

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>EXTERNAL INFUSION PUMPS FOR INSULIN DELIVERY AND AUTOMATED INSULIN DELIVERY SYSTEMS</b>
<b>POLICY NUMBER</b>	<b>MP 6.007</b>

<b>CLINICAL BENEFIT</b>	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
<b>Effective date:</b>	<b>5/1/2026</b>

### POLICY

External insulin infusion pumps for treatment of insulin dependent diabetes mellitus may be considered **medically necessary** in individuals who cannot be controlled by intermittent dosing. (Acceptable routes are SC and IV)

#### **Automated Insulin Delivery Systems (a.k.a artificial pancreas device systems):**

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 individuals with type 1 diabetes who meet all of the following criteria:

Age 6 years and older 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.

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 individuals 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.

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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.

Use of an FDA cleared or approved automated insulin delivery 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 individuals with type 2 diabetes who meet all the following criteria: (See policy guidelines)

Age 18 years and older, AND

- Diagnoses with type 2 diabetes for at least 12 months;
- On multiple daily injections (insulin administration  $\geq 3x/$  day or use of insulin infusion pump for at least 3 months);
- Glycated hemoglobin level  $\geq 7\%$  or experience significant hypoglycemia.

Use of an automated insulin delivery system (artificial pancreas device system) is **investigational** for individuals who do not meet the above criteria as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this device for any other indications.

Use of an automated insulin delivery system (artificial pancreas device system) not cleared or approved by the FDA is **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this device for any other indications.

**Note:** A programmable disposable external insulin infusion pump (e.g., OmniPod®) is an acceptable alternative to a standard insulin infusion pump.

### External Infusion Pump/Automated Insulin Delivery System 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 individual 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 are considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this device for any other indications.

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### Policy Guidelines

Individuals with DM should understand the technology, be motivated to use the device correctly and consistently, adhere to a comprehensive treatment plan supervised by a qualified provider, and be capable of recognizing alerts and alarms from the device.

The U.S. Food and Drug Administration (FDA) has approved two hybrid closed-loop insulin delivery systems for type 2 diabetes management: the Omnipod 5 AID system (Insulet Corporation) and t:slim X2 insulin pump equipped with Control-IQ+ technology (Tandem Diabetes Care).

- The Omnipod 5 AID system was approved following a pivotal clinical trial by Pasquel et al in 2025 (SECURE-T2D; NCT05815342). Trial participants aged 18 to 75 years, who had been on a stable insulin regimen for at least three months prior to screening (as per the above policy criteria), were selected. Additionally, they could be on other antihyperglycemic and weight loss drugs, provided there were no dose changes for at least 4 weeks before the trial commenced. However, those who experienced more than one severe hypoglycemic event or episode of diabetic ketoacidosis or hyperosmolar hyperglycemic syndrome within 6 months before screening were excluded.
- The t:slim X2 insulin pump equipped with Control-IQ+ technology was approved following a pivotal randomized controlled trial by Kudva et al in 2025 (2IQP; NCT05785832). Trial participants were aged 19 to 87 years and had type 2 diabetes for at least 6 months, according to clinical history and available laboratory data. All participants were receiving multiple daily injections of insulin with at least one injection containing rapid-acting insulin per day or were using an insulin pump for at least 3 months before enrollment. Mixed insulin use with a rapid-acting component was allowed. Concurrent treatment with noninsulin glucose-lowering medications or weight-reduction medications was permitted, provided the dose had been stable for the previous 3 months; during the trial, these medications were continued in both treatment groups.

### Cross-References:

#### MP 6.004 Continuous Glucose Monitoring

### PRODUCT VARIATIONS

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

**FEP PPO** - Refer to FEP medical policy manual. The FEP medical policy manual can be found at: [fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies](https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies).

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### DESCRIPTION/BACKGROUND

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, an 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.

There are over six hundred 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)).

### Automated Insulin Delivery Systems

Automated Insulin Delivery Systems (AID), also known as artificial pancreas device systems, have 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.

AID 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. A 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 AID 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 hybrid closed-loop system automatically increases or decreases basal insulin delivery in response to sensor glucose values. The user still needs to dose prandial insulin manually.

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Advanced hybrid AID systems are also available now. These next-generation systems not only adjust basal insulin delivery but also have the capacity to deliver automatic correction boluses. However, they still require the person with diabetes to dose prandial insulin.

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.

Table 1 summarizes the FDA cleared or approved automated insulin delivery systems.

**Table 1. U.S. Food and Drug Administration-Approved Automated Insulin Delivery Systems (Artificial Pancreas Device Systems)**

Device	Age Indication	Manufacturer	Date Approved	PMA No. / Device Code
MiniMed 530G System <sup>a</sup> (open-loop, LGS)	≥16 y	Medtronic	July 2013	P120010 / OZO
MiniMed 630G System with SmartGuard™ <sup>b</sup> (open-loop, LGS)	≥16 y ≥14 y	Medtronic	Aug 2016 Jun 2017	P150001/OZO P150001/S008
MiniMed 670G System <sup>c</sup> (HCL, LGS or PLGM)	≥14 y ≥7 to 13 y	Medtronic	Sep 2016 Jul 2018	P160017/OZP P160017/S031
MiniMed 770G System <sup>d</sup> (HCL)	≥2 y	Medtronic	Aug 2020	P160017/S076
MiniMed 780G System <sup>e</sup> (HCL)	≥7 y	Medtronic	May 2023	P160017/S091
t:slim X2 Insulin Pump with Basal-IQ Technology (LGS)	≥6 y	Tandem	Jun 2018	P180008/OZO, PQF
t:slim X2 Insulin Pump with Control-IQ Technology (HCL)	≥6 y	Tandem	Dec 2019	DEN180058/QFG
Omnipod 5 (HCL)	≥6 y	Insulet	Jan 2022	K203768 K203772
iLet Bionic Pancreas (CL)	≥6 y	Beta Bionics	May 2023	K220916 K223846

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CL: closed-loop; HCL: hybrid closed-loop; LGS: low glucose suspend; OZO: Artificial Pancreas Device System, threshold suspend; OZP: Automated Insulin Dosing Device System, Single Hormonal Control; PMA: premarket approval; PLGM: predictive low glucose management.

<sup>a</sup>MiniMed 530G System consists of the following devices that can be used in combination or individually: MiniMed 530G Insulin Pump, Enlite™ Sensor, Enlite™ Serter, the MiniLink Real-Time System, the Bayer Contour NextLink glucose meter, CareLink® Professional Therapy Management Software for Diabetes, and CareLink® Personal Therapy Management Software for Diabetes (at time of approval).

<sup>b</sup>MiniMed 630G System with SmartGuard™ consists of the following devices: MiniMed 630G Insulin Pump, Enlite® Sensor, One-Press Serter, Guardian® Link Transmitter System, CareLink® USB, Bayer's CONTOUR® NEXT LINK 2.4 Wireless Meter, and Bayer's CONTOUR® NEXT Test Strips (at time of approval).

<sup>c</sup>MiniMed 670G System consists of the following devices: MiniMed 670G Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, and the Contour NEXT Link 2.4 Glucose Meter (at time of approval).

<sup>d</sup>MiniMed 770G System consists of the following devices: MiniMed 770G Insulin Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, the Accu-Chek Guide™ Link blood glucose meter, and the Accu-Chek Guide™ Test Strips.

<sup>e</sup>MiniMed 780G System consists of the following devices: MiniMed 780G Insulin Pump, the Guardian 4 Transmitter, the Guardian 4 Sensor (3), One-Press Serter, the Accu-Chek Guide™ Link blood glucose meter, and the Accu-Chek Guide™ Test Strips.

The MiniMed 530G System includes a threshold suspend or low glucose suspend feature. The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is at or below a preset threshold within the 60- to 90-mg/dL range. When the glucose value reaches this threshold, an alarm sounds. If patients respond to the alarm, they can choose to continue or cancel the insulin suspend feature. If patients fail to respond, the pump automatically suspends action for 2 hours, and then insulin therapy resumes.

The MiniMed® 630G System with SmartGuard™, which is similar to the 530G, includes updates to the system components including waterproofing. The threshold suspend feature can be programmed to temporarily suspend delivery of insulin for up to 2 hours when the sensor glucose value falls below a predefined threshold value. The MiniMed 630G System with SmartGuard™ is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on the values provided by the MiniMed 630G system. The device is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the SmartGuard™ Suspend on Low alarm to take measures to prevent or treat hypoglycemia themselves.

The MiniMed® 670G System is a hybrid closed-loop insulin delivery system consisting of an insulin pump, a glucose meter, and a transmitter, linked by a proprietary algorithm and the SmartGuard Hybrid closed-loop. The system includes a low glucose suspend feature that

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suspends insulin delivery; this feature either suspends delivery on low-glucose levels or suspends delivery before low-glucose levels and has an optional alarm (manual mode). Additionally, the system allows semiautomatic basal insulin-level adjustment (decrease or increase) to preset targets (automatic mode). As a hybrid system, basal insulin levels are automatically adjusted, but the patient needs to administer premeal insulin boluses. The continuous glucose monitoring component of the MiniMed 670G System is not intended to be used directly for making manual insulin therapy adjustments; rather it is to provide an indication of when a glucose measurement should be taken. The MiniMed 670G System was originally approved for marketing in the United States on September 28, 2016 (P160017) and received approval for marketing with a pediatric indication (ages 7 to 13 years) on June 21, 2018 (P160017/S031).

The MiniMed 770G System is an iteration of the MiniMed 670G System. In July 2020, the device was approved for use in children ages 2 to 6 years. In addition to the clinical studies that established the safety and effectiveness of the MiniMed 670G System in users ages 7 years and older, the sponsor performed clinical studies of the 670G System in pediatric subjects ages 2 to 6 years. FDA concluded that these studies establish a reasonable assurance of the safety and effectiveness of the MiniMed 770G System because the underlying therapy in the 670G system, and the associated Guardian Sensor (3), are identical to that of the 770G System.

On June 21, 2018, the FDA approved the t:slim X2 Insulin Pump with Basal-IQ Technology (PMA P180008) for individuals who are 6 years of age and older. The System consists of the t:slim X2 Insulin Pump paired with the Dexcom G5 Mobile Continuous Glucose Monitoring, as well as the Basal-IQ Technology. The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the System as the receiver for a therapeutic continuous glucose monitoring. The t:slim X2 Insulin Pump running the Basal-IQ Technology can be used to suspend insulin delivery based on continuous glucose monitoring sensor readings.

In December 2019, FDA approved the t:slim X2 Insulin Pump with Control-IQ Technology through the De Novo process. The device uses the same pump hardware as the insulin pump component of the systems approved in t:slim X2 Insulin Pump with Basal-IQ Technology (P180008) and P140015. A custom disposable cartridge is motor driven to deliver patient programmed basal rates and boluses through an infusion set into subcutaneous tissue.

In 2022, FDA approved the Omnipod 5 ACE Pump for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

In May 2023, FDA approved the first closed-loop system through the 510(k) premarket clearance pathway.

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### RATIONALE

#### Summary of Evidence: External Infusion Pumps for Insulin Delivery

For individuals who have type 1 or type 2 diabetes who receive insulin therapy via external infusion pump, the American Diabetes Association Standards of Care in Diabetes 2024 states:

Insulin pumps have been available in the United States for over 40 years. These devices deliver rapid-acting insulin throughout the day to help manage glucose levels. Most studies that compare multiple daily injections with insulin pump therapy have been relatively small and of short duration. However, a systematic review and meta-analysis concluded that pump therapy has modest advantages for lowering A1C levels and for reducing severe hypoglycemia rates in children and adults. Real world data on insulin pumps use in individuals with type 1 diabetes show benefits in A1C levels and hypoglycemia reductions as well as total daily insulin dose reduction.

Real-world reports have shown reduction of A1C levels and reduction of total daily insulin dose in individuals with type 2 diabetes initiating insulin pump therapy.

Due to societal guidance, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

#### Summary of Evidence: Automated Insulin Delivery System

For individuals who have type 1 diabetes who receive an automated insulin delivery system with a low glucose suspend feature, the evidence includes 3 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, type 1 diabetes, glycated hemoglobin levels between 5.8% and 10.0%, and at least 2 nocturnal hypoglycemic events ( $\leq 65$  mg/dL) lasting more than 20 minutes during a 2-week run-in phase. Both trials required at least 6 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 automated insulin delivery system; however, findings from 1 trial were limited by nonstandard reporting of hypoglycemic episodes, and findings from the other trial were no longer statistically significant when 2 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, the etiology of the low glucose reading (activity, diet or medication), or 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 suggests that the magnitude of reduction for hypoglycemic events in the

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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 automated insulin delivery 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 (i.e., time spent in nocturnal hypoglycemia and time spent in preferred glycemic range) with the device than with standard care. The third study 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 automated insulin delivery 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 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.

### Additional Information

#### 2019 Input

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

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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.

### DEFINITIONS

NA

### DISCLAIMER

*Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.*

### CODING INFORMATION

**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	A9274
E0784	E0787	S1034	S1035	S1036	S1037	

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

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## POLICY HISTORY

<b>MP 6.007</b>	<b>03/05/2019 Consensus Review.</b> No change to policy statements.
	<b>01/01/2020 Administrative Update.</b> New 2020 codes added to policy, A4226 and E0787.
	<b>03/27/2020 Consensus Review.</b> No change to policy statement or coding. References updated.
	<b>06/17/2021 Consensus Review.</b> 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.
	<b>02/25/2022 Consensus Review.</b> No change to policy statements. References updated. HCPCS definitions removed.
	<b>06/08/2022 Minor Review.</b> Artificial Pancreas Devices have been placed into this policy. Coding table updated.
	<b>11/29/2022 Administrative Update.</b> Added New Codes A4239 & E2103.
	<b>12/14/2023 Minor Review.</b> Multiple daily injections are 3 or more per day. Deleted criteria re: self-adjustment for 6 months, which now allows for pumps at diagnosis. Deleted criteria re: T2D and needing to be on 2 oral drugs concomitantly (criteria is for any type of diabetes mellitus). Artificial Pancreas System renamed Automated Insulin Delivery System; changed title of policy. Modified criteria for AID System and also gave an allowance for those with T2D.
	<b>12/27/2024 Minor Review.</b> Automated insulin delivery system section criteria updated; allowance is only for those with T1D. Updated references. No changes to coding.
	<b>06/23/2025 Administrative Update.</b> Removed Benefit Variations Section and updated Disclaimer.
<b>11/20/2025 Minor review.</b> Updated criteria for external infusion pumps. Automated insulin delivery systems now MN for T2D when medical necessity criteria is met. References updated.	

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