MASSACHUSETTS

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Medical Policy

Artificial Pancreas Device Systems

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Policy Number: 720

BCBSA Reference Number: 1.01.30

NCD/LCD: N/A

Related Policies

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid, #107

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Use of a U.S Food and Drug Administration – approved artificial pancreas device system with a low glucose suspend feature may be considered **MEDICALLY NECESSARY** in patients age 16 and older with type 1 diabetes who meet at least one of the following criteria:

- Patients with recurrent, unexplained, severe, (generally blood glucose levels less than 50 mg/dl) hypoglycemia for whom hypoglycemia puts the patient or others at risk.
- Patients who become pregnant whose diabetes is poorly controlled.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue[SM]	Prior authorization is **not required**.
Medicare PPO Blue[SM]	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
S1034	Artificial pancreas device system (eg, low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (eg, 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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM diagnosis codes:	Code Description
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 Diabetic Nephropathy
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
E10.36	Type 1 Diabetes Mellitus With Diabetic Cataract
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 Neurological Complication
E10.51	Type 1 Diabetes Mellitus With Diabetic Peripheral 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 Complication
E10.8	Type 1 Diabetes Mellitus With Unspecified Complications
E10.9	Type 1 Diabetes Mellitus Without Complications

Description

Tight glucose control in patients with diabetes has been associated with improved outcomes. The American Diabetes Association recommends a glycated hemoglobin (HbA1c) 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 (eg, coma, seizure, transient ischemic attack, stroke), heart (eg, cardiac arrhythmia, myocardial ischemia, infarction), eye (eg, vitreous hemorrhage, worsening of retinopathy), as well as cause hypothermia and accidents that may lead to injury. Fear of 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 a LGS device systems to the more complex bihormonal control-to-target systems.

FDA has described 3 main categories of artificial pancreas device systems:

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.

FDA is actively involved in advancing the development of artificial pancreas device systems eg, providing guidance to industry, sponsoring public forums, facilitating discussions between government and non-governmental researchers, and seeking ways to reduce research and approval review time.

Summary

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.

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 (RCTs) conducted in real-world settings report that outcomes are improved in selected patients, ie, those who meet entry criteria of the clinical trials. 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 low glucose suspend may be considered medically necessary when criteria are met.

Policy History

Date	Action
4/2018	Policy criteria clarified to restore to the original version. 4/24/2018
4/2018	BCBSA National medical policy review. Medically necessary and investigational indications revised. Clarified coding information. Effective 4/1/2018.
12/2016	New references added from BCBSA National medical policy.
10/2016	Clarified coding information.
1/2016	New references added from BCBSA National medical policy.
5/2015	New medical policy describing medically necessary and investigational indications. Effective 5/1/2015.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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Endnotes

[1] Based on National MPRM and expert opinion