FEP 1.01.30 Artificial Pancreas Device Systems

Effective Date: April 15, 2018

Related Policies: None

Artificial Pancreas Device Systems

Description

Artificial pancreas device systems link a glucose monitor to an insulin infusion pump that automatically takes action (eg, suspends or adjusts insulin) 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.

FDA REGULATORY STATUS

In 2013, the MiniMed® 530G System (Medtronic) was approved by FDA through the premarket approval process (P120010). This system integrates an insulin pump and glucose meter and includes an LGS feature. The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is at or below a preset threshold within the 60- 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, 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.

In 2016, the MiniMed® 630G System with SmartGuard™ (Medtronic) was approved through the premarket approval process (P150001). It is also for use in patients 16 years and older. The system is similar to the 530G but offers updates to the system components including waterproofing. The threshold suspend feature is the same as in the 530G. FDA product code: OZO.

In 2016, the MiniMed® 670G System (Medtronic), a hybrid closed-loop insulin delivery system, was approved by FDA through the premarket approval process (P160017). It consists of an insulin pump, a glucose meter, and a transmitter, linked by a proprietary algorithm and, the SmartGuard Hybrid Closed Loop. The system includes an LGS feature that suspends insulin delivery; either suspend on low or suspend before low and have an optional alarm. Additionally, the system involves semiautomatic insulin-level adjustment to preset targets. As a hybrid system; basal insulin levels are automatically adjusted, but the patient needs to administer premeal insulin boluses. The system is approved for patients with type 1 diabetes who are at least 14 years old. It is contraindicated for children under age 7 and patients who require less than a total daily insulin dose of 8 units. The 670G system is expected to be available commercially in 2017 through a priority access program, which will be offered to patients already using the Medtronic 630G system.

FDA product code: OZP.

POLICY STATEMENT

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 with type 1 diabetes who meet all of the following criteria:

- Age 16 and older
- Type 1 diabetes
- Glycated hemoglobin level 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.

Use of hybrid closed loop insulin delivery system (including the Food and Drug Administration–approved device for age 14 and older) as an artificial pancreas device system is considered **not medically necessary.**

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a low-glucose suspend feature, the evidence includes 2 RCTs conducted in-home settings. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Primary eligibility criteria of the key RCT, the ASPIRE trial, were ages 16-to-70 years old, type 1 diabetes, glycated hemoglobin levels between 5.8% and 10.0%, and at least 2 nocturnal hypoglycemic events (≤65 mg/dL) lasting more than 20 minutes during a 2-week run-in phase. Both trials required at least 6 months of insulin pump use. Both RCTs reported significantly less hypoglycemia in the treatment group than in the control group. In both trials, primary outcomes were favorable for the group using an artificial pancreas system; however, 1 trial was limited by its nonstandard reporting of hypoglycemic episodes, and the other trial was no longer statistically significant when 2 outliers were excluded from analysis. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have type 1 diabetes who receive a hybrid closed-loop insulin delivery system, the evidence includes a single-arm study and a multicenter pivotal trial using a device cleared by the Food and Drug Administration and 3 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, submitted with other materials for device approval, evaluated the safety of the device and was not designed to address efficacy. Published data are needed on the efficacy of the semiautomatic insulin adjustment feature of the new device compared with current standard care. Of the 3 crossover RCTs assessing a related device conducted outside the United States, two found significantly better outcomes (ie, 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Diabetes Association

In 2017, the American Diabetes Association (ADA) confirmed its previous recommendation of sensoraugmented insulin pump therapy with a low-glucose suspend feature for patients with type 1 diabetes and nocturnal hypoglycemia.[1] 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.

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

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POLICY HISTORY

Date	Action	Description
March 2015	New Policy	Policy created with information on this topic previously addressed in Policy No. 1.01.20 and a literature review through December 20, 2014. FDA-approved artificial pancreas device system with low glucose suspend feature may be considered medically necessary for patients with type 1 diabetes who meet criteria; otherwise artificial pancreas device systems are considered not medically necessary.
June 2016	Update Policy	Policy updated with literature review through October 1, 2015; references 6, 11, and 12 added. Policy statements unchanged.
March 2018	Update Policy	Policy updated with literature review through October 15, 2017; references 1, 9, and 14 added. Per FEP PMPC, policy statement added that use of hybrid closed loop insulin delivery system as an artificial pancreas device system (including the Food and Drug Administration–approved device for age 14 and older) is considered medically necessary.