Artificial Pancreas Device Systems

Artificial pancreas device systems are medical devices that link a glucose monitor to an insulin infusion pump, in which the pump automatically takes action based on the glucose monitor reading. These devices are proposed to improve glycemic control in patients with insulin-dependent diabetes, in particular control of nocturnal hypoglycemia.

Tight glucose control in patients with diabetes has been associated with improved outcomes. The American Diabetes Association recommends a glycated hemoglobin level below 7% for most patients. However, hypoglycemia, defined as plasma glucose below 70 mg/dL, 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, presence of symptoms, and whether the episode can be self-treated or requires help for recovery.

Hypoglycemia affects many aspects of cognitive function, including attention, memory, and 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 hypoglycemia symptoms can also cause decreased motivation to adhere strictly to intensive insulin treatment regimens.

According to the United States Food and Drug Administration (FDA), an artificial pancreas is a medical device that links a glucose monitor to an insulin infusion pump where the pump automatically takes action (using a control algorithm) based on the glucose monitor reading. As control algorithms can vary significantly, there are a variety of artificial pancreas device systems currently under development. These systems span a wide range of designs from low glucose suspend (LGS) device systems to the more complex bihormonal control-to-target systems.

FDA has described 3 main categories of artificial pancreas device systems:

**Threshold Suspend Device System**
With threshold suspend device systems, also called low glucose suspend systems, the delivery of insulin is suspended for a set time when 2 glucose levels are below a specified low level indicating hypoglycemia.

**Control-to-Range System**
With these systems, the patient sets his or her own insulin dosing within a specified range, but the artificial pancreas device system takes over if glucose levels reach outside that range (higher or lower). Patients using this type of system still need to check blood glucose levels and administer insulin as needed.
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**Control-to-Target System**
With this type of device, the system aims to maintain glucose levels near a target level, such as 100 mg/dL. Control-to-target systems are automated and do not require participation of the user except for calibration of the continuous glucose monitoring system. Several device subtypes are being developed i.e., those that deliver insulin-only, bi-hormonal systems and hybrid systems.

The FDA is actively involved in advancing the development of artificial pancreas device systems, e.g., providing guidance to industry, sponsoring public forums, facilitating discussions between government and nongovernmental researchers, and seeking ways to reduce research and approval review time.

**Regulatory Status**
To date, a single artificial pancreas device has been cleared for marketing by FDA; it is classified as a Threshold Suspend Device System. The device is the MiniMed® 530G System (Medtronic), which integrates an insulin pump and glucose meter and includes a LGS feature; FDA clearance was granted in 2013. The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is at or lower than a preset threshold within the 60 mg/dL 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 to the alarm, the pump automatically suspends action for 2 hours, and then insulin therapy resumes. The device is approved only for use in patients 16 years and older.

***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.

**When Artificial Pancreas Device Systems are covered**

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 at risk of hypoglycemia who meet ALL of the following criteria:

- Age 16 and older
- Glycated hemoglobin value between 5.8% and 10.0%
- Used insulin pump therapy for more than 6 months
- At least 2 documented nocturnal hypoglycemic events (see Policy Guidelines section) in a 2-week period.

**When Artificial Pancreas Device Systems are not covered**

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

The definition of a hypoglycemic episode is not standardized. In the pivotal ASPIRE RCT (randomized controlled trial), a hypoglycemic episode was defined as sensor glucose value of 65 mg per deciliter or less between 10pm and 8am for more than 20 consecutive minutes in the absence of a pump interaction within 20 minutes.

The evidence base on artificial pancreas systems is small but increasing rapidly. For the FDA–approved artificial pancreas device system with a low glucose suspend (LGS) feature, evidence from 2 randomized controlled trials conducted in real-world settings report that outcomes are improved in selected patients i.e., those who meet entry criteria of the key clinical trial. These two studies used different eligibility criteria, different outcome measures, and each had some methodologic limitations; however, they both report significantly less hypoglycemia in the treatment group. As a result of this evidence, combined with results of clinical vetting, and consideration of current standard of care treatment, an artificial pancreas device system with LGS may be considered medically necessary when criteria are met.

The evidence is insufficient to support use of the FDA-approved artificial pancreas device system for any other clinical indication. No other artificial pancreas device system besides a LGS system is FDA approved and marketed in the United States, and therefore, all other types of artificial pancreas devices are considered investigational.

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. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 95250, 95251, S1034, S1035, S1036, S1037

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.

Scientific Background and Reference Sources


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)
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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.