HIGHMARK Delaware
HEALTH OPTIONS

CLINICAL MEDICAL POLICY	
Policy Name:	Artificial Pancreas
Policy Number:	MP-085-MD-DE
Responsible Department(s):	Medical Management
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Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 12

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the DME benefits of the Company's Medicaid products for medically necessary artificial pancreas devices.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Hypoglycemic Unawareness – A complication in which a diabetic patient is unaware of a precipitous drop in blood sugar (due to failure to trigger the secretion of epinephrine that would normally generate characteristic symptoms of hypoglycemia that serve to warn the patient of decreasing blood glucose levels). Hypoglycemia unawareness may result in prolonged exposure to hypoglycemia, resulting in a seizure, loss of consciousness, or brain damage. The development of hypoglycemia unawareness may also make intensified blood glucose control more difficult and put the patient at risk for severe hypoglycemia-related complications.

Hypoglycemia – A condition characterized by abnormally low blood glucose levels, usually less than 70 mg/dL. Symptoms may include shakiness, nervousness, sweating, chills and clamminess, and confusion including delirium, hunger, nausea, and tachycardia.

Severe Hypoglycemia – A condition that is the result of a blood sugar level that drops below 35-40 mg/dL. Assistance is required by another individual to treat this condition. If left untreated, permanent neurological damage and death can occur. Symptoms may include seizures or convulsions, loss of consciousness, coma, and hypothermia.

Artificial Pancreas Device System – This system consists of a series of devices (e.g., continuous glucose monitor [CGM], blood glucose device and an insulin pump), and a computer algorithm that communicates with all of these devices. Artificial pancreas systems are also known as closed-loop systems or autonomous systems for glucose control.

Type 1 Diabetes Mellitus (T1DM) – An autoimmune disease that was previously known as insulin-dependent diabetes mellitus (IDDM) or juvenile diabetes. This is a life-long condition that is the result of the immune system attacking the insulin-producing beta cells in the pancreas. The cause of T1DM is not known, and there is no known cure.

Type 2 Diabetes Mellitus (T2DM) – A metabolic disorder previously known as adult onset diabetes mellitus or non-insulin dependent diabetes mellitus (NIDDM). With this form of diabetes, the individual's pancreas cannot produce enough or properly use insulin.

PROCEDURES

1. The use of a U.S. FDA-approved artificial pancreas device system with a low-glucose suspend feature may be considered medical necessary for patients who meet the following criteria:
    - A history of Type 1 diabetes mellitus; AND
    - The device must be FDA approved (e.g., MiniMed 530G, MiniMed 630G); AND
    - The patient is 16 years of age and older; AND
    - There is supporting clinical documentation and prescription by an Endocrinologist; AND
    - Use of an insulin pump therapy for more than 6 months; AND
    - A history of recurrent hypoglycemia or nocturnal hypoglycemia or hypoglycemia unawareness; AND
    - The patient is motivated and knowledgeable in diabetes self-care; AND
    - There are two consecutive A1C levels over 7% within the past 12 months

Covered artificial pancreas devices include:

- MiniMed 530G; OR
- MiniMed 630G

Noncovered artificial pancreas devices include:

- Any non-FDA approved device; OR
- Hybrid closed loop systems such as the MiniMed 670G

The replacement of an FDA-approved artificial pancreas device system with a low glucose suspend feature is considered medically necessary when the criteria above AND all of the following are met:

- The device is out of warranty; AND
- The device is malfunctioning; AND
- The device cannot be refurbished

2. When artificial pancreas devices are not covered
   Artificial pancreas systems limited to closed-loop monitoring devices are not covered. The device is considered experimental and investigational and therefore, not medically necessary. Examples of noncovered conditions for artificial pancreas systems may include but are not limited to:
   - The patient has Type 2 diabetes; OR
   - The patient has gestational diabetes; OR
   - The patient is receiving dialysis; OR
   - The device is not an FDA-approved artificial pancreas device system; OR
   - The patient has a functioning model, and a newer or upgraded model is not medically necessary; OR
   - The use of a hybrid closed-loop insulin delivery system as an artificial pancreas system

3. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

4. Place of Service
   The place of service for artificial pancreas is outpatient.

GOVERNING BODIES APPROVAL

There are several FDA-approved artificial pancreas systems (e.g., MiniMed 530G and the MiniMed 630G). In 2013, the FDA approved the MiniMed 530G. In 2016, the FDA approved the MiniMed 630G and the MiniMed 670G systems as artificial pancreas device systems, single hormone control.

There are no closed-loop/autonomous systems for glycemic control artificial pancreas device systems approved by the FDA. In 2016, the FDA approved the MiniMed 670G, which is a hybrid closed-loop insulin delivery system.

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) on the artificial pancreas systems. There is an NCD (40.3) on the closed-loop blood glucose control device

(CBGCD) that allows for coverage in a hospital setting. The coverage is limited to short-term crisis management of patients with Type 1 diabetes, usually limited to a 24- to 48-hour period.

CODING REQUIREMENTS

Procedure Codes

HCPCS Codes	Description
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
S1036	Transmitter, external, for use with artificial pancreas device system
S1037	Receiver,(monitor); external, for use with artificial pancreas device system

Covered ICD-10 Codes

ICD-10 Codes	Description
E08.39	Diabetes mellitus due to underlying condition with other diabetic ophthalmic complication
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy unspecified
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly) neuropathy
E08.44	Diabetes mellitus due to underlying condition with diabetic amyotrophy
E08.49	Diabetes mellitus due to underlying condition with other diabetic neurological complication
E08.51	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy without gangrene
E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy
E08.618	Diabetes mellitus due to underlying condition with other diabetic arthropathy
E08.620	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E08.628	Diabetes mellitus due to underlying condition with other skin complications
E08.630	Diabetes mellitus due to underlying condition with periodontal disease
E08.638	Diabetes mellitus due to underlying condition with other oral complications
E08.641	Diabetes mellitus due to underlying condition with hypoglycemia with coma
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia
E08.69	Diabetes mellitus due to underlying condition with other specified complication
E08.8	Diabetes mellitus due to underlying condition with unspecified complications
E08.9	Diabetes mellitus due to underlying condition without complications
E09.01	Drug or chemical induced diabetes mellitus with hyperosmolarity with coma
E09.10	Drug or chemical induced diabetes mellitus with ketoacidosis without coma
E09.11	Drug or chemical induced diabetes mellitus with ketoacidosis with coma
E09.21	Drug or chemical induced diabetes mellitus with diabetic nephropathy

E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.319	Drug or chemical induced diabetes mellitus with unspecified diabetic with retinopathy without macular edema
E09.39	Drug or chemical induced diabetes mellitus with other diabetic ophthalmic complication
E09.40	Drug or chemical induced diabetes mellitus with neurological complications with diabetic neuropathy, unspecified
E09.41	Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy
E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic polyneuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly) neuropathy
E09.44	Drug or chemical induced diabetes mellitus with neurological complications with diabetic amyotrophy
E09.49	Drug or chemical induced diabetes mellitus with neurological complications with other diabetic neurological complication
E09.51	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy without gangrene
E09.610	Drug or chemical induced diabetes mellitus with diabetic neuropathic arthropathy
E09.618	Drug or chemical induced diabetes mellitus with other diabetic arthropathy
E09.620	Drug or chemical induced diabetes mellitus with diabetic dermatitis
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E09.628	Drug or chemical induced diabetes mellitus with other skin complications
E09.630	Drug or chemical induced diabetes mellitus with periodontal disease
E09.638	Drug or chemical induced diabetes mellitus with other oral complications
E09.641	Drug or chemical induced diabetes mellitus with hypoglycemia with coma
E09.649	Drug or chemical induced diabetes mellitus with hypoglycemia without coma
E09.65	Drug or chemical induced diabetes mellitus with hyperglycemia
E09.69	Drug or chemical induced diabetes mellitus with other specified complication
E09.8	Drug or chemical induced diabetes mellitus with unspecified complications
E09.9	Drug or chemical induced diabetes mellitus without complication
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
E10.21	Type 1 diabetes mellitus with other diabetic kidney complication
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral

E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E10.3312	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3313	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E10.3392	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E10.3393	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye

E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment,
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment,
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly) neuropathy
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49	Type 1 diabetes mellitus with other diabetic neurologic complication
E10.51	Type 1 diabetes mellitus with diabetic angiopathy without gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.59	Type 1 diabetes mellitus with other circulatory complications
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy
E10.620	Type 1 diabetes mellitus with diabetic dermatitis
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E10.628	Type 1 diabetes mellitus with other skin complications
E10.630	Type 1 diabetes mellitus with periodontal disease
E10.638	Type 1 diabetes mellitus with other oral complications
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma
E10.65	Type 1 diabetes mellitus with hyperglycemia

E10.69	Type 1 diabetes mellitus with other specified complications
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus with without complications
O24.011	Pre-existing diabetes mellitus, Type 1, in pregnancy, first trimester
O24.012	Pre-existing diabetes mellitus, Type 1, in pregnancy, second trimester
O24.013	Pre-existing diabetes mellitus, Type 1, in pregnancy, third trimester
O24.019	Pre-existing diabetes mellitus, Type 1, in pregnancy, unspecified trimester
O24.02	Pre-existing diabetes mellitus, Type 1, in childbirth
O24.03	Pre-existing diabetes mellitus, Type 1, in the puerperium
Z79.4	Long term (current) use of insulin

Non-covered Diagnosis Codes
Requests for the following diagnosis codes requires review by a Medical Director

ICD-10 Codes	**Description**
E16.9	Disorder of pancreatic internal secretion, unspecified [nesidioblastosis]
O24.111	Pre-existing diabetes mellitus, Type 2, in pregnancy, first trimester
O24.112	Pre-existing diabetes mellitus, Type 2, in pregnancy, second trimester
O24.113	Pre-existing diabetes mellitus, Type 2, in pregnancy, third trimester
O24.119	Pre-existing diabetes mellitus, Type 2, in pregnancy, unspecified trimester
O24.12	Pre-existing diabetes mellitus, Type 2, in childbirth
O24.13	Pre-existing diabetes mellitus, Type 2, in puerperium
O24.410	Gestational diabetes mellitus in pregnancy, diet controlled
O24.414	Gestational diabetes mellitus in pregnancy, insulin controlled
O24.419	Gestational diabetes mellitus in pregnancy, unspecified control
O24.420	Gestational diabetes mellitus in childbirth, diet controlled
O24.424	Gestational diabetes mellitus in childbirth, insulin controlled
O24.429	Gestational diabetes mellitus in childbirth, unspecified control
O24.430	Gestational diabetes mellitus in the puerperium, diet controlled
O24.434	Gestational diabetes mellitus in puerperium, insulin controlled
O24.439	Gestational diabetes mellitus in puerperium, unspecified control

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Diabetes mellitus is a well-known chronic disabling disease that affects an estimated 26 million people in the United States (ADA, 2011.) The Diabetes Control and Complications Trial highlighted the importance of tightly controlling glycemia in order to prevent long-term complications (Fleisher et al., 1993).

Artificial pancreas systems link a glucose monitor to an insulin infusion pump. The insulin pump automatically reduces and increases the subcutaneous delivery of insulin according to subcutaneous glucose levels based on control algorithms to mimic the glucose regulating function of a healthy pancreas.

The ideal artificial pancreas system would monitor glucose levels in the body and adjust the delivery of insulin automatically in order to reduce hyperglycemia and to minimize hypoglycemic events with little to no action of the patient. There are multiple devices available which are based on various control algorithms.

The FDA (2017) provides a description on the three main categories of artificial pancreas delivery systems, such as:

1) Threshold Suspend Device System
   The goal of a threshold suspend device system is to help reverse a dangerous drop in blood glucose level (hypoglycemia) or reduce its severity by temporarily suspending insulin delivery when the glucose level falls to or approaches a low glucose threshold. These are sometimes referred to as 'low glucose suspend systems'. This kind of system serves as a potential back-up when a patient is unable to respond to a low blood sugar (hypoglycemic) event. Patients using this system will still need to be active partners in managing their blood glucose levels by periodically checking their blood glucose levels and by eating or giving themselves insulin.
2) Insulin-Only System
   The insulin-only system achieves a target glucose level by automatically increasing or decreasing the amount of insulin infused based on the CGM values. These systems could be hybrid systems that only automatically adjust basal insulin with the user manually delivering bolus insulin to cover meals, or could be fully closed-loop systems, where the system can automatically adjust basal insulin and provide insulin for meals.
3) Bi-hormonal Control System
   The bi-hormonal control system achieves a target glucose level by using two algorithms to instruct an infusion pump to deliver two different hormones, one hormone (insulin) to lower glucose levels and another (such as glucagon) to increase blood glucose levels. This system mimics the glucose-regulating function of a healthy pancreas more closely than an insulin-only system.

American Diabetes Association

In 2017, the American Diabetes Association (ADA) confirmed its previous recommendation of sensor augmented insulin pump therapy with a low-glucose suspend feature for patients with Type 1 diabetes and nocturnal hypoglycemia. Additionally, ADA referenced several trials of artificial pancreas devices, determining that "this technology may be particularly useful in insulin-treated patients with hypoglycemia unawareness and/or frequent hypoglycemic episodes." The ADA's 2017 standards in diabetes acknowledged that, while more long-term studies of continuous glucose monitoring are needed, the evidence indicates the safety of hybrid closed-loop systems.

Low-Glucose Suspend Device

There is evidence from a multi-center randomized controlled clinical trial in which individuals with Type 1 diabetes utilized an artificial pancreas device system with a low-glucose suspend feature (Bergenstal et al., 2013). In the 2011 ASPIRE (automation to simulate pancreatic insulin response) trial, the selected patients were between the ages of 16 to 70 years old, had been diagnosed with Type 1 diabetes, had A1C levels between 5.8% and 10.0%, had been using an insulin pump for at least six months, and had at least two nocturnal hypoglycemic events (≤ 65 mg/dL) that lasted more than 20 minutes. The three-month study was to examine the efficacy of the low-glucose suspend sensor in exercise-induced hypoglycemia. The relevant outcomes of the trial were that there were significantly less hypoglycemia in the treatment group compared to the control group. The combined daytime and nighttime hypoglycemic events were significantly reduced in the intervention group.

Hybrid Closed-Loop Insulin Delivery System

The hybrid closed-loop insulin delivery system evidence includes a single-arm study and a multicenter pivotal trial using a device cleared by the Food and Drug Administration and three 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-arm study 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. The pivotal trial evaluated the safety of the device and was not designed to address efficacy.

There is a need for published data on the efficacy of the semiautomatic insulin adjustment feature of the hybrid closed-loop insulin delivery devices compared with current standard care. Of the three crossover RCTs assessing a related device conducted outside the United States, two found significantly better outcomes (i.e., time spent in nocturnal hypoglycemia and time spent in preferred glycemic range) with the new 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). The evidence is insufficient to determine the effects of the technology on health outcomes.

Professional Societies	Comments
American Diabetes Association (ADA)	Recommends a sensor-augmented, low glucose threshold suspend pump for patients with frequent nocturnal hypoglycemia and/or hypoglycemic unawareness. (2018)
CMS	There is no NCD or LCD addressing artificial pancreas systems. The CMS NCD 40.3, Closed-Loop Blood Glucose Control Device (CBGCD) provides direction that this system is only covered when provided as a short-term treatment for critically ill patients that are inpatient.
Hayes	In October 2016, Hayes reported on the MiniMed 670G and indicated that there was insufficient evidence to support coverage.
American Association of Clinical Endocrinologists and American College of Endocrinology	Recommends a sensor-augmented, low glucose threshold suspend pump for patients with frequent nocturnal hypoglycemia and/or hypoglycemic unawareness. (2015)

Hypoglycemia Awareness Questionnaire

Question	Never	Rarely	Occasionally	Usually
I get tired or exhausted				
I forget things easily				
I feel sleepy during the day				
I get down or depressed				
I get down over nothing				
I have trouble concentrating				
I get nervous or shaky				
I easily get angry				
I eat or crave sweets, or once used to				
I awaken during the night				

Total				

Scoring
Total the number of checks in each column for RARELY, OCCASIONALLY, AND USUALLY and then calculate as follows:

Rarely (Total) x 1=	
Occasionally (Total) x 2 =	
Usually (Total) x 3 =	
Total Score	

If your **TOTAL SCORE** is:
Less than 8: Hypoglycemic disease is unlikely.
Between 8 to 15: Hypoglycemic disease is possible.
Above 15: Hypoglycemic disease is present.

POLICY SOURCE(S)

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CMS NCD for Closed-Loop Glucose Control Device (CBGCD) (40.3) CMS web site. Accessed December 4, 2018.

Policy History

Date	Description
03/22/2019	Based on feedback, a separate artificial pancreas medical policy was created from information originally included in the CGM medical Policy, MP-040-MD-DE
07/16/2019	QI/UM Committee Review Approval
09/16/2019	Provider effective date