Regence Oregon and Utah | Regence Idaho and select counties of Washington

**Medical Policy Manual** Durable Medical Equipment, Policy No. 77

# *Artificial Pancreas Device System (APDS)*

**Effective**: November 1, 2018

**Next Review:** October 2019
**Last Review:** October 2018

## 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

Artificial Pancreas Device Systems (APDS), is a closed-loop system which monitors glucose levels and automatically adjusts the delivery of insulin to help achieve tight glucose control.

## 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**.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## CROSS REFERENCES

None

## BACKGROUND

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.

Development of the APDS is occurring in stages. One stage uses technology *associated with* artificial pancreas development and has 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.

There are several hybrid or LGS systems that are FDA approved. One such system is the MiniMed® 670G System with SmartGuard™ by Medtronic© which 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.

The next stage will have all the components working together (insulin pump, CGM, and control algorithm), with little or no user input. The user will not have to check blood sugar or inject insulin manually. According to the FDA, the control algorithm can be in a computer, cellular phone or the insulin pump.[2] The FDA does not require the control algorithm be integrated into the insulin pump. There are APDSs undergoing clinical trials that include algorithms to control the insulin.[4,5]

## REGULATORY STATUS

Currently there are no closed-loop/autonomous systems for glycemic control APDSs that can truly replace the function of a pancreas approved by the U.S. Food and Drug Administration (FDA) for commercial use.

## EVIDENCE SUMMARY

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.

Randomized controlled trials have evaluated insulin pumps with various functionalities including a low glucose suspend (LGS) feature which is thought to be an initial step toward the development of an automated, closed-loop artificial APDS.[6-11] However, these devices are not true "closed-loop" systems and do not replace the function of a pancreas; therefore, are not addressed by this policy.

There are additional studies evaluating APDSs that include algorithms used in conjunction with an insulin pump and CGM, but clinical trials are ongoing and no true APDSs are FDA approved.[4,5,12-14]

## PRACTICE GUIDELINE SUMMARY

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

## SUMMARY

Currently, there are no artificial pancreas device systems (APDS) that truly replace the function of a pancreas that have been approved by the U.S Food and Drug Administration (FDA). Therefore, APDSs are considered investigational for people living with diabetes.

## REFERENCES


1. Skyler, JS, Bergenstal, R, Bonow, RO, et al. Intensive glycemic control and the prevention of cardiovascular events: implications of the ACCORD, ADVANCE, and VA diabetes trials: a position statement of the American Diabetes Association and a scientific statement of the American College of Cardiology Foundation and the American Heart Association. *Circulation*. 2009 Jan 20;119(2):351-7. PMID: 19095622
2. U.S. Food and Drug Administration (FDA). Medical Devices: Artifical Pancreas Device System (APDS). What is the Pancreas? What is an artificial pancreas device system? Page last updated: 03/30/2015. [cited 10/4/2018]; Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ArtificialPancreas/ucm259548.htm
3. FDA website. MiniMed® 670G System by Medtronic©. [cited 10/4/2018]; Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017b.pdf

4. Trevitt, S, Simpson, S, Wood, A. Artificial Pancreas Device Systems for the Closed-Loop Control of Type 1 Diabetes: What Systems Are in Development? *J Diabetes Sci Technol*. 2016 May;10(3):714-23. PMID: 26589628
5. Nimri, R, Danne, T, Kordonouri, O, et al. The "Glucositter" overnight automated closed loop system for type 1 diabetes: a randomized crossover trial. *Pediatric diabetes*. 2013 May;14(3):159-67. PMID: 23448393
6. Ly, TT, Nicholas, JA, Retterath, A, Lim, EM, Davis, EA, Jones, TW. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycemia in patients with type 1 diabetes: a randomized clinical trial. *JAMA : the journal of the American Medical Association*. 2013 Sep 25;310(12):1240-7. PMID: 24065010
7. Garg, S, Zisser, H, Schwartz, S, et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006 Jan;29(1):44-50. PMID: 16373894
8. Phillip, M, Battelino, T, Atlas, E, et al. Nocturnal glucose control with an artificial pancreas at a diabetes camp. *N Engl J Med*. 2013 Feb 28;368(9):824-33. PMID: 23445093
9. Hirsch, IB. Reducing hypoglycemia in type 1 diabetes: an incremental step forward. *Diabetes Technol Ther*. 2013 Jul;15(7):531-2. PMID: 23789651
10. Bergenstal, RM, Welsh, JB, Shin, JJ. Threshold insulin-pump interruption to reduce hypoglycemia. *N Engl J Med*. 2013 Oct 10;369(15):1474. PMID: 24106952
11. Bergenstal, RM, Klonoff, DC, Garg, SK, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. *N Engl J Med*. 2013 Jul 18;369(3):224-32. PMID: 23789889
12. Haidar, A, Legault, L, Messier, V, Mitre, TM, Leroux, C, Rabasa-Lhoret, R. Comparison of dual-hormone artificial pancreas, single-hormone artificial pancreas, and conventional insulin pump therapy for glycaemic control in patients with type 1 diabetes: an open-label randomised controlled crossover trial. *The lancet Diabetes & endocrinology*. 2015 Jan;3(1):17-26. PMID: 25434967
13. Weisman, A, Bai, JW, Cardinez, M, Kramer, CK, Perkins, BA. Effect of artificial pancreas systems on glycaemic control in patients with type 1 diabetes: a systematic review and meta-analysis of outpatient randomised controlled trials. *The lancet Diabetes & endocrinology*. 2017 Jul;5(7):501-12. PMID: 28533136
14. Overnight Type 1 Diabetes Control Under MD-Logic Closed Loop System at the Patient's Home. [cited 9/25/17]; Available from: https://clinicaltrials.gov/ct2/show/NCT01726829
15. BlueCross BlueShield Association Medical Policy Reference Manual "Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid." Policy No. 1.01.20
16. BlueCross BlueShield Association Medical Policy Reference Manual "Artificial Pancreas Device Systems." Policy No. 1.01.30

## CODES

| Codes | Number | Description |
|---|---|---|
| CPT | None | |
| HCPCS | 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 |

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| | S1035 | Sensor; Invasive (eg, Subcutaneous), Disposable, For Use With Artificial Pancreas Device System |
| | S1036 | Transmitter; External, For Use With Artificial Pancreas Device System |
| | S1037 | Receiver (Monitor); External, For Use With Artificial Pancreas Device System |

***Date of Origin:*** *September 2000*