Medical Coverage Policy | Artificial Pancreas Device System

EFFECTIVE DATE: 10|01|2019
POLICY LAST UPDATED: 07|02|2020

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

BlueCHiP for Medicare and Commercial Products

Use of a U.S. Food and Drug Administration (FDA)-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 the following criteria:

- Age 14 and older
- 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

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**.**

- Age 7 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.

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 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 BlueCHiP for Medicare 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 BlueCHiP for Medicare 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 recommends 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, presence of symptoms, and whether the episode can be self-treated or requires help for recovery. Children and adolescents represent a population of type 1 diabetics who have challenges in controlling hyperglycemia and avoiding hypoglycemia. Hypoglycemia is the most common acute complication of type 1 diabetes.

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.

For individuals who have type 1 diabetes (T1D) who receive an artificial pancreas device system with a low-glucose suspend feature, the evidence includes two 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. Limitations of the published evidence preclude determining the effects of the technology on overall glycemic control as assessed by HbA1c and other parameters and thus, net health outcomes. Evidence reported through clinical input supports 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. 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 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). For the U.S. regulatory registration pivotal trial, the primary outcomes were safety and not efficacy. 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 is sufficient that the magnitude of reduction for hypoglycemic events in the T1D population is likely to be clinically significant. The variations in the definition of primary and secondary outcomes in the study design and conduct of the published evidence are limitations that preclude determining the effects of the technology on net health outcomes. Evidence reported through clinical input supports that the use of hybrid closed loop APDS 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. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

CODING

BlueCHiP for Medicare 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 (new code effective 1/1/20)

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

A4226 Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week (new code effective 1/1/20)

A9276 Sensor; invasive (e.g. subcutaneous) disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply

A9277 Transmitter; external, for use with interstitial continuous glucose monitoring system

A9278 Receiver (monitor); external, for use with interstitial continuous glucose monitoring system

K0553 Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service

K0554 Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system

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, September 2020
Provider Update, August 2019
Provider Update, March 2018
Provider Update, November 2017
Provider Update, September 2016

REFERENCES

1. Agiostratidou G, Anhalt H, Ball D, et al. Standardizing clinically meaningful outcome measures beyond HbA1c 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

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. 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 October 31, 2018.

5. 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 October 31, 2018.

6. Food and Drug Administration (FDA). Premarket Approval (PMA): MINIMED 630G SYSTEM WITH SMARTGUARD(TM). 2016; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=320606. Accessed October 31, 2018.

7. 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 October 31, 2018.

8. Blue Cross and Blue Shield Technology Evaluation Center (TEC). Artificial Pancreas Device Systems. TEC Assessments. 2013;Volume 28:Tab 14. PMID

9. Bergenstal RM, Klonoff DC, Garg SK, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. N Engl J Med. Jul 18 2013;369(3):224-232. PMID 23789889

10. 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):205-209. PMID 22316089

11. 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):1240-1247. PMID 24065010

12. Agrawal P, Zhong A, Welsh JB, et al. Retrospective analysis of the real-world use of the threshold suspend feature of sensor-augmented insulin pumps. Diabetes Technol Ther. May 2015;17(5):316-319. PMID 25611577

13. Gomez AM, Marin Carrillo LF, Munoz Velandia OM, et al. Long-term efficacy and safety of sensor augmented insulin pump therapy with low-glucose suspend feature in patients with type 1 diabetes. Diabetes Technol Ther. Feb 2017;19(2):109-114. PMID 28001445

14. 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 4 2016;316(13):1407-1408. PMID 27629148

15. 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

16. 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

17. 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

18. 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

19. 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

20. 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

21. 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

22. Chiang JL, Maahs DM, Garvey KC, et al. Type 1 diabetes in children and adolescents: A Position Statement by the American Diabetes Association. Diabetes Care. Sep 2018;41(9):2026-2044. PMID 30093549

23. American Diabetes Association. 7. Diabetes Technology: Standards of Medical Care in Diabetes-2019. Diabetes Care. Jan 2019;42(Suppl 1):S71-s80. PMID 30559233

24. Grunberger G, Handelsman Y, Bloomgarden ZT, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2018 Position Statement on integration of insulin pumps and continuous glucose monitoring in patients with diabetes mellitus. Endocr Pract. Mar 2018;24(3):302-308. PMID 29547046

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS