>.

Specialty Matched Consultant Advisory Panel review 06/2024

Medical Director review 6/2024

## Policy Implementation/Update Information

---

- |         |   |
|---------|---|
| 10/1/15 | New policy issued. Use of an FDA-approved artificial pancreas device system with a low glucose suspend feature may be considered medically necessary in patients with type 1 diabetes who meet criteria. (sk) |
| 1/26/16 | References added. Policy Guidelines updated. (sk)   |
| 8/30/16 | Specialty Matched Consultant Panel Review meeting 7/27/2016. No change to policy statement. (an)  |

# Artificial Pancreas Device Systems

- 12/30/16 Revised description section to include information regarding two new artificial pancreas device systems. Coverage statement revised to read: “Use of an FDA-approved artificial pancreas device system with a low glucose suspend feature, with or without semi-automatic adjustment of basal insulin levels, may be considered medically necessary in patients with type 1 diabetes who meet **ALL** of the following criteria...” Policy Guidelines section was updated. The following statement was added to the Billing/Coding section: *Requests for an upgraded device (hybrid closed loop system) must include physician documentation indicating rationale for necessity of the upgrade if the existing device is still under warranty.* (an)
- 8/11/17 Specialty Matched Consultant Advisory Panel review meeting 7/26/2017. (an)
- 3/9/18 Minor editorial revisions in Description section. Moved definition of nocturnal hypoglycemic event from Policy Guidelines section to the When Covered section. Updated Policy Guidelines. References added. No change to coverage criteria. (an)
- 7/27/18 Specialty Matched Consultant Advisory Panel review 6/27/2018. No change to policy statement. (an)
- 7/16/19 Description Section revised to include new devices. Coverage criteria revised to change age from 16 to 14 and definition of nocturnal hypoglycemia removed. Statement added to Non-Covered criteria: Use of an automated insulin delivery system (artificial pancreas device system) not approved by the FDA is investigational. Policy Guidelines updated and reference added. Specialty Matched Consultant Advisory Panel review 6/19/2019. (eel)
- 7/14/20 References added. Added A4226 and E0787 to Coding section. Policy Guideline and Description updated. Specialty Matched Consultant Advisory Panel review 6/17/2020. When covered criteria statement added for coverage of hybrid closed-loop system. (eel)
- 10/27/20 Policy Guideline and Description updated. When covered statement criteria updated to “Device is age appropriate per FDA approved indications.” (eel)
- 11/10/20 Description section regarding FDA approved MiniMed™ 770G Systems changed from “age 2-6 years” to read “ages 2 years and up” for clarification. (bb)
- 7/1/21 References added. Specialty Matched Consultant Advisory Panel review 6/16/2021. Medical Director review. No change to policy statement. (lpr)
- 7/12/22 Related policies added. References added. Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. No change to policy statement. (tt)
- 6/30/23 Description updated regarding FDA approved devices and indications. References added. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. No change to policy statement. (tt)
- 7/17/24 Description and Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 6/2024. Updated When covered to remove requirement for “at least 2 documented nocturnal hypoglycemic events in a 2-week period”, updated requirement for insulin pump therapy from 6 months to 3 months, added medical necessity criteria for closed loop delivery systems, and removed HgbA1c limit of 10% from when covered. Medical Director review 6/2024. (tt)
- 10/1/24 Added the following statement to When Not Covered section, “The use of d-Nav technology for automated, intermittent glucose monitoring and insulin titration is considered investigational.” Updated Billing/Coding section to add 0740T and 0741T. (tt)



# Artificial Pancreas Device Systems

---

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.