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OVERVIEW

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.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

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 in a 2-week period

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products and is obtained via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Use of an FDA-approved artificial pancreas device system with a low glucose suspend feature may be considered **medically necessary** in patients with type 1 diabetes when medical criteria are met.

Use of an artificial pancreas device system is considered **not medically necessary** in all other situations.

COVERAGE

Benefits may vary by groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable office visit benefits/coverage, Medical Equipment, Medical Supplies and Prosthetic Devices benefits/coverage and Diabetic equipment/supplies benefits/coverage.

BACKGROUND

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 (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 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 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

2. 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.

3. 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 such as those that deliver insulin-only, bi-hormonal systems and hybrid systems.

The evidence base on artificial pancreas systems is small but increasing rapidly. For the 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 such as 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 U.S, and therefore, all other types of artificial pancreas devices are considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are covered when medical criteria are met.

S1034

S1036

S1037

RELATED POLICIES

Continuous Glucose Monitoring

Preauthorization via Web-Based Tool for Durable Medical Equipment (DME)

PUBLISHED

Provider Update, July 2015

Provider Update, October 2014

REFERENCES

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