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

<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artificial pancreas device system</td>
<td>Use of a U.S. Food and Drug Administration (FDA) approved automated insulin delivery system (artificial pancreas device)</td>
</tr>
<tr>
<td>Device</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>--------</td>
<td>------------------</td>
</tr>
</tbody>
</table>
|        | system) with a low-glucose suspend feature may be considered medically necessary in patients with **type 1 diabetes** who meet all of the following criteria:  
- Age 6 years of age or older  
- Glycated hemoglobin (hemoglobin A1c) value 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 | Use of a U.S. Food and Drug Administration (FDA) approved automated insulin delivery system (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:  
- Age 6 years of age and older  
- Glycated hemoglobin 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 |

<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| 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 approved by the Food and Drug Administration is considered investigational. |
Documentation Requirements

The patient’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

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1034</td>
<td>Artificial pancreas device system (eg, low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices</td>
</tr>
<tr>
<td>S1035</td>
<td>Sensor; invasive (eg, subcutaneous), disposable, for use with artificial pancreas device system, 1 unit = 1 day supply</td>
</tr>
<tr>
<td>S1036</td>
<td>Transmitter; external, for use with artificial pancreas device system</td>
</tr>
<tr>
<td>S1037</td>
<td>Receiver (monitor); external, for use with artificial pancreas device system</td>
</tr>
</tbody>
</table>

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 is based on the FDA 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 (eg, 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.

Background

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 T1D clinical management and research.

Table 1. Outcome Measures for Type 1 Diabetes

<table>
<thead>
<tr>
<th>Measure</th>
<th>Definition</th>
<th>Guideline type</th>
<th>Organization</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoglycemia</td>
<td></td>
<td>Stakeholder survey, expert opinion with evidence review</td>
<td>Type 1 Diabetes Outcome Program&lt;sup&gt;1&lt;/sup&gt;</td>
<td>2017</td>
</tr>
<tr>
<td>Level 1</td>
<td>Glucose &lt;70 mg/dl but ≥ 54 mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 2</td>
<td>Glucose &lt;54 mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td>Event characterized by altered mental/physical status requiring assistance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure</td>
<td>Definition</td>
<td>Guideline type</td>
<td>Organization</td>
<td>Date</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>--------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>Same as Type 1 Diabetes Outcome Program&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Professional Practice Committee with systematic literature review</td>
<td>ADA&lt;sup&gt;2&lt;/sup&gt;</td>
<td>2019</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>Clinical alert for evaluation and/or treatment</td>
<td>Clinical Practice Consensus</td>
<td>ISPAD&lt;sup&gt;3&lt;/sup&gt;</td>
<td>2018</td>
</tr>
<tr>
<td></td>
<td>Clinically important or serious</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe hypoglycemia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Glucose &lt;70mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Glucose &lt;54 mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe cognitive impairment requiring external assistance by another person</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperglycemia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 1</td>
<td>Glucose &gt;180 mg/dL and ≤250 mg/dL</td>
<td></td>
<td>Type 1 Diabetes Outcome Program&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2017</td>
</tr>
<tr>
<td>Level 2</td>
<td>Glucose &gt;250 mg/dL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time in Range&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Percentage of glucose readings in the range of 70–180 mg/dL per unit of time</td>
<td></td>
<td>Type 1 Diabetes Outcome Program&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2017</td>
</tr>
<tr>
<td>Diabetic ketoacidosis (DKA)</td>
<td>Elevated serum or urine ketones &gt; ULN</td>
<td></td>
<td>Type 1 Diabetes Outcome Program&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2017</td>
</tr>
<tr>
<td></td>
<td>Serum bicarbonate &lt;15 mEq/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood pH &lt;7.3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<sup>a</sup> 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.

<sup>b</sup> Time in range: has also been adopted by researchers evaluating the precision and effectiveness of emerging glucose monitoring and automated insulin delivery technologies.
Hypoglycemia

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 (eg, coma, seizure, transient ischemic attack, stroke), heart (eg, cardiac arrhythmia, myocardial ischemia, infarction), eye (eg, 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 American Diabetes Association 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.

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.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. 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.

**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 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.
**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 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.

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

**Summary of Evidence**

The following conclusions are based on a review of the evidence, including but not limited to, published evidence and clinical expert opinion, solicited via BCBSA’s Clinical Input Process.

**Low-Glucose Suspend Device**

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. 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 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. Limitations of the published evidence preclude determining the effects of the technology on overall glycemic control as assessed by HbA1c and other parameters and thus, net health outcomes. Evidence reported through clinical input supports 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. The evidence is sufficient to determine that the technology results in a meaningful 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 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 (ie, 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 variations in the definition of primary and secondary outcomes in the study design and conduct of the published evidence are limitations that preclude determining the effects of the technology on net health outcomes. Evidence reported through clinical input supports that the use of hybrid closed loop APDS 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. The evidence is sufficient to determine that the technology results in meaningful improvement in the net health outcome.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 2.
Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02748018a</td>
<td>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</td>
<td>1500</td>
<td>Dec 2021</td>
</tr>
<tr>
<td></td>
<td>Artificial Pancreas with Exercise Behavior Recognition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03739099</td>
<td>Assessment of the Efficacy of Closed-loop Insulin Therapy (Artificial Pancreas) on the Control of Type 1 Diabetes in Prepubertal Child in Free-life: Comparison Between Nocturnal and 24-hour Use on 18 Weeks, Followed by an Extension on 18 Weeks</td>
<td>120</td>
<td>Sep 2020</td>
</tr>
<tr>
<td>NCT03844789a</td>
<td>The International Diabetes Closed Loop (iDCL) Trial: Clinical Acceptance of the Artificial Pancreas in Pediatrics: A Study of t:Slim X2 With Control-IQ Technology</td>
<td>101</td>
<td>Mar 2020</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03859401</td>
<td>Hypoglycemia Prevention During and After Moderate Exercise in Adults With Type 1 Diabetes Using an Artificial Pancreas With Exercise Behavior Recognition</td>
<td>18 (actual)</td>
<td>Jan 2020</td>
</tr>
<tr>
<td>NCT02733211</td>
<td>An Open-label, Two-center, Randomized, Cross-over Study to Evaluate the Safety and Efficacy of Night Closed-loop Control Using the MD-Logic Automated Insulin Delivery System Compared to Sensor Augmented Pump Therapy in Poorly Controlled Patients With Type 1 Diabetes at Home</td>
<td>28</td>
<td>Dec 2019 (Withdrawn)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* 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

In response to requests, while this topic was under review in 2019, clinical input on the use of an artificial pancreas device system with a hybrid closed-loop insulin delivery system for individuals with type 1 diabetes was received from four respondents, including four physician-level responses identified through two specialty societies including physicians with academic medical center affiliations. Evidence from clinical input is integrated within the Summary of Evidence.

2015

In response to requests, input on artificial pancreas device systems was received from two physician specialty societies and four academic medical centers when the policy was under review in 2015. Input was mixed on whether artificial pancreas systems, including closed-loop monitoring devices with a low-glucose suspend threshold feature, are considered medically necessary. Most reviewers thought there was sufficient supportive data on devices with a low-glucose suspend feature in patients at high risk of hypoglycemia, but some thought the data insufficient.

Practice Guidelines and Position Statements

American Diabetes Association

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Publication Type</th>
<th>Recommendation</th>
<th>LOE</th>
</tr>
</thead>
</table>
| 2020 | Standards of Medical Care in Diabetes                                 | Guideline standard \(^{17}\) | Automated insulin delivery systems improve glycemic control and reduce hypoglycemia in adolescents and should be considered in adolescents with type 1 diabetes                                                                 | A (adults)  
   B (children) |
| 2017 | Standardizing Clinically Meaningful Outcome Measures Beyond HbA1c for Type 1 Diabetes | Consensus report \(^{25, a}\) | Developed definitions for hypoglycemia, hyperglycemia, time in range, and diabetic ketoacidosis in type 1 diabetes                                                                                               | N/A   |

HbA1c: hemoglobin A1c; LOE: Level of Evidence.

\(^{a}\) 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.

American Association of Clinical Endocrinologists et al

In 2018, The American Association of Clinical Endocrinologists and American College of Endocrinology published a joint position statement on the integration of insulin pumps and continuous glucose monitoring in patients with diabetes.\(^{26}\) The statement emphasized the use of continuous glucose monitoring and insulin pump therapy for type 1 diabetes patients who are not in glycemic target ranges despite intensive attempts at self-blood glucose monitoring and multiple insulin injection therapy.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Table 4 summarizes the FDA-approved automated insulin delivery systems.
### Table 4. FDA-Approved Automated Insulin Delivery Systems (Artificial Pancreas Device Systems)

<table>
<thead>
<tr>
<th>Device</th>
<th>Age Indication</th>
<th>Manufacturer</th>
<th>Date Approved</th>
<th>PMA No./Device Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiniMed 530G System&lt;sup&gt;a&lt;/sup&gt; (open-loop, LGS)</td>
<td>≥16 y</td>
<td>Medtronic</td>
<td>Jul 2013</td>
<td>P120010/OZO</td>
</tr>
<tr>
<td>MiniMed 630G System with SmartGuard™&lt;sup&gt;b&lt;/sup&gt; (open-loop, LGS)</td>
<td>≥16 y</td>
<td>Medtronic</td>
<td>Aug 2016</td>
<td>P150001/OZO</td>
</tr>
<tr>
<td></td>
<td>≥14 y</td>
<td></td>
<td>Jun 2017</td>
<td>P150001/S008</td>
</tr>
<tr>
<td>MiniMed 670G System&lt;sup&gt;c&lt;/sup&gt; (hybrid closed-loop, LGS or PLGM)</td>
<td>≥14 y</td>
<td>Medtronic</td>
<td>Sep 2016</td>
<td>P160017/OZP</td>
</tr>
<tr>
<td></td>
<td>≥7-13 y</td>
<td></td>
<td>Jul 2018</td>
<td>P160017/S031</td>
</tr>
<tr>
<td>t:slim X2 Insulin Pump with Basal-IQ Technology (LGS)&lt;sup&gt;d&lt;/sup&gt;,</td>
<td>≥6 y</td>
<td>Tandem</td>
<td>Jun 2018</td>
<td>P180008/OZO, PQF</td>
</tr>
<tr>
<td>t:slim X2 Insulin Pump with Control-IQ Technology (HCL)</td>
<td>≥6 y</td>
<td>Tandem</td>
<td>Dec 2019</td>
<td>DEN180058/QFG</td>
</tr>
</tbody>
</table>


<sup>a</sup> 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).

<sup>b</sup> 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).

<sup>c</sup> 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.<sup>7</sup> 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.<sup>8</sup> 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.9 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 most recent supplemental approval for the MiniMed® 670G System in July 2018 followed the granting a designation of breakthrough device status.5

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.10 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.11 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.
References


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


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/10/15</td>
<td>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.</td>
</tr>
<tr>
<td>01/12/16</td>
<td>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.</td>
</tr>
<tr>
<td>04/12/16</td>
<td>Minor update. Removal of related policy 1.01.522, policy was archived on April 30, 2016.</td>
</tr>
<tr>
<td>11/08/16</td>
<td>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.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>02/01/17</td>
<td>Annual Review, approved January 10, 2017. Policy updated with literature review through October 4, 2016; references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>04/11/17</td>
<td>Policy moved into new format; no change to policy statements. Evidence Review section reformatted.</td>
</tr>
<tr>
<td>02/01/18</td>
<td>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.</td>
</tr>
<tr>
<td>9/01/18</td>
<td>Minor update. Re-added language supporting that this policy applies to those age 16 and older; it was inadvertently removed in a previous update.</td>
</tr>
<tr>
<td>03/01/19</td>
<td>Minor update, added Documentation Requirements section.</td>
</tr>
<tr>
<td>07/01/19</td>
<td>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.</td>
</tr>
<tr>
<td>04/01/20</td>
<td>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.</td>
</tr>
<tr>
<td>07/02/20</td>
<td>Delete policy.</td>
</tr>
<tr>
<td>11/01/20</td>
<td>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.</td>
</tr>
</tbody>
</table>

**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. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

**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.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Amharic):
لا يحق هذا الإشعار للمعلمين أو الأطباء أو أي شخص آخر في Premera Blue Cross. يجدر بالذكر أن هذه المعلومات متاحة للجميع.
translated information can be obtained by calling 800-722-1471 (TTY: 800-842-5357).

Chinese (Chinese):
本通知有重要的信息。本通知可能有关於您透過 Premera Blue Cross 提交的申請或保單的重要訊息。本通知可能有重要的日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):
Lakkooofi biilabaa 800-722-1471 (TTY: 800-842-5357) ti biilabaa.

Italian (Italian):
Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero essere date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza in tua lingua gratuitamente.
Chiama 800-722-1471 (TTY: 800-842-5357).
Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir dados importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Тагаолаг (Tagalog):

ไทย (Thai):
ประกาศนี้มีข้อสังเกตสัญญา ประกาศนี้มีข้อสังเกตสัญญาเกี่ยวกับการติดต่อของคุณกับสิทธิของส่วนของคุณ Premera Blue Cross และมีที่มาจากภาษาภาษาที่คุณสะดวก ในกรณีที่มีข้อสังเกตสัญญาตั้งแต่การติดต่อของคุณกับสิทธิของส่วนของคุณที่มีการสัญญาที่ไม่สามารถใช้ได้สิทธิของส่วนของคุณตามที่ต้องการ โปรดติดต่อที่ 800-722-1471 (TTY: 800-842-5357).

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути важливі у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити перші кроки у конкретній ситуації для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):