Medical Policy Manual

**Topic:** Artificial Pancreas Device System (APDS)  
**Date of Origin:** September 2000

**Section:** DME  
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**IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

**DESCRIPTION**

Maintenance of a target blood glucose and target glycated hemoglobin (HgA1c < 7%), a marker which is used as a proxy for average blood glucose, is now considered standard of care for diabetic patients. Also known as tight diabetic control, this strategy is intended to prevent severe hypoglycemic events and lower the risk of cardiovascular disease mortality associated with uncontrolled glycemia.[1] The strategy involves frequent home blood glucose checks (fingersticks) several times each day (i.e., before meals and at bedtime). Measurement of blood glucose at such specific points in time may not reveal trends in blood glucose, particularly those associated with nighttime sleep.

Artificial pancreas or artificial pancreas device systems (APDSs) are currently under development by device manufacturers as an adjunct to traditional self blood glucose monitoring to help achieve tight glucose control. According to the U.S. Food and Drug Administration (FDA)[2], an artificial pancreas device system is sometimes referred to as a “closed-loop” system or an ‘autonomous system for glycemic control.’ “In the future, APDSs will not only monitor glucose levels in the body but also automatically adjust the delivery of insulin to reduce high blood glucose levels (hyperglycemia) and minimize the incidence of low blood glucose (hypoglycemia) with little or no input from the patient.” According to the FDA, an artificial pancreas device systems consists of 3 components that work together to provide an autonomous system for glycemic control:

- Continuous glucose monitor (CGM) device which may be calibrated based on blood glucose measures.
- Control algorithm-software which calculates dosing instructions sent to the infusion pump.
Infusion pump-the pump adjusts the insulin delivery.

One technology associated with artificial pancreas development is a “low glucose suspend (LGS)” feature included with an insulin pump. The LGS feature is designed to suspend insulin delivery when plasma glucose levels fall below a pre-specified threshold. The LGS feature is not considered an artificial pancreas as it does not autocorrect for highs and lows with minimal patient involvement, also known as a closed-loop system. The LGS is, however, a step toward the development of APDSs. Currently there is no closed-loop APDSs approved by the U.S. Food and Drug Administration (FDA) for commercial use.

**Regulatory Status**

**Hybrid Closed-Loop Insulin Pump Systems**

Recently, the MiniMed® 670G System with SmartGuard™ by Medtronic© received PMA approval from the FDA.[3] This hybrid closed-loop system uses a CGM to automatically adjust basal insulin pump delivery to a target blood glucose of 120mg/dl. While it does automatically increase or decrease the basal insulin in response to CGM readings using algorithm software, it is not a completely closed-loop system, and the user is still required to provide input for insulin boluses after meals. Therefore, it does not meet the definition of an APDS.


**Insulin Pumps with Low Glucose Suspend (LGS) or Threshold (LGT) Feature**

The MiniMed® 630G System from Medtronic© has also recently received PMA approval from the FDA.[4] Like the earlier Medtronic© MiniMed® 530G System, it includes a CGM device system with a “low glucose suspend” feature.[5] Although the FDA has classified these MiniMed® Systems as artificial pancreas device systems, they do not meet the definition of an APDS as they are not closed-loop systems. According to the FDA PMA summaries, these devices are “not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required,” and “not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond” to the system alarms to prevent or treat their hypoglycemia.


The MiniMed 530G System consists of the following devices: MiniMed® 530G Insulin Pump, Enlite® Sensor, and the MiniLink Real-Time System.

**MEDICAL POLICY CRITERIA**

**Note:** This policy is not intended to address insulin pumps that include a basal insulin delivery algorithm and/or a low glucose or low threshold suspend feature, which may be considered medically necessary.
Use of an artificial pancreas device system, is considered investigational.

SCIENTIFIC EVIDENCE

The key clinical outcomes regarding the clinical utility of artificial pancreas device systems (APDSs) relate to their ability to improve the morbidity/mortality associated with clinically significant, severe, and acute hypoglycemia or hyperglycemic events. Because diabetic control encompasses numerous variables including diabetic regimen and patient self-management, randomized, controlled trials are important to isolate the contribution of APDSs to the overall diabetic management.

Literature Appraisal

Insulin Pump Systems with Low Glucose Suspend Features

The data submitted to the FDA on the MiniMed® 670G System included the results of a multicenter, single-arm, nonrandomized pivotal trial of the device in 123 patients, aged 14-75 years, with type I diabetes. The trial consisted of a 2-week run-in period in which the device was used as a sensor augmented pump without automated features. This was followed by a 3-month in-home period, with patients using the pump in Manual Mode for the first 6 days to allow collection of baseline data prior to the study phase, in which the device was used in Auto Mode for the remaining time. There were no serious adverse events, including severe hypoglycemic events, related to the device use during the study. Because this trial had no comparison group, there were no statistically powered endpoints and no evaluation of the device’s relative effectiveness.

To date, there are several randomized controlled trials (RCTs) evaluating insulin pumps with a low glucose suspend (LGS) feature[6-11], which is thought to be an initial step toward the development of an automated, closed-loop artificial APDSs

Artificial Pancreas Device System (APDS)

A number of RCTs[12-14] have evaluated the safety and efficacy of closed-loop APDSs, which automatically monitors glucose levels and adjust insulin doses; however, none of these devices have received FDA approval.

Conclusions

Evidence is insufficient regarding the use of an artificial pancreas device system (APDS) to reduce high blood glucose levels (hyperglycemia) and minimize the incidence of low blood glucose (hypoglycemia) in patients with diabetes. To date, no true APDS have been approved by the U.S Food and Drug Administration (FDA). Evidence from well-designed trials[15] with comparable outcome measures[16] is needed to demonstrate the risks and benefits of APDSs for diabetic patients. In-home studies with long-term follow-up will also be important for evaluating the safety and efficacy of these devices, to replicate real use conditions.[17] Therefore, APDSs are considered investigational for the purpose of improving glucose control in the general diabetic population.

Clinical Practice Guidelines
There are no evidence-based clinical practice guidelines that recommend the use of an artificial pancreas for the management of diabetes.

Summary

There is not enough research to demonstrate that an artificial pancreas device system (APDS) will maintain blood glucose levels in a healthy range for patients with diabetes. At this time, no APDSs have been approved by the U.S Food and Drug Administration (FDA). More research is needed to show the safety of APDs in addition to how APDSs can improve important health outcomes for diabetic patients. Therefore, APDSs are considered investigational for the purpose of glucose control in people living with diabetes.

REFERENCES


**CROSS REFERENCES**

None

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