Artificial Pancreas Device Systems

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, 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.

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. Because 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.

The 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.

**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. FDA provides guidance to industry, sponsors public forums, facilitates discussions between government and nongovernmental researchers, and seeks ways to reduce research and approval review time. To date, two artificial pancreas device systems have been approved by the FDA. One is a threshold suspend device. The other includes a threshold suspend feature and also includes...
Artificial Pancreas Device Systems

semi-automatic adjustment of basal insulin levels. The second device uses a combination of control-to-range and control-to-target strategies.

Regulatory Status
In 2013, the MiniMed® 530G System (Medtronic) was approved by the FDA through the premarket approval process. This system integrates an insulin pump and glucose meter and includes a low-glucose suspend (LGS) feature. 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.

In 2016, the MiniMed® 670G System (Medtronic) hybrid closed-loop insulin delivery system was approved by the FDA through the premarket approval process. It consists of an insulin pump, a glucose meter, and a transmitter, linked by a proprietary algorithm, the SmartGuard HCL. The system includes an LGS feature that suspends insulin delivery when glucose levels get low and has an optional alarm. Additionally, the system involves semi-automatic insulin level adjustment to preset targets. It is called a hybrid system; basal insulin levels are automatically adjusted but the patient needs to administer premeal insulin boluses. The system is approved for patient with type 1 diabetes who are at least 14 years old. It is contraindicated in children under age 7 and in patient who require less than as total daily insulin dose of 8 units. The 670G system is expected to be available commercially in early 2017.

***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, 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:
- 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.
Artificial Pancreas Device Systems

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 for artificial pancreas device systems with a low-glucose suspend (LGS) feature in patients who have type 1 diabetes includes 2 randomized controlled trials (RCTs) conducted in home settings. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. The RCTs both reported significantly less hypoglycemia in the treatment group than in the control group. 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 (≤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. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have type 1 diabetes who receive a hybrid closed-loop insulin delivery system, the evidence includes 1 single-arm study using an FDA-cleared device and two crossover RCTs using a similar device approved outside of the US. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. The single published analysis is part of an ongoing study; it was not designed to evaluate the impact of the device on glycemic control and did not include a comparison intervention. Published data are needed on the efficacy of the semiautomatic insulin adjustment feature of the new device compared with current standard care. Of the two crossover RCTs on a related device conducted outside the US, one found significantly better outcomes with the new device versus standard care and the other had mixed findings. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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.

Scientific Background and Reference Sources


Artificial Pancreas Device Systems


Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>10/15</td>
<td>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)</td>
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<tr>
<td>1/26/16</td>
<td>References added. Policy Guidelines updated. (sk)</td>
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<tr>
<td>8/30/16</td>
<td>Specialty Matched Consultant Panel Review meeting 7/27/2016. No change to policy statement. (an)</td>
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<tr>
<td>12/30/16</td>
<td>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 <strong>ALL</strong> of the following criteria…” Policy Guidelines section was updated. The following statement was added to the Billing/Coding section: <strong>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.</strong> (an)</td>
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<tr>
<td>8/11/17</td>
<td>Specialty Matched Consultant Advisory Panel review meeting 7/26/2017. (an)</td>
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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.