MEDICAL POLICY

POLICY TITLE	EXTERNAL INFUSION PUMPS FOR INSULIN DELIVERY AND ARTIFICIAL PANCREAS DEVICE
POLICY NUMBER	MP-6.007

Effective Date:	1/1/2023

I. POLICY

Insulin infusion pumps for treatment of diabetes mellitus may be considered **medically necessary** in patients who meet all of the following set of criteria***:**

- Supporting clinical documentation from either the patient's primary physician or a consulting endocrinologist must be submitted for review when requesting the insulin pump; and
- The patient/family has completed a comprehensive diabetes education program; and
- A complete assessment that provides documented evidence of patient/family commitment to self-management of the insulin pump, including documentation of very good compliance with the current self-management program and demonstrated mastery of carbohydrate counting; and
- The patient has been on a program of multiple daily injections of insulin (i.e., two [2] to three [3] injections per day); and
- The patient/family has had frequent self-adjustments of insulin dose for at least six (6) months prior to initiation of the insulin pump; and
- The patient/family has documented glucose self-testing at least four (4) times per day during the two (2) months prior to initiation of the insulin pump; and
- Meets one or more of the following criteria while on the multiple daily injection regimen:
    - Glycosylated hemoglobin level (HbA1c) greater than 7.0 percent;
    - History of recurring hypoglycemia (usually documented blood glucose levels less than 70 mg/dL and/or when an individual becomes symptomatic);
    - Wide fluctuations in blood glucose before mealtime;
    - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl; or
    - History of severe glycemic excursions.

Note: Individual consideration is provided for diabetic women who are pregnant.

In addition, a patient with Type 2 diabetes may be considered for an insulin pump if he/she meets the above criteria as well as the following:

- Has been on a combination of at least two oral agents used concomitantly, prior to beginning insulin therapy (either alone or while continuing oral therapy).

Note: A programmable disposable external insulin infusion pump (e.g., OmniPod®) is an acceptable alternative to a standard insulin infusion pump for persons who meet medical necessity criteria for external insulin infusion pumps.

External Infusion Pump Replacement:

Requests for replacement of an insulin pump that is out of warranty must include one of the following;

- Clear and conclusive documentation from either the treating physician's office notes or the device supplier's customer service notes, that the pump is non-operational; or
- Documentation that the patient has reverted to use of multiple daily injections of insulin or a loaner pump because the pump is non-operational.

Replacement of insulin pumps for reasons other than those stated above is considered **not medically necessary**.

Artificial Pancreas Device Systems

An FDA approved artificial pancreas device system (i.e., low glucose suspend feature or hybrid closed loop system) may be considered **medically necessary** in patients with diabetes who meet **ALL** of the following criteria*:

- Type 1 diabetes
- Glycated hemoglobin value between 5.8% and 10.0%
- Used insulin pump therapy for greater than or equal to three (3) months
- At least two (2) documented nocturnal hypoglycemic events in a 2-week period

Note: The definition of a hypoglycemic episode is not standardized. In the pivotal ASPIRE randomized controlled trial, a nocturnal hypoglycemic episode was defined as a sensor glucose value of 65mg/dL or less between 10 P.M. and 8 A.M. for more than 20 consecutive minutes in the absence of a pump interaction within 20 minutes. For purposes of this policy, the nocturnal hypoglycemic value can be 70mg/dL or less.

Use of an artificial pancreas device system is considered **investigational** in all other situations as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this device for any other indications.

Replacement criteria:

Replacement of an FDA-approved artificial pancreas device system with a low glucose suspend feature may be considered **medically necessary** when all of the above criteria are met, and all of the additional criteria found below have been met:

- The device is out of warranty; **and**
- The device is malfunctioning; **and**
- The device cannot be refurbished.

Replacement of an FDA-approved artificial pancreas device system with a low glucose suspend feature is considered **not medically necessary** when the criteria above have not been met.

*To demonstrate that medical necessity criteria have been met, please submit the following:

- Certificate of Medical Necessity
- Chart Notes supporting the Certificate of Medical Necessity
- Blood Glucose Logs documenting sugars and any interventions (such as sliding scale insulin dose etc.).

Note: *Glucose logs of less than 30 days will be considered on a case-by-case basis should the provider feel there is a danger to the member's health, please provide an explanation.*

Cross-reference:
MP 1.058 Implantable Infusion Pumps for Pain and Spasticity
MP 6.004 Continuous Glucose Monitoring

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO – Refer to FEP Medical Policy Manual. The FEP Medical Policy Manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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External Infusion Pump (EIP) is a portable battery-operated device intended to provide continuous ambulatory drug infusion therapy over an extended time period. The EIP is also known as an external pump, ambulatory pump, or a mini infuser. Proposed drug delivery routes using the EIP include the intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural, intrathecal, and intraventricular routes. A heparinized saline solution may be used during an

interruption of drug therapy to maintain catheter patency. A catheter from the pump is attached to the desired access route for drug delivery. The drug reservoir refilling is non-invasive.

Some external insulin infusion pumps (e.g., Paradigm Real-Time Insulin Pump and Continuous Glucose Monitoring System) are able to take results of the blood glucose reading, calculate the appropriate insulin infusion rate, wirelessly transmit the results from the blood glucose monitor to the pump, and automatically adjust the insulin infusion rate, saving the member some extra steps. These insulin pump features, when present, are considered integral to the external insulin infusion pump and blood glucose monitor.

There are over 600 different models of pumps, most of which have received clearance for marketing by the Food and Drug Administration (FDA) through a pre-notification application (510 (K)).

Artificial Pancreas Device

The Food and Drug Administration (FDA) describes the basic design of an artificial pancreas device system (APDS) as a CGM linked to an insulin pump with the capability to automatically stop, reduce, or increase insulin infusion based on specified thresholds of measured interstitial glucose.

The APDS components are designed to communicate with each other to automate the process of maintaining blood glucose concentrations at or near a specified range or target and to minimize the incidence and severity of hypoglycemic and hyperglycemic events. An APDS control algorithm is embedded in software in an external processor or controller that receives information from the CGM and performs a series of mathematical calculations. Based on these calculations, the controller sends dosing instructions to the infusion pump.

Different APDS types are currently available for clinical use. Sensor augmented pump therapy (SAPT) with low glucose suspend (LGS) (suspend on low) may reduce the likelihood or severity of a hypoglycemic event by suspending insulin delivery temporarily when the sensor value reaches (reactive) a predetermined lower threshold of measured interstitial glucose. Low glucose suspension (LGS) automatically suspends basal insulin delivery for up to two hours in response to sensor-detected hypoglycemia.

A sensor augmented pump therapy with predictive low glucose management (PLGM) (suspend before low) suspends basal insulin infusion with the prediction of hypoglycemia. Basal insulin infusion is suspended when sensor glucose is at or within 70 mg/dL above the patient-set low limit and is predicted to be 20 mg/dL above this low limit in 30 minutes. In the absence of a patient response, the insulin infusion resumes after a maximum suspend period of two hours. In certain circumstances, auto-resumption parameters may be used.

When a sensor value is above or predicted to remain above the threshold, the infusion pump will not take any action based on CGM readings. Patients using this system still need to monitor their blood glucose concentration, set appropriate basal rates for their insulin pump, and give pre-meal bolus insulin to control their glucose levels.

A control-to-range system reduces the likelihood or severity of a hypoglycemic or hyperglycemic event by adjusting insulin dosing only if a person's glucose levels reach or approach

predetermined higher and lower thresholds. When a patient's glucose concentration is within the specified range, the infusion pump will not take any action based upon CGM readings. Patients using this system still need to monitor their blood glucose concentration, set appropriate basal rates for their insulin pump, and give pre-meal bolus insulin to control their glucose levels.

A control-to-target system sets target glucose levels and tries to maintain these levels at all times. This system is fully automated and requires no interaction from the user (except for calibration of the CGM). There are two subtypes of control-to-target systems: insulin-only and bi-hormonal (e.g., glucagon). There are no systems administering glucagon marketed in the United States.

An APDS may also be referred to as a “closed-loop” system. A closed-loop system has automated insulin delivery and continuous glucose sensing and insulin delivery without patient intervention. The systems utilize a control algorithm that autonomously and continually increases and decreases the subcutaneous insulin delivery based on real-time sensor glucose levels. There are no completely closed-loop insulin delivery systems marketed in the United States.

A hybrid closed-loop system also uses automated insulin delivery with continuous basal insulin delivery adjustments. However, at mealtime, the patient enters the number of carbohydrates they are eating in order for the insulin pump to determine the bolus meal dose of insulin. A hybrid system option with the patient administration of a pre-meal or partial pre-meal insulin bolus can be used in either control-to-range or control-to-target systems.

IV. RATIONALE

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Summary of Evidence: Artificial Pancreas Device

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 (i.e., 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.

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V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes						
A4224	A4225	A4226	A4230	A4231	A4232	A4239
A9274	E0784	E0787	E2103	S1034	S1035	S1036
S1037						

Specific ICD-10-CM Codes do not apply; must meet policy criteria above.

IX. REFERENCES

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Artificial Pancreas Device Systems

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X. POLICY HISTORY

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MP 6.007	**3/5/2019** Consensus review. No change to policy statements**.**
	1/1/2020 Coding update. New 2020 codes added to policy, A4226, and E0787.
	3/27/2020 Consensus review. No change to policy statement or coding. References updated.
	6/17/2021 Consensus review. Added guideline for hypoglycemia "(usually documented blood glucose levels less than 70 mg/dL and/or when an individual becomes symptomatic)" within policy statement. References updated.
	2/25/2022 Consensus Review. No change to policy statements. References updated**.** HCPCS definitions removed.
	6/8/2022 Ad hoc review. Artificial Pancreas Devices have been placed into this policy. Coding table updated.
	11/29/2022 Admin update. Added New Codes A4239 & E2103.

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