Introduction

An artificial pancreas device system combines a glucose monitor and an insulin infusion pump. The goal is to try to match how the pancreas works. A 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 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</td>
<td>Use of an artificial pancreas device system with a low-glucose suspend feature that has been approved by the FDA, may be</td>
</tr>
</tbody>
</table>
Device Medical Necessity
---

**considered medically necessary in patients who meet all of the following criteria:**

- Have a diagnosis of type 1 diabetes
- Are 16 years of age or older
- Have a glycated hemoglobin (hemoglobin A1c) value between 5.8% and 10.0%
- Have used insulin pump therapy for more than 6 months
- Have at least two documented nocturnal hypoglycemic events in a two-week period

**Note:** The definition of a hypoglycemic episode is not standardized. In the pivotal ASPIRE RCT, a hypoglycemic episode was defined as sensor glucose value of 65 mg per deciliter or less between the hours of 10 p.m. and 8 a.m. for more than 20 consecutive minutes in the absence of an insulin pump interaction within 20 minutes.

Use of an artificial pancreas device system is considered investigational when criteria are not met.

**Coding**

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1034</td>
<td>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</td>
</tr>
<tr>
<td>S1035</td>
<td>Sensor; invasive (e.g., 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

N/A

Evidence Review

Description

An artificial pancreas device system (classified as a threshold-suspend device system) links a glucose monitor to an insulin infusion pump. The medical device automatically suspends or adjusts insulin dosage based on the blood glucose level shown on the monitor. In patients with insulin-dependent diabetes (type 1 diabetes) these devices are proposed to improve overall glycemic control and specifically to control episodes of very low blood sugar levels occurring at night (nocturnal hypoglycemia).

Background

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 U.S. 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 a low glucose suspend (LGS) device systems to the more complex bi-hormonal control-to-target systems. A 2016 horizon scan review identified 18 automated “closed-loop” or semi-automated systems under development worldwide.¹

**FDA has Described 3 Main Categories of Artificial Pancreas Device Systems**²

*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 ie, those that deliver insulin-only, bi-hormonal systems and hybrid systems.
Summary of Evidence

**Low-Glucose Suspend Device**

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a low-glucose suspend feature, the evidence 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. Both RCTs 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 that the technology results in a meaningful improvement in the net health outcome.

**Hybrid Closed-Loop Insulin Delivery System**

For individuals who have type 1 diabetes who receive a hybrid closed-loop insulin delivery system, the evidence includes 1 single-arm study using a device cleared by the Food and Drug Administration and 2 crossover RCTs using a similar device approved outside the United States. 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 2 crossover RCTs on a related device conducted outside the United States, 1 found significantly better outcomes (i.e., time spent in nocturnal hypoglycemia and time spent in preferred glycemic range) with the new device versus 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). The evidence is insufficient to determine the effects of the technology on health outcomes.
Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

In 2016, the National Institute for Health and Care Excellence (NICE) published guidance on use of the MiniMed Paradigm Veo system (available in the European Union). Recommendations are as follows:

1. The MiniMed Paradigm Veo system is recommended as an option for managing blood glucose levels in people with type 1 diabetes only if:
   - They have episodes of disabling hypoglycaemia despite optimal management with continuous subcutaneous insulin infusion, and
   - The company arranges to collect, analyse and publish data on the use of the MiniMed Paradigm Veo system.

2. The MiniMed Paradigm Veo system should be used under the supervision of a trained multidisciplinary team who are experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring for managing type 1 diabetes only if the person or their carer:
   - Agrees to use the sensors for at least 70% of the time
   - Understands how to use it and is physically able to use the system, and
   - Agrees to use the system while having a structured education programme on diet and lifestyle, and counselling.

3. People who start to use the MiniMed Paradigm Veo system should only continue to use it if they have a decrease in the number of hypoglycaemic episodes that is sustained. Appropriate targets for such improvements should be set.

American Diabetes Association

The American Diabetes Association’s (ADA) 2015 Standards in Diabetes included the following recommendation: “For patients with frequent nocturnal hypoglycemia and/or hypoglycemia unawareness, a sensor-augmented low glucose threshold suspend pump may be considered.”
Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

To date, two artificial pancreas device systems have been approved by the U.S. Food and Drug Administration (FDA).

In 2013, the MiniMed® 530G System (Medtronic), which integrates an insulin pump and glucose meter and includes a LGS feature, was approved by FDA through the premarket approval process. The system integrates an insulin pump and glucose meter that include a low-glucose suspend (LGS) feature. The threshold suspend tool temporarily stops 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 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. FDA product code: OZO.

A similar device, the Medtronic Paradigm Veo system, has been used outside of the United States and used in published studies.

In 2016, the MiniMed® 670G System (Medtronic) hybrid closed-loop insulin delivery system was approved by 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 semiautomatic insulin-level adjustment to preset targets to minimize blood glucose variability. 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 patients with type 1 diabetes who are at least 14 years old. It is contraindicated for children under age 7 and patients who require less than a total daily insulin dose of 8 units. The 670G system is expected to be available commercially in early 2017. FDA product code: OZP.


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>01/10/17</td>
<td>Annual Review. 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>
</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). ©2017 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 with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4537, 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 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
Office for Civil Rights Complaint Portal, available at
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Toll free 855-332-4537, Fax 425-918-5592, TTY 800-842-5357

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 (Arabic):
لا يوجد هذا الإشعار باللغة العربية. قد تكون هناك إشعار باللغة العربية. ينصح بإلتقاط نسخة من الإشعار باللغة العربية إذا لم تكن هناك نسخة باللغة العربية. للحصول على نسخة باللغة العربية، يرجى الاتصال بالرقم 800-722-1471 (TTY: 800-842-5357).

Chinese (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。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):

Italiano (Italian):
Este aviso podrá contener información importante. Es posible que deba tomar alguna medida antes de determinadas fechas, tengan o no relación con su aplicación o cobertura por medio de Premera Blue Cross. Poderán existir datos importantes en este aviso. Tal vez sea necesario que usted tome providencias dentro de determinados plazos para mantener su cobertura o ayuda de custodia. Es posible que se dé el caso de que obtenga esta información y ayuda en su idioma sin costo alguno. Llame al 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 o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves 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 en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Тагальский (Tagalog):

ไทย (Thai):
ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และท่านจะมีข้อมูลที่จำเป็นต้องทราบในบางกรณีที่ท่านต้องทำการรับการประกันสุขภาพของคุณหรือสิทธิที่คุณมีสิทธิ์ที่จะได้รับข้อมูลและความช่วยเหลือในภาษาของคุณโดยไม่มีค่าใช้จ่าย โปรดติดต่อกับ Premera Blue Cross ที่ 800-722-1471 (TTY: 800-842-5357)

日本語 (Japanese):
この通知には重要な情報が含まれています。この通知では、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれています。この通知には、記録されている情報が重要な日付をご確認ください。健康保険や無料サポートを維持するには、特定の期限までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관련하여 그리고 Premera Blue Cross를 통해 커버지에 관한 정보를 포함하고 있는 것입니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하는 귀하의 건강 커버리지 제한을 유지하려고 하거나 필요로 할 때, 이에 대한 정보를 얻을 수 있습니다. 귀하는 이러한 정보를 얻어 귀하의 안전을 위해 방해없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)으로 전화하세요.

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉, 이 통지서는 귀하의 신청에 관련하여 그린 Premera Blue Cross를 통해 커버지에 관한 정보를 포함하고 있는 것입니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하는 귀하의 건강 커버리지 제한을 유지하려고 할 때, 이에 대한 정보를 얻을 수 있습니다. 귀하는 이러한 정보를 얻어 귀하의 안전을 위해 방해없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)으로 전화하세요.

हिंदी (Punjabi):
इस विवरण में कुछ महत्त्वपूर्ण जानकारी हो सकती है। अगर आपकी अपलोड़ को मालिक का निर्देशन है या उसके साथ केवल उन संबंध में हो सकता है जो आपको आपके पैसों का क्रोध प्रदर्शन करने का मौका प्रदान करते हैं। इस विवरण में कुछ शर्त संदर्भ में हो सकते हैं जो आपकी अपलोड या अपलोड का आयोजन के तौर पर दिलचस्पी व्यक्त करते हैं। यदि आप इसके साथ आपके अपलोड के लिए जरूरी विवरण नहीं हैं तो आप 800-722-1471 (TTY: 800-842-5357) पर कॉल कर सकते हैं।