Medical Coverage Policy | Artificial Pancreas Device System

EFFECTIVE DATE: 10|01|2019
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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 of 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.

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
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, August 2019
Provider Update, March 2018
Provider Update, November 2017
Provider Update, September 2016
Provider Update, July 2015

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