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.

Related Policies

- N/A

Policy

Use of a U.S. Food and Drug Administration (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 all of the following criteria:

- Age 16 and older
- Type 1 diabetes
- 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) in a 2 week period

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

Policy Guidelines

The definition of a hypoglycemic episode is not standardized. In the pivotal ASPIRE randomized control trial (RCT), 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.

Coding

The following HCPCS codes are specific to the “artificial pancreas” 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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**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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**Rationale**

**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 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:\(^1\):

**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.

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. FDA product code: OZO.

This policy was based in part on a 2013 TEC Assessment on artificial pancreas device systems.\(^2\)

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

**Threshold Suspend Devices**
The first device (Medtronic MiniMed 530G) categorized by the U.S. Food and Drug Administration (FDA) as an artificial pancreas device system (subcategory: threshold suspend device system) was cleared for marketing by FDA in September 2013. The
system integrates a continuous glucose monitor (CGM) and insulin pump and includes a low glucose suspend (LGS) feature that can automatically temporarily suspend insulin delivery when glucose levels fall below a prespecified level. A similar device, the Medtronic Paradigm Veo system, has been used outside of the United States and has also been used in published studies.

A December 2013 TEC Assessment reviewed studies that reported on use of these devices in patients with type 1 diabetes, or with type 2 diabetes taking insulin, who were 16 years and older. It included studies that compared an artificial pancreas device system containing a LGS feature with the best alternative treatment, focused on patients age 16 and older who had type 1 diabetes or type 2 diabetes using insulin, had at least 15 patients per arm, and reported on hypoglycemic episodes. A single trial met the inclusion criteria, and the authors stated that, although the trial results are generally favorable, the study has limitations and further studies are needed. The TEC Assessment concluded that there was insufficient evidence to draw conclusions about the impact of an artificial pancreas device system, with a LGS feature, on health outcomes.

The study referred to in the TEC Assessment was the in-home arm of the Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial, published by Bergenstal et al in 2013. This was an industry-sponsored trial using the Medtronic Paradigm Veo pump. A total of 247 patients were randomly assigned to an experimental group, in which a CGM with the LGS feature was used (n=121), or a control group that used the CGM but not the LGS feature (n=126). Key eligibility criteria were 16-to-70 years old, type 1 diabetes, and a glycated hemoglobin (HbA1c) level between 5.8% and 10.0%. In addition, patients needed to have at least 2 nocturnal hypoglycemic events (≤65 mg/dL) lasting more than 20 minutes during a 2-week run-in phase. The randomized intervention phase lasted 3 months. Patients in the LGS group were required to use the feature at least between 10 PM and 8 AM. The threshold value was initially set at 70 mg/dL and could be adjusted to a value between 70 to 90 mg/dL. Seven patients withdrew early from the study; all 247 were included in the intention-to-treat (ITT) analysis. The primary efficacy outcome was the area under the curve (AUC) for nocturnal hypoglycemia events. This was calculated by multiplying the magnitude (in mg per deciliter) and duration (in minutes) of each qualified hypoglycemic event. The primary safety outcome was change in HbA1c.

The primary end point, mean (SD) AUC for nocturnal hypoglycemic events, was 980 (1200) in the LGS group and 1568 (1995) in the control group. The difference between groups was statistically significant (p<0.001), favoring the intervention group. The mean (SD) magnitude of events was 980 (1200) mg/dL/min in the LGS group and 1568 (1995) mg/dL/min in the control group.

Similarly, the mean AUC for combined daytime and nighttime hypoglycemic events, a secondary outcome, significantly favored the intervention group (p<0.001). Mean (SD) AUC values were 798 (965) in the intervention group and 1164 (1590) in the control group. Moreover, the intervention group experienced fewer hypoglycemic episodes than the control group, a mean (SD) of 3.3 (2.0) per patient-week versus a mean of 4.7 (2.7) per patient-week (p<0.001). For patients in the LGS group, the mean number of times the feature was triggered per patient was 2.08 per 24-hour period and 0.77 per each night (10 PM-8 AM). The median duration of nighttime threshold-suspend events was 11.9 minutes; 43% of events lasted for less than 5 minutes and 19.6% lasted more than 2 hours. In both groups, the mean sensor glucose value at the beginning of nocturnal events was 62.6 mg/dL. After 4 hours, the mean value was 162.3 mg/dL in the LGS group compared with 140.0 mg/dL in the control group.

In terms of safety outcomes and adverse events, change in HbA1c level was minimal, and there was not a statistically significant difference between groups. Mean HbA1c
decreased from 7.26 to 7.24 in the low glucose suspend group and from 7.21 to 7.14 in the control group. During the study period, there were no severe hypoglycemic events in the LGS group, and there were 4 events in the control group (nadir glucose sensor values in these events ranged from 40 mg/dL to 76 mg/dL). There were no deaths or serious device-related adverse events.

Before reporting on in-home findings, in 2012 the ASPIRE researchers (Garg et al) published data from the in-clinic arm of the study. This was a randomized crossover trial that included 50 patients with type 1 diabetes who had at least 3 months of experience with an insulin pump system. After a 2-week run-in period to verify and optimize basal rates, patients underwent 2 in-clinic exercise sessions to induce hypoglycemia. The LGS feature on the insulin pump was turned on in 1 session and off in the other session, in random order. When on, the LGS feature was set to suspend insulin delivery for 2 hours when levels reached 70 mg/dL or less. The goal of the study was to evaluate whether the severity and duration of hypoglycemia was reduced when the LGS feature was used. The study protocol called for patients to start exercise with a glucose level of 100 to 140 mg/dL and to use a treadmill or stationary bicycle until their plasma glucose level was 85 mg/dL or less. The study outcome, duration of hypoglycemia, was defined as the period of time glucose values were lower than 70 mg/dL and above 50 mg/dL, and hypoglycemia severity was defined as the lowest observed glucose value. A successful session was defined as an observation period of 3 to 4 hours with glucose levels above 50 mg/dL. Patients who did not attain success could repeat the experiment up to 3 times.

The 50 patients attempted 134 exercise sessions; 98 of these were successful. Duration of hypoglycemia was significantly less during the LGS-on sessions (mean, 138.5 minutes; SD=68) than the LGS-off sessions (mean, 170.7 minutes; SD=91; p=0.006). Hypoglycemia severity was significantly lower in the LGS-on group. The mean (SD) lowest glucose level was 59.5 (72) mg/dL in the LGS-on group and 57.6 (5.7) mg/dL in the LGS-off group (p=0.015). The Garg study evaluated the LGS feature in a research setting and over a short time period.

There is a second RCT evaluating in-home use of the Medtronic Paradigm Veo System. The study, by Ly et al in Australia was excluded from the 2013 TEC Assessment due to the inclusion of children, as well as adults and lack of analyses stratified by age group (the artificial pancreas system approved in the United States is only intended for individuals aged 16 and older). The Ly study included 95 patients with type 1 diabetes who used an insulin pump and were between the ages of 4 to 50 years (mean age, 18.6 years). Patients were randomized to 6 months of in-home use of the Paradigm Veo system with automated insulin suspension when the sensor glucose reached a preset glucose threshold of 60 mg/dL or to continued use of an insulin pump without the LGS feature. The primary study outcome was combined incidence of severe hypoglycemic events (defined as hypoglycemic seizure or coma) and moderate hypoglycemic events (defined as an event requiring assistance from another person). Findings were not reported separately for children and adults. The mean age was 18.6 years, and over 30% of the study population was under 18 years old.

The baseline rate of severe and moderate hypoglycemia was significantly higher in the LGS group than the pump-only group (129.6 vs. 20.7 events per 100 patient-months). After 6 months of treatment, and controlling for the baseline hypoglycemia rate, the incidence rate per 100 patient-months was 34.2 (95% confidence interval [CI]: 22.0 to 53.3) in the pump-only group and 9.6 (95% CI: 5.2 to 17.4) in the LGS group. The incidence rate ratio was 3.6 (95% CI: 1.7 to 7.5), which was statistically significant favoring the LGS group. Although results were not reported separately for children and adults, the
authors conducted a sensitivity analysis in patients younger than 12 years (15 patients in each treatment group). The high baseline hypoglycemia rates can be explained in part by 2 outliers; these were children (ages 9 and 10 years). When these 2 children were excluded from the analysis, the primary outcome was no longer statistically significant. The incidence rate ratio for moderate and severe events excluding the 2 children was 1.7 (95% CI: 0.7 to 4.3). Mean HbA1c level (%), a secondary outcome, did not differ between groups at baseline or at 6 months. Change in HbA1c during the treatment period was -0.06% (95% CI: -0.2 to 0.09) in the pump-only group and -0.1 (95% CI: -0.3 to 0.03) in the LGS group; the difference between groups was not statistically significant.

**Section Summary**

There are several RCTs evaluating the first FDA-approved artificial pancreas device, which includes an LGS feature, or a similar device used outside of the United States. Two RCTs were conducted in real-life home settings. The study that was limited to adults, the intended use of the FDA-approved device, showed an improvement in the primary outcome, AUC for nocturnal hypoglycemic events. This is an unusual way to report hypoglycemic outcomes and not equivalent to reporting hypoglycemic episodes. However, the magnitude of reduction for hypoglycemic events in this population, which was a secondary outcome, is likely to be clinically significant.

The other RCT included adults and children. Data were not stratified by age group, and when all data were included, the primary outcome (moderate and severe hypoglycemia events) was significantly decreased in a group assigned to a device with an LGS feature compared with a pump-only group. However, when 2 children with outlying data were excluded, the difference between groups was no longer significant, thus raising uncertainty on whether the LGS feature improves clinical outcomes in the adult population.

**Control-to-Range and Control-to-Target Devices**

Several crossover RCTs conducted outside the United States have evaluated control-to-range or control-to-target artificial pancreas device systems, none of which have been approved by FDA. Nimri et al in Israel have developed and tested an artificial pancreas device system called the MD-Logic. This device is a closed loop system that uses a combination of control-to-range and control-to-target strategies and provides safety alerts before hypoglycemia and hypoglycemia events. Their initial studies were conducted in controlled settings (i.e., children’s camp or inpatient), and more recently, they have reported data on home use of the MD-Logic artificial pancreas device system in small numbers of patients.

In 2014, Nimri et al published findings of an in-home randomized crossover trial with 24 patients. Eligible patients were between the ages of 12 and 65, had type 1 diabetes diagnosed at least 1 year ago, used an insulin pump for at least 3 months and HbA1c at least 6.5% and less than 10.0%. Patients were excluded if they had a history of diabetic ketoacidosis or severe hypoglycemia within the past month. In random order, patients used the MD-Logic closed loop system for 6 weeks and standard continuous subcutaneous glucose infusion for 6 weeks, with a 5-week washout period between study arms. Before the intervention period, patients had a 1-month run in period with the MD-Logic device. Sensor thresholds on the device were initially set to sound a 20-minute alarm at 350 mg/dL (high-glucose) and 75 mg/dL (low glucose), but patients were permitted to modify or shut off these settings.

Twenty-one patients completed the study, and 19 had valid data from at least 12 nights and were included in the main analyses. In the ITT analysis, the primary outcome, time spent with glucose level below 70 mg/dL was significantly lower in the MD-Logic group.
(median, 2.53%) than the control group (5.16%; p=0.020). Time spent between 70 and 140 mg/dL, a secondary outcome, was significantly higher in the closed loop (47.4%) than the control group (36.26%; p=0.003). There was not a statistically significant between-group difference in the time spent below 50 mg/dL, but this was low in both groups. During the study, severe hypoglycemia occurred in 1 participant in the control arm and none in the intervention arm.

Also in 2014, Nimri et al reported an interim analysis of data from 1 center participating in a multinational 2-arm crossover study. The analysis included 15 patients. Study eligibility criteria included age 10 to 65 years, type 1 diabetes diagnosed at least 1 year ago, use of an insulin pump for at least 3 months, and HbA1c at least 7.0% and less than 10.0%. As in the other Nimri et al study, patients were excluded if they had a history of diabetic ketoacidosis or severe hypoglycemia within the past month. The intervention consisted of 4 consecutive nights of home use of the MD-Logic device and an open-loop glucose monitor and insulin pump system, in random order. The primary end points were the overall time spent in nocturnal hypoglycemia (defined as glucose levels <70 mg/dL) and the percentage of nights mean overnight glucose levels were between 90 and 140 mg/dL in each patient. One of the primary outcomes, time spent below 70 mg/dL was significantly lower in the MD-Logic group (p=0.003), and there was not a significant difference between groups in the other primary outcome.

In 2014, Haidar et al in Canada published data evaluating other non-FDA approved devices. The study compared conventional insulin pump therapy, a single hormone (insulin) artificial pancreas system and a dual hormone (insulin and glucagon) artificial pancreas system. It included 40 patients with type 1 diabetes who were at least 12-years old, had used an insulin pump for at least 3 months, and had an HbA1c no higher than 12%. Each patient had three 24-hour visits to a research facility, during which time they used 1 of the 3 technologies, in random order. The study visits included 3 meals, snacks, social activities, evening exercise and an overnight stay; venous blood samples were taken every 30 minutes during the clinic visits. When the single-hormone device was used, insulin was delivered based on glucose sensor readings and a predictive algorithm. With the dual hormone device, insulin was delivered in the same manner and in addition glucagon was delivered during times of low or falling glucose. During conventional pump sessions, patients received continuous insulin infusion.

The primary study outcome was the proportion of time that plasma glucose concentrations were in the target range (4.0-10.0 mmol/L for 2 hours postprandially, 4.0-8.0 mmol/L at other times). This proportion was 62% (SD=18) in the single-hormone device group, 63% in the dual-hormone device group, and 51% in the conventional pump group. There was a statistically significant difference in the proportion of time spent in the target range between each of the artificial pancreas systems and conventional pump therapy but no significant difference between the single and dual hormone systems. (A p value less than 0.0167 was considered statistically significant.) Findings were similar regarding hypoglycemic episodes, which were defined as plasma glucose concentration below 3.3 mmol/L with symptoms or below 3.0 mmol/L, irrespective of symptoms. The total number of hypoglycemic events was 52 in the conventional pump group, 13 in the single hormone device group, and 9 in the dual hormone device group. There were 13 nocturnal hypoglycemic events in the conventional pump group and no events in either of the artificial pancreas device groups.

**Section Summary**

Several RCTs were identified on control-to-range and control-to-target devices, some of which were conducted in the real-world setting. Findings of the small randomized crossover trials conducted in real-world settings suggest that a combination control-to-
Medical Policy

range and control-to-target device reduces the time spent in the hypoglycemic range compared with conventional pump treatment. However, no devices in this subcategory are approved by the FDA and marketed in the United States.

Ongoing and Unpublished Clinical Trials

An online search of ClinicalTrials.gov on November 14, 2014, identified a number of open-label randomized crossover trials evaluating artificial pancreas device systems. This includes the following trials:

The Performance of an Artificial Pancreas at Home in People With Type 1 Diabetes (NCT02040571): This randomized crossover study, sponsored by St Vincent's Hospital Melbourne, is recruiting patients age 14 and older with type 1 diabetes. A closed loop artificial pancreas device will be compared with an open-loop insulin pump system. A Medtronic artificial pancreas device will be used, and the company is collaborating on the study. The estimated enrollment is 24 patients, and the expected date of study completion is January 2015.

Overnight Type 1 Diabetes Control Under MD-Logic Closed Loop System at the Patient's Home (NCT01726829): This trial is evaluating blood glucose control overnight with MD-Logic Artificial Pancreas system in patients with type 1 diabetes. The intervention consists of 4 consecutive nights using the artificial pancreas device and 4 nights using regular pump therapy, with a 10-day washout period between treatments. The study is currently recruiting patients; estimated enrollment is 75 patients. An interim analysis of this ongoing study was published in 2014 by Nimri et al and is described in an earlier section of the policy.

Clinical Input Received 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.

In response to requests from Blue Cross Blue Shield Association, input on artificial pancreas device systems was received from 2 physician specialty societies and 4 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 threshold suspend feature, is considered medically necessary. Most reviewers thought that there are sufficient supportive data on devices with a LGS feature in patients at high-risk of hypoglycemia, but some thought the data on artificial pancreas device systems remain insufficient.

Summary of Evidence

The evidence base on artificial pancreas systems is small but increasing rapidly. For the U.S. Food and Drug Administration (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.

Supplemental Information

Practice Guidelines and Position Statements

The American Diabetes Association’s 2014 Standards in Diabetes, which addressed continuous glucose monitoring, did not include recommendations concerning artificial pancreas device systems or closed loop systems.\(^9\)

U.S. Preventive Services Task Force Recommendations

Not applicable.

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.

References


**Documentation Required for Clinical Review**

**Initial Request:**
- History and physical and/or consultation notes from referring physician including:
  - Age of patient
  - Type of diabetes and duration, insulin management, and reason for the request
  - Clinical findings supporting inadequate glycemic control
  - Frequency and severity of hypoglycemic episodes or glycemic excursions
  - Patient compliance with diabetes management
  - At least 2 documented nocturnal hypoglycemic events in a 2-week period
- Two serial HbA1c lab results, three months apart and prior to the current request
- Documented frequency of glucose self-testing and number of insulin injections per day or self adjustments on an insulin pump (i.e., blood sugar and insulin logs), for the past 30 days
- Insulin pump therapy usage over the past 6 months

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT®</td>
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<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of</td>
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<tr>
<td>HCPC</td>
<td>Description</td>
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<tr>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report</td>
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<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>
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<td>S1035</td>
<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system, 1 unit = 1 day supply</td>
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<tr>
<td>S1037</td>
<td>Receiver (monitor); external, for use with artificial pancreas device system</td>
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</tbody>
</table>

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or
conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.