Artificial Pancreas

Policy ID:	HHO-DE-MP-1048
Approved By:	Highmark Health Options – Market Leadership
Provider Notice Date:	
Original Effective Date:	N/A
Annual Approval Date:	10/2022
Last Revision Date:	10/08/2021
Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 8

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

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.

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

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.

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently serves Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

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.

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.

2. Covered artificial pancreas devices include:

    - MiniMed 530G; or
    - MiniMed 630G

3. Noncovered artificial pancreas devices include:

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

4. 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

5. 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.

6. 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.

7. 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.

ELIGIBLE DIAGNOSIS CODES

Code						
E08.39	E08.40	E08.41	E08.42	E08.43	E08.44	E08.49
E08.51	E08.610	E08.618	E08.620	E08.622	E08.628	E08.630
E08.638	E08.641	E08.65	E08.69	E08.8	E08.9	E08.01
E09.10	E09.11	E09.21	E09.311	E09.319	E09.39	E09.40
E09.41	E09.42	E09.43	E09.44	E09.49	E09.51	E09.610
E09.618	E09.620	E09.622	E09.628	E09.630	E09.638	E09.641
E09.649	E09.65	E09.69	E09.8	E09.9	E10.10	E10.11
E10.21	E10.22	E10.29	E10.311	E10.319	E10.3211	E10.3212

E10.3213	E10.3291	E10.3292	E10.3293	E10.3311	E10.3312	E10.3313
E10.3391	E10.3392	E10.3393	E10.3411	E10.3412	E10.3413	E10.3491
E10.3492	E10.3493	E10.3511	E10.3512	E10.3513	E10.3521	E10.3522
E10.3523	E10.3531	E10.3532	E10.3533	E10.3541	E10.3542	E10.3543
E10.3551	E10.3552	E10.3553	E10.3591	E10.3592	E10.3593	E10.36
E10.37X1	E10.37X2	E10.37X3	E10.39	E10.40	E10.41	E10.42
E10.43	E10.44	E10.49	E10.51	E10.52	E10.59	E10.610
E10.618	E10.620	E10.621	E10.622	E10.628	E10.638	E10.641
E10.649	E10.65	E10.69	E10.8	E10.9	O24.011	O24.012
O24.013	O24.019	O24.02	O24.03	Z79.4		

THE FOLLOWING DIAGNOSIS CODES REQUIRE A REVIEW BY A MEDICAL DIRECTOR TO BE ELIGIBLE

Codes						
E16.9	O24.111	O24.112	O24.113	O24.119	O24.12	O24.13
O24.410	O24.414	O24.419	O24.420	O24.424	O24.429	O24.430
O24.434	O24.439					

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 SOURCES

American Diabetes Association. Chapter 8. Pharmacologic approaches to glycemic treatment: standards of medical care in diabetes-2018. 2018. Diabetes care. 2018.41(Suppl 1):S78-S85. Accessed December 4, 2018.

Beklari E et al. Artificial pancreas treatment for outpatients with type 1 diabetes: systematic review and meta-analysis. BMJ 2018 April 18; 361:k1310. Accessed December 4, 2018.

Bergenstal RM, Klonoff DC, Garg SK, et al. Threshold-based insulin pump interruption for reduction of hypoglycemia. N Eng J Med. Jul 18 2013;369(3):224-232. Accessed December 4, 2018.

Bergenstal RM, Klonoff DC, Garg SK, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. N Engl J Med. 2013; 369(3):224-32. Accessed on November 15, 2016.

Boughton CK, Hovorko R. Is an artificial pancreas (closed loop system) for Type 1 diabetes effective? Diabetic Med 2018 Sept DOI 10.1111/dme. 13816. Accessed December 4, 2018.

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

Hayes Inc., Hayes Medical Technology Report. MiniMed 670Gsystem (Medtronic, Inc.). Lansdale, PA. Hayes Inc.; October 16, 2016. Accessed December 4, 2018.

Medtronic, Inc. MiniMed 530G system. Summary of Safety and Effectiveness Data. Premarket Approval Application No. P120010. Rockville, MD: U.S. Food and Drug Administration; September 26, 2013.

Nørgaard K, Scaramuzza A, Bratina N, et al. Interpret Study Group O. Routine sensor-augmented pump therapy in Type 1 diabetes: The INTERPRET Study. Diabetes Technol Ther. 2013; 15(4):273-280. Accessed on November 11, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: # 01/2016-001. Artificial Pancreas. 1/7/2016. Option #4. Accessed on November 4, 2016.

U.S. Food and Drug Administration. Types of artificial pancreas device systems. Last update 12/17/2017. Accessed December 4, 2018.

POLICY UPDATE HISTORY

3/22/2019	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.

REQUIRED APPROVAL SIGNATURES

Name	Signature	Date