**Medical Coverage Policy |** Artificial Pancreas Device System

**EFFECTIVE DATE:** 02/01/2024
**POLICY LAST REVIEWED:** 10/04/2023

## OVERVIEW

Automated insulin delivery systems, also known as artificial pancreas device systems, link a glucose monitor to an insulin infusion pump that automatically takes action (eg, suspends or adjusts insulin infusion) based on the glucose monitor reading. These devices are proposed to improve glycemic control in patients with insulin-dependent diabetes, in particular, reduction of nocturnal hypoglycemia.

## MEDICAL CRITERIA

**Medicare Advantage Plans and Commercial Products**

Use of a U.S. Food and Drug Administration (FDA) cleared or approved automated insulin delivery system (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 6 years and older
- 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 an FDA cleared or approved automated insulin delivery system (artificial pancreas device system) designated as a hybrid closed-loop insulin delivery system (with low glucose suspend and suspend before low features) may be considered medically necessary in patients with type 1 diabetes who meet all of the following criteria:

- Over age 6 years AND
  - 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.

OR

- Age 2 to 6 years AND
  - Clinical diagnosis of type 1 diabetes for 3 months or more
  - Used insulin pump therapy for more than 3 months
  - Glycated hemoglobin level <10.0%
  - Minimum daily insulin requirement (Total Daily Dose) of greater than or equal to 8 units

Use of an FDA cleared or approved automated insulin delivery system (artificial pancreas device system) designated as a closed-loop insulin delivery system may be considered medically necessary in individuals with type 1 diabetes who meet all of the following criteria:

- Age 6 years and older AND
  - Clinical diagnosis of type 1 diabetes for 12 months or more;
  - Using insulin for at least 12 months;
  - Diabetes managed using the same regimen (either pump or multiple daily injections, with or without continuous glucose monitoring) for 3 months or longer.

## PRIOR AUTHORIZATION

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

## POLICY STATEMENT

**Medicare Advantage Plans and Commercial Products**

Use of an FDA cleared or approved automated insulin delivery system (artificial pancreas device system) with a low-glucose suspend feature may be considered medically necessary in patients with type 1 diabetes when the medical criteria above are met.

Use of an FDA-approved automated insulin delivery system (artificial pancreas device system) designated as hybrid closed-loop insulin delivery system (with low glucose suspend and suspend before low features) may be considered medically necessary in patients with type 1 diabetes when the medical criteria above are met**.**

Use of an automated insulin delivery system (artificial pancreas device system) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products for individuals who do not meet the above criteria.

Use of an automated insulin delivery system (artificial pancreas device system) not approved by the Food and Drug Administration is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products.

## COVERAGE

Benefits may vary by groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable medical equipment, medical supplies and prosthetic devices and diabetic equipment/supplies or not medically necessary/not covered benefits/coverage.

## BACKGROUND

Tight glucose control in patients with diabetes has been associated with improved health outcomes. The American Diabetes Association has recommended a glycated hemoglobin level below 7% for most patients. However, hypoglycemia 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, the presence of symptoms, and whether the episode can be self-treated or requires help for recovery. Children and adolescents represent a population of individuals with type 1 diabetes who have challenges in controlling hyperglycemia and avoiding hypoglycemia. Hypoglycemia is the most common acute complication of type 1 diabetes.

Type 1 diabetes is caused by the destruction of the pancreatic beta cells which produce insulin, and the necessary mainstay of treatment is insulin injections. Multiple studies have shown that intensive insulin treatment, aimed at tightly controlling blood glucose, reduces the risk of long-term complications of diabetes, such as retinopathy and renal disease. Optimal glycemic control, as assessed by glycated hemoglobin, and avoidance of hyper- and hypoglycemic excursions have been shown to prevent diabetes-related complications. Currently, insulin treatment strategies include either multiple daily insulin injections or continuous subcutaneous insulin infusion with an insulin pump.

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a hybrid closed-loop insulin delivery system, the evidence includes multicenter pivotal trials using devices cleared by the U.S. Food and Drug Administration, supplemental data and analysis for expanded indications, and more recent studies focused on children and adolescents. Three crossover RCTs using a similar first-generation device studied and approved outside the United States have been reported. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Of these 3 crossover RCTs 2 found significantly better outcomes (ie, time spent in nocturnal hypoglycemia and time spent in preferred glycemic range) with the device than with standard care. The third study r had mixed findings (significant difference in time spent in nocturnal hypoglycemia and no significant difference in time spent in preferred glycemic range). Additional evidence from device performance studies and clinical studies all demonstrate reductions in time spent in various levels of hypoglycemia, improved time in range (70-180 mg/ dL), rare diabetic ketoacidosis, and few device-related adverse events. The evidence suggests that the

magnitude of reduction for hypoglycemic events in the type 1 diabetes population is likely to be clinically significant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a closed-loop insulin delivery system, the evidence includes a 13-week multicenter RCT of the iLet Bionic Pancreas System compared to usual care in 326 individuals ages 6 to 79 years with type 1 diabetes. Comparator group participants continued their pre-study subcutaneous insulin delivery (either multiple daily injections, an insulin pump without automation of insulin delivery, an insulin pump with predictive low glucose suspend feature, or an insulin pump as part of an HCL system) plus real-time CGM. The glycated hemoglobin level decreased from 7.9% to 7.3% in the closed-loop insulin delivery system group and did not change (7.7% at both time points) in the standard-care group (mean adjusted difference at 13 weeks, −0.5%; 95%CI −0.6 to −0.3; p <0.001). The rate of severe hypoglycemia was 17.7 events per 100 participant-years in the closed-loop insulin delivery system group and 10.8 events per 100 participant-years in the standard-care group (p = 0.39). No episodes of diabetic ketoacidosis occurred in either group. The trial's results for the subgroups of adults (ages 18 and older) and youth (ages 6 to 17 years) have additionally been reported and were similar to the main results for the full cohort. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. For individuals who have type 1 diabetes (T1D) who receive an artificial pancreas device system with a low-glucose suspend feature, the evidence includes three randomized controlled trials (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 Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial, were ages 16-to-70 years old, T1D , 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 six 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, findings from one trial were limited by nonstandard reporting of hypoglycemic episodes, and findings from the other trial were no longer statistically significant when two outliers (children) were excluded from analysis. The RCT limited to adults showed an improvement in the primary outcome (area under the curve for nocturnal hypoglycemic events). The area under the curve is not used for assessment in clinical practice but the current technology does allow user and provider review of similar trend data with continuous glucose monitoring. Results from the ASPIRE study suggested that there were increased risks of hyperglycemia and potential diabetic ketoacidosis in subjects using the threshold suspend feature. This finding may be related to whether or not actions are taken by the user to assess glycemic status, etiology of the low glucose (activity, diet or medication) and to resume insulin infusion. Both retrospective and prospective observational studies have reported reductions in rates and severity of hypoglycemic episodes in automated insulin delivery system users. The evidence is sufficient that the magnitude of reduction for hypoglycemic events in the T1D population is likely to be clinically significant. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have T1D who receive an artificial pancreas device system with a hybrid closed-loop insulin delivery system, the evidence includes multicenter pivotal trials using devices cleared by the U.S. Food and Drug Administration, supplemental data and analysis for expanded indications and more recent studies focused on children and adolescents. Three crossover RCTs using a similar first- generation device approved outside the United States have been reported. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Of the three 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 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). Additional evidence from device performance studies and clinical studies all demonstrate reductions in time spent in various levels of hypoglycemia, improved time in range (70-180mg/dl), rare diabetic ketoacidosis and few device-related adverse events. The evidence suggests that the magnitude of reduction for hypoglycemic events in the T1D

population is likely to be clinically significant. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Clinical input supported that the outcome of hypoglycemia prevention provides a clinically meaningful improvement in net health outcome, and this use is consistent with generally accepted medical practice. Clinical input also supported that the use of hybrid closed loop artificial pancreas device systems provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Reduction in the experience of hypoglycemia and inappropriate awareness of hypoglycemia and glycemic excursions were identified as important acute clinical outcomes in children, adolescents, and adults and are related to the future risk for end-organ complications.

## CODING

**Medicare Advantage Plans and Commercial Products**

The following codes are covered when medical criteria are met.

**E0787** External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing

**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

**S1036** Transmitter; external, for use with artificial pancreas device system

**S1037** Receiver (monitor); external, for use with artificial pancreas device system

The following code is covered when the device is approved:

**S1035** Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system

*Please note Blue Cross Blue Shield of Rhode Island considers it inappropriate to bill the artificial pancreas device system using the following codes specific to a continuous glucose monitoring system and insulin pump when the technology functions as an artificial pancreas and no manual intervention is needed. These codes include but are not limited to the following list:*

*E0784 External ambulatory infusion pump, insulin*

*E2103 Non-adjunctive, non-implanted continuous glucose monitor or receiver (New Code Effective 1/1/2023)*

*A4226 Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week*

*A4239 Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service (New Code Effective 1/1/2023)*

*A9276 Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one unit = 1 day supply (Text Revision Effective 1/1/2023)*

*A9277 Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system (Text Revision Effective 1/1/2023)*

*A9278 Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system (Text Revision Effective 1/1/2023)*

*K0553 Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service (Code Deleted Effective 12/31/2022)*

*K0554 Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system (Code Deleted Effective 12/31/2022)*

*S1030 Continuous non-invasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)*

*S1031 Continuous non-invasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)*

## RELATED POLICIES

Glucose Monitoring - Continuous

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

## PUBLISHED

Provider Update, December 2023
Provider Update, November/December 2022
Provider Update, October 2021
Provider Update, September 2020
Provider Update, August 2019

## REFERENCES


1. American Diabetes Association. 6. Glycemic Targets. Diabetes Care. Jan 2017; 40(Suppl 1): S48-S56. PMID 27979893
2. American Diabetes Association. 6. Glycemic Targets: Standards of Medical Care in Diabetes-2019. Diabetes Care. Jan 2019; 42(Suppl 1): S61-S70. PMID 30559232
3. Abraham MB, Jones TW, Naranjo D, et al. ISPAD Clinical Practice Consensus Guidelines 2018: Assessment and management of hypoglycemia in children and adolescents with diabetes. Pediatr Diabetes. Oct 2018; 19 Suppl 27: 178-192. PMID 29869358
4. Agiostratidou G, Anhalt H, Ball D, et al. Standardizing Clinically Meaningful Outcome Measures Beyond HbA 1c for Type 1 Diabetes: A Consensus Report of the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange. Diabetes Care. Dec 2017; 40(12): 1622-1630. PMID 29162582
5. Food and Drug Administration (FDA). Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems [draft]. 2012; https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259305.pdf. Accessed June 23, 2023
6. Food & Drug Administration. MiniMed 770G System. Summary of Safety and Effectiveness Data. 2020. https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017S076B.pdf. July 3, 2022.
7. Food & Drug Administration. 2023. MiniMed 780G System- P160017/S091. https://www.fda.gov/medical-devices/recently-approved-devices/minimed-780g-system-p160017s09. Accessed June 25, 2023.
8. Forlenza GP, Li Z, Buckingham BA, et al. Predictive Low-Glucose Suspend Reduces Hypoglycemia in Adults, Adolescents, and Children With Type 1 Diabetes in an At-Home Randomized Crossover Study: Results of the PROLOG Trial. Diabetes Care. Oct 2018; 41(10): 2155-2161. PMID 30089663
9. Food & Drug Administration. 2023. FDA Clears New Insulin Pump and Algorithm-Based Software to Support Enhanced Automatic Insulin Delivery. https://www.fda.gov/news-events/press-announcements/fda-clears-new-insulin-pump-and-algorithm-based-software-support-enhanced-automatic-insulin-delivery. Accessed June 26, 2023.
10. Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 530G System. 2013; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120010. Accessed June 21, 2023
11. Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 630G System with Smartguard. 2016; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=320606. Accessed June 20, 2023
12. Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 670G System. 2016; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160017. Accessed June 19, 2023.
13. Food and Drug Administration (FDA). t:slim X2 Insulin Pump with Basal-IQ Technology Premarket Approval (2018). https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180008A.pdf. Accessed June 27, 2023.
14. Faulds ER, Zappe J, Dungan KM. REAL-WORLD IMPLICATIONS OF HYBRID CLOSE LOOP (HCL) INSULIN DELIVERY SYSTEM. Endocr Pract. May 2019; 25(5): 477-484. PMID 30865545

15. Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a Hybrid Closed-Loop Insulin Delivery System in Patients With Type 1 Diabetes. JAMA. Oct 04 2016; 316(13): 1407-1408. PMID 27629148
16. Ly TT, Nicholas JA, Retterath A, et al. 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. Sep 25 2013; 310(12): 1240-7. PMID 24065010
17. Forlenza GP, Ekhlaspour L, Breton M, et al. Successful At-Home Use of the Tandem Control-IQ Artificial Pancreas System in Young Children During a Randomized Controlled Trial. Diabetes Technol Ther. Apr 2019; 21(4): 159-169. PMID 30888835
18. American Diabetes Association. 7. Diabetes Technology: Standards of Medical Care in Diabetes-2021. Diabetes Care. Jan 2021; 44(Suppl 1): S85-S99. PMID 33298418
19. Garg SK, Weinzimer SA, Tamborlane WV, et al. Glucose Outcomes with the In-Home Use of a Hybrid Closed-Loop Insulin Delivery System in Adolescents and Adults with Type 1 Diabetes. Diabetes Technol Ther. Mar 2017; 19(3): 155-163. PMID 28134564
20. Beato-Víbora PI, Gallego-Gamero F, Lázaro-Martín L, et al. Prospective Analysis of the Impact of Commercialized Hybrid Closed-Loop System on Glycemic Control, Glycemic Variability, and Patient-Related Outcomes in Children and Adults: A Focus on Superiority Over Predictive Low-Glucose Suspend Technology. Diabetes Technol Ther. Dec 2020; 22(12): 912-919. PMID 31855446
21. Garg S, Brazg RL, Bailey TS, et al. Reduction in duration of hypoglycemia by automatic suspension of insulin delivery: the in-clinic ASPIRE study. Diabetes Technol Ther. Mar 2012; 14(3): 205-9. PMID 22316089
22. Forlenza GP, Deshpande S, Ly TT, et al. Application of Zone Model Predictive Control Artificial Pancreas During Extended Use of Infusion Set and Sensor: A Randomized Crossover-Controlled Home-Use Trial. Diabetes Care. Aug 2017; 40(8): 1096-1102. PMID 28584075
23. Pinsker JE, Dassau E, Deshpande S, et al. Outpatient Randomized Crossover Comparison of Zone Model Predictive Control Automated Insulin Delivery with Weekly Data Driven Adaptation Versus Sensor-Augmented Pump: Results from the International Diabetes Closed-Loop Trial 4. Diabetes Technol Ther. Sep 2022; 24(9): 635-642. PMID 35549708
24. Tauschmann M, Thabit H, Bally L, et al. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial. Lancet. Oct 13 2018; 392(10155): 1321-1329. PMID 30292578
25. Abraham MB, Nicholas JA, Smith GJ, et al. Reduction in Hypoglycemia With the Predictive Low-Glucose Management System: A Long-term Randomized Controlled Trial in Adolescents With Type 1 Diabetes. Diabetes Care. Feb 2018; 41(2): 303-310. PMID 29191844
26. Wood MA, Shulman DI, Forlenza GP, et al. In-Clinic Evaluation of the MiniMed 670G System "Suspend Before Low" Feature in Children with Type 1 Diabetes. Diabetes Technol Ther. Nov 2018; 20(11): 731-737. PMID 30299976
27. Breton MD, Kanapka LG, Beck RW, et al. A Randomized Trial of Closed-Loop Control in Children with Type 1 Diabetes. N Engl J Med. Aug 27 2020; 383(9): 836-845. PMID 32846062
28. Kanapka LG, Wadwa RP, Breton MD, et al. Extended Use of the Control-IQ Closed-Loop Control System in Children With Type 1 Diabetes. Diabetes Care. Feb 2021; 44(2): 473-478. PMID 33355258
29. Cobry EC, Kanapka LG, Cengiz E, et al. Health-Related Quality of Life and Treatment Satisfaction in Parents and Children with Type 1 Diabetes Using Closed-Loop Control. Diabetes Technol Ther. Jun 2021; 23(6): 401-409. PMID 33404325
30. Forlenza GP, Pinhas-Hamiel O, Liljenquist DR, et al. Safety Evaluation of the MiniMed 670G System in Children 7-13 Years of Age with Type 1 Diabetes. Diabetes Technol Ther. Jan 2019; 21(1): 11-19. PMID 30585770
31. Messer LH, Forlenza GP, Sherr JL, et al. Optimizing Hybrid Closed-Loop Therapy in Adolescents and Emerging Adults Using the MiniMed 670G System. Diabetes Care. Apr 2018; 41(4): 789-796. PMID 29444895
32. Brown SA, Forlenza GP, Bode BW, et al. Multicenter Trial of a Tubeless, On-Body Automated Insulin Delivery System With Customizable Glycemic Targets in Pediatric and Adult Participants With Type 1 Diabetes. Diabetes Care. Jul 2021; 44(7): 1630-1640. PMID 34099518
33. Russell SJ, Beck RW, Damiano ER, et al. Multicenter, Randomized Trial of a Bionic Pancreas in Type 1 Diabetes. N Engl J Med. Sep 29 2022; 387(13): 1161-1172. PMID 36170500

34. Kruger D, Kass A, Lonier J, et al. A Multicenter Randomized Trial Evaluating the Insulin-Only Configuration of the Bionic Pancreas in Adults with Type 1 Diabetes. Diabetes Technol Ther. Oct 2022; 24(10): 697-711. PMID 36173236
35. Messer LH, Buckingham BA, Cogen F, et al. Positive Impact of the Bionic Pancreas on Diabetes Control in Youth 6-17 Years Old with Type 1 Diabetes: A Multicenter Randomized Trial. Diabetes Technol Ther. Oct 2022; 24(10): 712-725. PMID 36173237
36. Lynch J, Kanapka LG, Russell SJ, et al. The Insulin-Only Bionic Pancreas Pivotal Trial Extension Study: A Multi-Center Single-Arm Evaluation of the Insulin-Only Configuration of the Bionic Pancreas in Adults and Youth with Type 1 Diabetes. Diabetes Technol Ther. Oct 2022; 24(10): 726-736. PMID 36173238
37. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. Endocr Pract. Jun 2021; 27(6): 505-537. PMID 34116789
38. ElSayed NA, Aleppo G, Aroda VR, et al. 7. Diabetes Technology: Standards of Care in Diabetes-2023. Diabetes Care. Jan 01 2023; 46(Suppl 1): S111-S127. PMID 36507635
39. Brown SA, Kovatchev BP, Raghinaru D, et al. Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. N Engl J Med. Oct 31 2019; 381(18): 1707-1717. PMID 31618560