

***For Dates of Service July 1, 2017 and After:  
This Policy does not apply to “MBG” prefix (Grp 90100)  
and “WLG” prefix (Group 74606).  
Refer to LCD 33822 and Article 52464***



**BlueCross BlueShield  
of Alabama**

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**Name of Blue Advantage Policy:  
Artificial Pancreas Device Systems**

Policy #:636

Category: Durable Medical Equipment

Latest Review Date: April 2021

Policy Grade: A

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**BACKGROUND:**

*Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational\*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
  - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;*
  - *Furnished in a setting appropriate to the patient’s medical needs and condition;*
  - *Ordered and furnished by qualified personnel;*
  - *One that meets, but does not exceed, the patient’s medical need; and*
  - *At least as beneficial as an existing and available medically appropriate alternative.*

*\*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Page 1 of 16

## **POLICY:**

### **Effective for dates of service on or after June 21, 2018:**

**Blue Advantage** will treat use of an FDA-approved automated insulin delivery system (artificial pancreas device) with a low-glucose suspend feature/hybrid closed-loop insulin delivery system, as a **covered benefit** when **ALL** of the following prerequisites are met and clearly documented in the patient's medical record:

- At least minimum FDA-approved age for device (See Governing Bodies)
- Type 1 diabetes
- Glycated hemoglobin value between 5.8% and 10.0%
- Must meet medical criteria for coverage for a CGM, as listed in medical policy #038, Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid.
- Must meet medical criteria for coverage for an external insulin pump as listed in medical policy #046, External Ambulatory Insulin Infusion Pump.

**Blue Advantage** will treat **use of an automated insulin delivery system (artificial pancreas device system)** as a **noncovered benefit** and as **investigational** in all other situations.

**Blue Advantage** will treat **use of an automated insulin delivery system (artificial pancreas device system)** **not approved by the Food and Drug Administration** as a **noncovered benefit** and as **investigational**.

**Blue Advantage** will treat **replacement or upgrade of existing, properly functioning equipment**, even if warranty has expired, as a **noncovered benefit** and as **investigational**.

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### **Effective for dates of service on or after April 15, 2017 and prior to June 21, 2018:**

**Blue Advantage** will treat use of an FDA approved artificial pancreas device with a low-glucose suspend feature as a **covered benefit** when **ALL** of the following prerequisites are met and are clearly documented in the patient's medical record:

- At least minimum FDA approved age for device (age 16 and older for MiniMed 530G / 630G and age 14 and older for MiniMed 670G)
- Type 1 diabetes
- Glycated hemoglobin value between 5.8% and 10.0%
- Must meet medical criteria for coverage for a CGM, as listed in medical policy #38, Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid.
- Must meet medical criteria for coverage for an external insulin pump as listed in External Infusion Pumps LCD 33794.

**Blue Advantage** will treat **Medtronic's MiniMed 670G**, a sensor augmented insulin pump with a low glucose threshold suspend feature, as a **non-covered benefit** and as **investigational** in **children younger than 14 years**.

**Blue Advantage** will treat **Medtronic’s MiniMed 530G/630G**, sensor augmented insulin pumps with a low glucose threshold suspend feature, as a **non-covered benefit** and as **investigational in children younger than 16 years**.

**Blue Advantage** will treat use of an **artificial pancreas device system** as a **non-covered benefit** and as **investigational** in all other situations.

**Blue Advantage** will treat **replacement or upgrade of existing, properly functioning equipment**, even if warranty has expired, as a **non-covered benefit**.

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## **DESCRIPTION OF PROCEDURE OR SERVICE:**

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 patients with insulin-dependent diabetes, in particular, reduction of nocturnal hypoglycemia.

### **Diabetes and Glycemic Control**

Tight glucose control in patients with diabetes has been associated with improved health outcomes. The American Diabetes Association has recommended a glycated hemoglobin level below 7% for most patients. 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 type 1 diabetics 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 Type 1 diabetes clinical management and research.

**Table 1. Outcome Measures for Type 1 Diabetes**

Measure	Definition	Guideline type	Organization	Date
Hypoglycemia		Stakeholder	Type 1	2017

		survey, expert opinion with evidence review	Diabetes Outcome Programa	
Level 1	Glucose <70mg/dl but ≥ 54 mg/dl			
Level 2	Glucose <54 mg/dl			
Level 3	Event characterized by altered mental/physical status requiring assistance			
Hypoglycemia	Same as Type 1 Diabetes Outcome Programa	Professional Practice Committee with systematic literature review	ADA	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	2018
Hyperglycemia				
Level 1	Glucose >180 mg/dL and ≤250 mg/dL		Type 1 Diabetes Outcome Programa	
Level 2	Glucose >250 mg/dL			2017
Time in Rangeb	Percentage of glucose readings in the range of		Type 1 Diabetes	2017

	70–180 mg/dL per unit of time		Outcome Programa	
Diabetic ketoacidosis (DKA)	Elevated serum or urine ketones > ULN Serum bicarbonate <15 mEq/L Blood pH <7.3		Type 1 Diabetes Outcome Programa	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, 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

### 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.

The use of the continuous glucose monitoring (CGM) component of diabetes self-management is specifically addressed in Medical Policy #038 Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid.

### KEY POINTS:

This evidence review was performed through March 4, 2021.

### **Summary of Evidence:**

For individuals who have type 1 diabetes (T1D) who receive an artificial pancreas device system with a low-glucose suspend feature, the evidence includes two 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, T1D, 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 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 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, etiology of the low glucose (activity, diet or medication) and 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 is sufficient 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 hybrid closed-loop insulin delivery system, the evidence includes multicenter pivotal trials using devices cleared by the 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 United States have been reported. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Of the three crossover RCTs assessing a related device conducted outside the United States, 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 and the other had mixed findings (significant difference in time spent in nocturnal hypoglycemia and no significant difference in time spent in preferred glycemic range). For the U.S. regulatory registration pivotal trial, the primary outcomes were safety and not efficacy. Additional evidence from device performance studies and clinical studies all demonstrate reductions in time spent in various levels of hypoglycemia, improved time in range (70-180mg/dl), rare diabetic ketoacidosis and few device-related adverse events. The evidence is sufficient 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.

**Practice Guidelines and Position Statements**

**American Diabetes Association**

The American Diabetes Association has released multiple publications on controlling type 1 diabetes (see Table 2).

**Table 2. Recommendations on Diabetes**

Date	Title	Publication Type	Recommendation (Level of Evidence)
2021	Standards of Medical Care in Diabetes	Guideline standard[American Diabetes Association. 7. Diabetes Technol.... ppl 1): S85-S99. PMID 33298418]	Sensor-augmented pump therapy with automatic low glucose suspend may be considered for adults and youth with diabetes to prevent/mitigate episodes of hypoglycemia.(B) Automated insulin delivery systems may be considered in youth and adults with type 1 diabetes to improve glycemic control. (A) Individual patients may be using systems not approved by the U.S. Food and Drug Administration, such as do-it-yourself closed-loop systems and others; providers cannot prescribe these systems but should provide safety information/troubleshooting/backup advice for the individual devices to enhance patient safety. (E)
2017	Standardizing Clinically Meaningful Outcome Measures Beyond HbA1c for Type 1 Diabetes	Consensus report,a	Developed definitions for hypoglycemia, hyperglycemia, time in range, and diabetic ketoacidosis in type 1 diabetes

HbA1c: hemoglobin A1c

a Jointly published with American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange.LOE: Level of Evidence. HbA1c: hemoglobin A1c

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**KEY WORDS:**

Medtronic Minimed® 670G, Medtronic Minimed® 530G, Medtronic Minimed® 630G, artificial pancreas, insulin pump, SmartGuard HCL, LGS, low glucose suspend, Medtronic Paradigm Veo system, t:slim X2 Insulin Pump, Basal-IQ Technology, automated insulin delivery system, T slim x2 Control-IQ technology, Control-IQ, automated insulin dosing (AID) system, Minimed 770G

**APPROVED BY GOVERNING BODIES:**

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. 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 (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 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.

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.

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

**Table 3 FDA-Approved Automated Insulin Delivery Systems (Artificial Pancreas Device Systems)**

Device	Age Indication	Manufacturer	Date Approved	PMA No./ Device Code
MiniMed 530G Systema (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)(hybrid closed-loop, LGS or PLGM)	≥14 y ≥7-13 y	Medtronic	Sep 2016 Jul 2018	P160017/OZP P160017/S031
MiniMed 770G System hybrid closed-loop	≥2 y	Medtronic	Aug 2020	P160017/S076
t:slim X2 Insulin Pump with Basal-IQ Technology (LGS)	≥6y	Tandem	June 2018	P180008/OZO, PQF
t:slim X2 Insulin Pump with Control-IQ Technology (HCL)	≥6y	Tandem	Dec 2019	DEN180058/QFG

FDA: Food and Drug Administration; 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).

The MiniMed® 530G System includes a threshold suspend or LGS 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 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. 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. 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 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 CGM (Continuous Glucose Monitor), 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. Control-IQ™ technology automatically adjusts insulin levels based on Dexcom G6 continuous glucose monitoring (CGM) readings. 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 motordriven to deliver patient programmed basal rates and boluses through an infusion set into subcutaneous tissue.

**BENEFIT APPLICATION:**

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

**CURRENT CODING:**

**HCPCS:**

A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week (effective 01/01/20)
A4255	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each

A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
E0784	External ambulatory infusion, pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing (effective 01/01/20)
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM) system, includes all supplies and accessories, 1 month supply = 1 unit of service.
K0554	Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system.
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
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

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## **POLICY HISTORY:**

Adopted for Blue Advantage, November 2016

Medical Policy Group, January 2017

Available for comment February 20 through April 5, 2017

Medical Policy Group, April 2017

Available for comment April 24 through June 8, 2017

Medical Policy Group, December 2017

Medical Policy Group, March 2018

Medical Policy Group, August 2018 (6): Updated policy statement to include new FDA approval of Medtronic 670G for ages 7 and older. Governing Bodies updated to include new age allowance for 670G.

Medical Policy Group, December 2019

Medical Policy Group, April 2020

Medical Policy Group, July 2020

Medical Policy Group, September 2020

Medical Policy Group, January 2021: Added coding (K0553/K0554).

Medical Policy Group, April 2021

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*