KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Insulin Pump
- InPen System

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Infusion Pumps (280.14)
Local Coverage Determinations (LCD)	External Infusion Pumps (L33794)
Local Coverage Article	External Infusion Pumps – Policy Article (A52507)
Kaiser Permanente Medical Policy	For **InPen System Requests** Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"***InPen System***"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Initial Insulin Pump:

I. To qualify for an insulin pump the member must meet **ALL of the following:**
   - A. Patient has Type 1 diabetes of at least six months' duration or Type 2 diabetes requiring a basal/bolus insulin regimen of multiple daily injections using long-acting basal insulin and a rapid-acting analogue
   - B. Referral initiated by a Diabetes specialist* that will manage therapy with an insulin pump.
   - C. Documentation from the Diabetes specialist* that includes **ALL of the following:**
     1. Assessment for clinical therapeutic value of an insulin pump.
     2. Assessment of patient pump education and skill training preparation prior to pump start (either one-on-one or within a group).
     3. Assessment of the patient's (or caregiver's) ability to safely and appropriately participate in an insulin-pump self-management plan.
   - D. Has been on a treatment regimen of multiple daily injections (MDI) of insulin that includes a trial of both a long-acting insulin analog and a short-acting insulin analog with a plan for pre-meal short acting insulin dose adjustment for at least 3 – 6 months prior to initiation of the insulin pump.
   - E. Require less than 200 units of total insulin per day prior to pump therapy.
   - F. Has documented logs of glucose self-testing or CGM results - at least 4 times per day during the 1 month prior to consideration of an insulin pump.
   - G. Meets **ONE or more of the following** while on an MDI regimen:
     1. Recent history (within last six months) of significant, recurring hypoglycemia (blood glucose < 70 mg/dl).
     2. Wide fluctuations (well below and above the set glycemic targets) in blood glucose before and after mealtimes, despite appropriate MDI using up to date insulins (analogs) and dose adjustments to affect control.
   - H. Patient has advanced carbohydrate counting skills and actively uses this information for insulin dosing

Back to Top

I. Patient demonstrates ability to recognize their glucose patterns and safely problem-solve these
J. Has no other illness that could impede use of the pump (i.e., alcohol/chemical abuse, psychological instability, difficulty with digital dexterity, visual impairment).
K. Pediatric Patients
    1. On a case-by-case basis, upon review by a clinical review medical director, pediatric patients under the age of 13 may waive the 6-month time period, if patient monitoring is occurring per the diabetes management plan outlined by an Endocrinologist.

*Note – Requests for an insulin infusion pump used with continuous glucose sensing (HCPCS code E0787 or E0784 for Medicare) will only be authorized if the patient meets both criteria for initial or replacement insulin pump as outlined in this criteria and all criteria outlined in the Continuous Glucose Monitoring clinical review criteria including that current device is no longer under warranty.

Ongoing Coverage of Pump and Supplies:
To qualify for ongoing coverage of an insulin pump the member must meet **ALL of the following**:
A. There is documentation that patient monitors glucose at least four times daily, or appropriately uses a continuous glucose monitor.
B. Patient maintains advanced carbohydrate counting skills and actively uses this information for insulin dosing
C. Patient maintains ability to recognize their glucose patterns and safely and appropriately problem-solve these, including troubleshooting pump malfunction
D. Patient does not have other conditions or psychosocial stressors which might impede safe use of an insulin pump
E. Patient has at least one visit per year with diabetes specialist* (face-to-face, secure message, or telephone encounter)

InPen System
To qualify for an InPen System the member must meet **ALL of the following:**
A. Patient has Type 1 diabetes of at least six months' duration or Type 2 diabetes requiring a basal/bolus insulin regimen of multiple daily injections using long-acting basal insulin and a rapid-acting analogue
B. Referral initiated by a Diabetes specialist* that will manage therapy with an InPen System.
C. Documentation from the Diabetes specialist* that includes **ALL of the following:**
    1. Assessment for clinical therapeutic value of an InPen System.
    2. Assessment of patient InPen education and skill training preparation prior to InPen start (either one-on-one or within a group).
    3. Assessment of the patient's (or caregiver's) ability to safely and appropriately participate in an InPen System self-management plan.
D. Has been on a treatment regimen of multiple daily injections (MDI) of insulin that includes a trial of both a long-acting insulin analog and a short-acting insulin analog with a plan for pre-meal short acting insulin dose adjustment for at least 3 – 6 months prior to initiation of the InPen System.
E. Has documented logs of glucose self-testing or CGM results - at least 4 times per day during the 1 month prior to consideration of an InPen System.
F. Meets **ONE or more of the following** while on an MDI regimen:
    1. Recent history (within last six months) of significant, recurring hypoglycemia (blood glucose < 70 mg/dl).
    2. Wide fluctuations (well below and above the set glycemic targets) in blood glucose before and after mealtimes, despite appropriate MDI using up to date insulins (analogs) and dose adjustments to affect control.
G. Patient has advanced carbohydrate counting skills and actively uses this information for insulin dosing
H. Patient demonstrates ability to recognize their glucose patterns and safely problem-solve these
I. Prescriber has documented a need for detailed electronic monitoring the patient's blood glucose levels and insulin dose administered

Ongoing Coverage of InPen System:
To qualify for ongoing coverage of an InPen System the member must meet **ALL of the following**:
A. There is documentation that patient monitors glucose at least four times daily, or appropriately uses a continuous glucose monitor.
B. Patient maintains advanced carbohydrate counting skills and actively uses this information for insulin dosing
C. Patient maintains ability to recognize their glucose patterns and safely and appropriately problem-solve these, including troubleshooting InPen malfunction
D. Patient has at least one visit per year with diabetes specialist* (face-to-face, secure message, or telephone encounter)

Back to Top

Replacement When Insulin Pump is No Longer under Warranty

The following considerations apply for replacement of an insulin pump that is no longer under warranty:

A. The warranty for the current device has expired (requests for replacement are not covered when the device is still under warranty). Currently, Medtronic and Tandem have 4-year warranty periods, OmniPod Dash does not have a warranty period. It is recommended to check the manufacturer's website for current information.
   A prior-authorization request from the treating diabetes specialist* managing the insulin pump to the Kaiser Permanente Pre-Service department is always required when an insulin pump is being replaced.
B. A face-to-face visit with the treating diabetes specialist* managing the insulin pump is documented within the past year.
C. The reason for the replacement request is fully documented in the member's medical treatment plan.
D. The current pump was previously approved by Kaiser Permanente or the current pump was approved by another non-Medicare plan, and the member meets the medical necessity and coverage criteria for Kaiser Permanente.
E. Suitability for continuance of pump therapy has been reviewed and confirmed by the Diabetes specialist*.
F. The item is not lost or damaged as a result of abuse.

A treating provider may order ongoing pump supplies in the interval between annual visits with the Diabetes specialist*

*Diabetes Specialist= Adult or Pediatric Endocrinologist or a provider under his or her direct supervision (eg. PA or ARNP with CDE or BC-ADM certification or Diabetes Team RN-CDE) or a Perinatologist managing a patient with diabetes during pregnancy.

Documentation requirements to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (endocrinology, primary care)
- Last 6 months of lab work
- Last 1-2 months of legible home monitoring logs or a printout of CGM results

Links to Request Forms:
Insulin Pump Request for New Pump Start Form
Insulin Pump Replacement Request Form

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 1998, the state of Washington passed the Diabetes Cost Reduction Act that requires that major health carriers provide coverage (all, or in part) for diabetes supplies (insulin, syringes, and delivery devices) and education. This new law includes insulin pumps.

Insulin pumps are high technology infusion devices, about the size of a small tape cassette. Flexible tubing connects to the pump that contains the insulin, and then to the patient via a needle that is put in place and changed every 2 to 3 days. The pump itself can then be programmed to deliver 'background' insulin on a continuous basis, and also allow pre-meal "boluses" to accommodate meals. The pump is NOT a system that a patient can just plug into and forget diabetes.

In fact, patients who use the pump have to learn how to program and trouble-shoot the technology, and also learn how to do complex decision-making. This intensive management approach requires multiple daily blood testing, learning how to recognize and use types of food in a very sophisticated way, keeping records, and learning to use the information for complex problem solving. This education is an absolute prerequisite to being on the insulin pump, so special education classes and supervised care are required.

Medical Technology Assessment Committee (MTAC)

Insulin Pump Type II Diabetes
04/20/2015: MTAC REVIEW

Back to Top

Evidence Conclusion: *Effectiveness* At baseline, the mean HbA1c was 9.0% (75 mmol/mol) in both groups. At six months, both groups saw a decrease in HbA1c (7.9% in the pump group vs. 8.6% in the MDI group) with a -0.7% (95% CI -0.9 to -0.4; -8 mmol/mol, 95% CI -10 to -4 mmol/mol, adjusted p<0.0001) difference between groups favoring pump treatment. Reduction in HbA1c in the pump group was also associated with a 20% lower daily dose of insulin compared with the MDI group, and was not accompanied by an increase in hypoglycemia or weight gain. Ultimately, the investigators concluded that patients with poorly controlled T2DM who received CSII over six months achieved significantly greater reductions in HbA1c.In a separate analysis, the investigators retrospectively stratified the study population according to concentrations of two different biomarkers determined from plasma collected at baseline. The first biomarker, anti-glutamic acid decarboxylase (anti-GAD) antibody (Ab), was present in 18% of the population at baseline indicating that the study population may include patients with T1DM. The investigators attribute this high rate to false-positives, relatively low cutoff values or a combination of both. The second biomarker, C-peptide, a measure of insulin production, did not appear to be associated with A1C level. Ultimately, the analysis demonstrated that HbA1c values were independent of both biomarkers (Reznik and Huang 2014). *Safety* The investigators reported five episodes of hyperglycemia related to the device or study procedure in the pump group and two diabetes related serious adverse events (SAE) resulting in hospital admission. Comparison with the MDI group is not possible as the collection of safety data appears to be incomplete. The investigators noted that data on self-reported mild hypoglycemia and hyperglycemia were not collected, nor were data for hyperglycemia in the MDI group. The studies strengths include randomization, sufficient sample size and the utilization of an intent-to-treat (ITT) analysis. To add to this, the study was conducted across 36 hospitals in five different countries. Methodological limitations of the study can be attributed to the nature of the treatments preventing blinding of patients and assessors. In addition, the investigators acknowledge that the average number of daily glucose self-monitoring tests in both groups was below the generally recommended standard of care, however, this may be consistent with real-life experiences. Finally, the investigators note that due to the inclusion/exclusion criteria and run-in phase, the results of the study may not be generalizable. As a final note, the study was designed and sponsored by Medtronic, the manufacturer of the device. Although they had no role in data collection, the analysis was carried out by statisticians employed by Medtronic. Conclusions: There is evidence to support the efficacy of CSII in achieving glycated hemoglobin targets in highly motivated patients with T2DM with have poor glycemic control, who are taking a total daily dose of insulin less than 220 units. There is limited evidence to support the safety of CSII patients with T2DM.
Articles: The literature was searched for studies assessing the effectiveness of CSII for glycemic control in patients with T2DM. A variety of publications were revealed including several observational studies and four small randomized controlled trials (RCT) with conflicting results. The best available evidence was a recent RCT comparing CSII with multiple daily injections (MDI). The following articles were selected for critical appraisal:
Reznik Y, Cohen O, Aranson R, et al. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (opT2mise): a randomized open-label controlled trial. The Lancet. 2014;384(9950):1265-1272.
See Evidence Table 1

The use of Insulin Pump for Type II diabetes does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Pancreas

BACKGROUND

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action or both. More specifically, in type 1 diabetes, the pancreas is unable to produce insulin which results in increased blood glucose levels, and ultimately, leads to complications which may affect the eyes, kidneys, nerves, heart and blood vessels. As a result, an essential part of diabetes management is to maintain blood glucose levels to as near normal as possible over all hours of the day. Implementation of this approach requires the individual to be capable of and committed to a day-to-day medical program. It requires ongoing compliance with multiple daily glucose measurements accompanied by appropriate adjustments in insulin dose and insulin injection. Additionally, successful intensive diabetic management requires response to a variety of external factors including changes in diet, exercise, and presence of infection.

Typically, patients self-monitor their blood glucose via fingerprick in an effort to optimize glycemic control, however, this technique is tedious and uncomfortable for the patient. In addition, this technique only provides information about a single point in time making it difficult to recognize trends. In any case, intensive glucose monitoring and insulin therapy can be challenging as they require obtaining, retaining, processing and applying vast amounts of information in the course of everyday life (Watkins, Connell et al. 2000; Boland, Monsod et al. 2001; Brauker 2009).

Back to Top

Evolving technologies such as continuous subcutaneous insulin infusion (CSII), and continuous glucose monitoring (CGM) have allowed patients to safely maintain glycemic goals and prevent other related complications. While there is evidence to support the efficacy of CSII (Misso, Egberts et al. 2010), the reliability and robustness of CGMs leaves much to be desired. Even with the aid of these devices, maintaining blood glucose concentrations within a suggested optimal range is a constant struggle.

Most recent technologic advancements have integrated these components into an Artificial Pancreas Device System (APDS). In addition to CSII and CGM, the APDS incorporates a control algorithm designed to facilitate communication between the different components thus automating the process of maintaining blood glucose concentrations at or near a specified target or range and, ultimately, improving glucose control, preventing complications, and decreasing disease burden. With a wide range of current products available on the market, there is potential for a large variety of different types and designs of ADPSs.

In an effort to help advance the development of the diabetes technologies, the U.S. Food and Drug Administration (FDA), in 2011, established three new product classifications for APDSs including threshold suspend, single hormonal control, and bihormonal control, all of which are regulated as class III device systems (general controls and premarket approval). In September of 2013, Medtronic's MiniMed® 530G was the first system approved under this new product classification. ADPSs have not previously been reviewed by the Medical Technology Assessment Committee (MTAC) and are currently being reviewed due to provider request.

The development of an "artificial pancreas" has been the "holy grail" for management of Type 1 diabetes for several decades. To understand why this is such a difficult task it helps to understand what the normal non-diabetic person's body actually does in response to changes in blood glucose. Within the pancreas we all have 1-2 million groups of cells called the Islets of Langerhans which function together to help maintain the blood glucose levels within a quite narrow range (of around 70-160mg/dl). The islets make two main hormones (insulin from the beta-cells and glucagon from the alpha cells) which work together in concert. These islet cells monitor the blood glucose flowing through them constantly. Whenever the blood goes up (after a meal, for example) the islets increase the amount of insulin that they are secreting from the beta-cells and decrease the amount of glucagon that they are secreting from the alpha cells. Whenever the blood glucose drops below normal the beta-cells turn off completely (so that no insulin is secreted) and the alpha cells crank out lots of glucagon. Glucagon (as well as other hormones like epinephrine, growth hormone and cortisol) stimulate the liver to release glucose into the blood stream (the liver stores about 300 grams of glucose in the form of a kind of starch called glycogen). The insulin and glucagon are released directly into the portal circulation of blood flowing from the pancreas to the liver. In other words, a non-diabetic person is functioning with millions of blood glucose measurements being done every day with the results connected to a continuously variable secretion of both insulin and glucagon released directly into the blood flowing to the liver. Even though the commercially made components of an "artificial pancreas" may seem very sophisticated they are a very crude and imprecise way of trying to do what the real non-diabetic person's pancreas can do.

First consider the delivery of insulin. Rather than having both insulin and glucagon being released directly into the blood flowing to the liver we have a continuous subcutaneous infusion of insulin alone. The insulin is absorbed out of the subcutaneous fat into the peripheral systemic circulation and only then gets to the liver. This can give a fairly accurate and stable basal delivery of insulin but when larger amounts of insulin are delivered immediately before meals (bolus insulin delivery) the rate of rise and fall of insulin in the bloodstream is a lot slower than in a healthy non-diabetic person's body.

Second, consider the measurement of blood glucose. Typically, diabetic patients test the capillary glucose level in their fingertips 2-8 times per day. This can give useful information but does not show the constant rising and falling of blood glucose excursions throughout the day. If needle sensors are placed in the subcutaneous tissue this can give a reading of interstitial fluid glucose (similar to plasma glucose) every 10-20 minutes throughout the day and so can show the trends as the blood glucose rises and falls. Several companies now make these continuous glucose monitoring systems (CGMS). There are two practical issues with CGMS, however: a) the interstitial fluid glucose lags behind the actual plasma glucose by 15-20 minutes and so can give a falsely low or high value if it is measured at times when the blood glucose is rising rapidly (after a meal) or is falling rapidly (after exercise or after injecting a bolus of insulin), and b) the glucose oxidase enzyme system for measuring blood glucose can drift over time and so the readings from a CGMS will be inaccurate unless they are calibrated several times a day by doing a capillary blood glucose test at a time when the blood glucose is expected to be stable (not rising or falling rapidly).

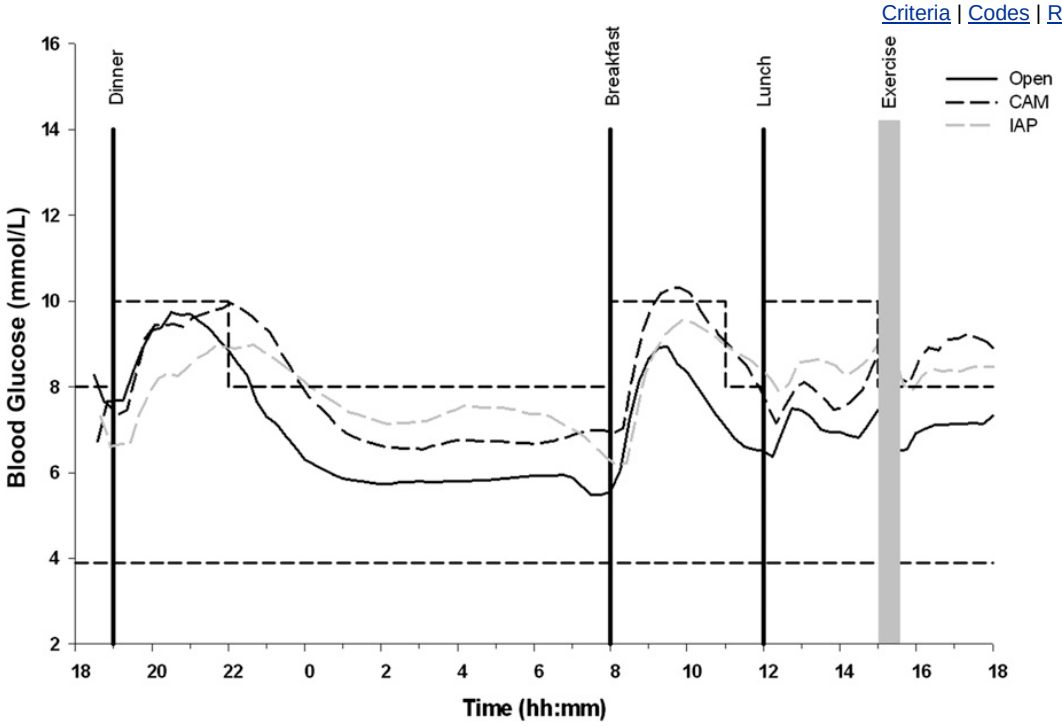
The concept of an "artificial pancreas" is that a person could wear both and insulin pump and a CGMS device and that the insulin pump uses the information from the CGMS to automatically make adjustments to the rate of insulin

 Back to Top

infusion. The person would not need to worry about testing their blood glucose or of thinking about what they eat and when they exercise but could go about their day-to-day life safe in the knowledge that their blood glucose would stay within normal limits. It is because of the practical limitations of the technology (outlined above) that we are still a long way away from that idealized situation.

02/14/2014: MTAC REVIEW
Artificial Pancreas
Evidence Conclusion: In this review, the results of four RCTs were included. One of these studies compared sensor-augmented insulin pumps to multiple daily insulin injections while two of them compared threshold suspense systems with standard insulin pumps. The last study compared two closed-loop algorithms to patient self-control with CSII. *Effectiveness*: Comparison of the effectiveness of sensor augmented pump therapy versus multiple daily injections (MDI) was examined in a one year multicenter, randomized and controlled phase of the sensor-augmented pump therapy for hemoglobin A_{1C} reduction (STAR-3) study. Compared with 241 subjects on MDI, those on pump therapy (n=244) experienced greater reductions in A_{1C} levels by three months, with the trend continuing throughout the remainder of the study. By the end of the study, the baseline A_{1C} level (8.3% in the two study groups) had decreased to 8.1% in the MDI group compared with 7.5% in the pump therapy group (P<0.001). Participants were offered an optional six-month continuation phase which allowed subjects in the pump therapy group to continue therapy and allowed subjects in the MDI group to cross over to pump therapy. The continuation phase resulted in a sustained lower mean A_{1C} value for patients in the pump therapy group and decreased the mean A_{1C} values to 7.6% (P<0.001) among MDI subjects who crossed over to pump therapy for the continuation phase. (Bergenstal, Tamborlane et al. 2010; Bergenstal, Tamborlane et al. 2011).See Evidence Table. In the three-month automation to simulate pancreatic insulin response trial (ASPIRE), 247 patients with type 1 diabetes and nocturnal hypoglycemia were randomized to sensor augmented insulin pump therapy with the threshold suspend feature (Paradigm group) or to the standard sensor-augmented insulin pump therapy (control group). The primary efficacy outcome was the area under the curve (AUC) for nocturnal hypoglycemic events. At the end of three months, the mean AUC for nocturnal hypoglycemic events was found to be significant through supportive analysis at 37.5% lower in the Paradigm group than in the control group (P<0.001) (Bergenstal, Klonoff et al. 2013). See Evidence Table. In another trial, 95 adults and children with type 1 diabetes were randomized to use of a sensor-augmented insulin pump with threshold suspension or a standard insulin pump. After six months, the combined incidence of moderate and severe hypoglycemic events was significantly lower in patients using the pump with the threshold suspension compared with the standard insulin pump (9.5 vs. 34.2 per 100 patient-months) (Ly, Nicholas et al. 2013). See Evidence Table. Most recently, Luijf and colleagues compared two validated closed-loop algorithms versus patient self-control with CSII in terms of glycemic control. The investigators concluded that both the algorithm developed by the University of Cambridge (CAM) and the algorithm developed by the University of Pavia, Padova, University of Virginia and University of California Santa Barbara (international artificial pancreas [iAP]) provide safe glycemic control. This study, however, occurred in a highly controlled environment for short periods of time. While the algorithms may have the benefit of less time in hypoglycemia, this came at the expense of higher mean glucose values when compared to self-management (open loop) and thus, more time spent in hyperglycemia (Luijf, DeVries et al. 2013). See Evidence Table.

Back to Top



Safety and Adverse Events: Safety and adverse events were included as endpoints in two of the four selected studies. In the STAR 3 study, data on adverse events were collected at each follow up clinic visit. Severe hypoglycemia was defined as an episode requiring assistance and was confirmed by documentation of a blood glucose value of less than 50 mg per deciliter (Bergenstal, Tamborlane et al. 2010). In the ASPIRE study, the primary safety endpoint was the change in glycated hemoglobin level. The change in the glycated hemoglobin level from randomization to study end was not significant in both groups, and the difference in hemoglobin level between groups was only 0.05 percentage points. Beyond that, no episodes of diabetic ketoacidosis occurred in either group or no severe hypoglycemic events occurred in the Paradigm group. During the study phase there were seven adverse events thought to be related to the study device which included skin irritation and device malfunction resulting in severe hyperglycemia (Bergenstal, Klonoff et al. 2013). Generally speaking, the studies had the advantage of randomization and control, however, the lack of blinding makes the evidence vulnerable to bias. In addition, the Ly et al. study relied on patient recall for their results and some of the experimental subjects may have had more contact with physicians opening up the results to recall and observation bias. Sample size ranged anywhere from 48 to 495 participants and most of the studies, with the exception of the STAR 3 Trail, did not report on the racial and ethnic composition of the study samples, and for those that did, participants were predominantly white. Furthermore, inclusion criteria were extremely selective with few studies including children younger than 12 years. In the same way, the data lack generalizability because management was limited to expert settings and among highly motivated patients. Further limitations include heterogeneity in definitions of hypoglycemia and short duration of follow-up ranging anywhere from 24 hours to 18 months. With many complications of diabetes developing over many years it would be ideal to see results allowing for multiple periods of sensor wear and to evaluate changes in subject needs over time. With that said, at the current point in time, APDSs are a rapidly evolving technology that should only be considered in select patients.

Conclusion:

- The results of the published studies suggest that APDS may be effective in reducing hypoglycemia in highly selected, motivated and compliant groups of individuals.
- There is some evidence to support the safety of APDS in highly compliant adult patients.

Articles: The search revealed over 500 articles many of which were commentary, discussion, or systematic review articles. Articles were screened for randomized, comparison studies of outcomes between patients using APDS and a control group of patients using currently available technology. The following articles were selected for critical appraisal: Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy for type 1 diabetes. *New England Journal of Medicine*. 2010;**363**(4):311-320. See Evidence Table. Bergenstal RM, Klonoff DC, Garg SK, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. *New England Journal of Medicine*. 2013;**369**(3):224-232. See Evidence Table. Ly TT, Nicholas JA, Retterath A, et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspensions vs standard insulin pump therapy on hypoglycemia in patients with type 1 diabetes a randomized clinical trial. *JAMA*. 2013; 310:1240-1247. See Evidence Table**.** Luijf YM, DeVries JH, Zwinderman K, et al. Day and night closed-loop control in adults with type 1 diabetes. *Diabetes Care.* 2013;**36**: 3882-3887. See Evidence Table.

Back to Top

The use of Artificial Pancreas does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Insulin Pump and supplies – Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E0784	External ambulatory infusion pump, insulin
A4230	Infusion set for external insulin pump, nonneedle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3 cc
K0552	Supplies for external noninsulin drug infusion pump, syringe type cartridge, sterile, each

Insulin Pump *used with continuous glucose monitor*
Medicare - Considered not medically necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week

Artificial Pancreas -
Medicare - Considered not medically necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

InPen Smart Insulin Pen –
Considered medically necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes – often submitted as *E1399 Durable medical equipment, miscellaneous* or *A4211 Supplies for self-administered injections*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

******To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised

Back to Top

09/1988	12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012 [MDCRPC], 06/04/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPCC], 07/07/2015[MPC], 08/04/2015[MPC], 09/01/2015[MPC], 06/07/2016[MPC], 01/03/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC], 01/09/2024[MPC]	12/02/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description of Change
04/07/2015	Revised C-peptide testing requirement.
04/27/2015	Added MTAC review on Insulin Pump for Type II Diabetes
07/07/2015	Revised criteria to include indications for Type II Diabetes
09/03/2015	Added criteria for Pediatrics – 18 years and under
11/09/2015	Merged Artificial Pancreas criteria with Insulin Pump
02/17/2016	Added HCPCS codes
01/03/2017	Revisions made to insulin pump criteria; combined adult and pediatric into one policy
02/07/2017	MPC approved criteria to manage insulin pumps for pregnant patients
10/08/2018	Updated request form links
11/03/2020	Added note about combined insulin pump/CGM device and documentation requirements to support medical necessity; removed insulin brand names
07/20/2021	Added note about InPen Smart Insulin Pen not currently considered medically necessary pending MTAC review.
11/02/2021	MPC approved to waive the 6-month period typically used to learn how to monitor diet and other factors that impact blood sugar results prior to being eligible for an insulin pump for patients under the age of 13. This will be on a case-by-case basis as approved by a medical director. Requires 60-day notice, effective 04/01/2022.
01/04/2022	Updated required length of time to provide self-testing/CGM logs from 2 months to 1 month for initial insulin pump. MPC approved clinical criteria for the InPen System. 60-day notice is required; effective June 1, 2022.
02/24/2022	Updated applicable codes
07/05/2022	MPC approved to cover the Omnipod 5 system and will apply to the Insulin Pump criteria.
12/02/2022	Updated Medicare Policy to defer to KP Non-Medicare criteria for InPen system requests. Updated Medicare LCD L33794 and LCA A52507 links.

Back to Top