Continuous Glucose Monitoring Systems and Insulin Pumps for Management of Diabetes

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INSTRUCTIONS:

“This Medical Policy provides assistance in interpreting UCare benefits. When deciding coverage, the member specific Evidence of Coverage (EOC) document must be referenced. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice. UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.”
POLICY DESCRIPTION:

This policy describes the use of continuous glucose monitoring and insulin pumps for the management of diabetes mellitus. Continuous glucose monitoring systems (CGMS) are minimally invasive or noninvasive devices that measure glucose levels in interstitial fluid at frequent intervals over a period of several days. CGM systems are designed to obtain information regarding diurnal patterns in glucose levels that, when evaluated in real time or reviewed retrospectively by a physician, can guide adjustments to therapy, with the goal of improving overall glycemic control. The glucose measurements provided during continuous monitoring are not intended to replace standard self-monitoring of blood glucose (SMBG) obtained using fingerstick blood samples, but can alert the patient to the need to perform SMBG.

Insulin pumps deliver insulin to patients with diabetes mellitus via intraperitoneal, subcutaneous or intravenous routes in a programmed and controlled manner. Insulin pumps are battery operated and controlled by a small computer that is programmed to deliver a steady "basal" amount of insulin. Pumps may also release a "bolus" dose at meals and at programmed intervals. CGM devices may be used with insulin pumps forming a closed-loop system.

An external insulin pump, also known as a continuous subcutaneous insulin infusion pump, ambulatory pump, or mini-infuser, can be worn on the patient’s waistband or in a shoulder harness.

An implantable insulin pump (IIP) consists of the pump, an intraperitoneal delivery catheter, and a patientpump communicator used to program the device. The pump is surgically implanted under the skin of the abdomen. A remote control prompts the pump to give specified insulin amounts. The pump is refilled with insulin every 2-3 months.

COVERAGE RATIONALE: /COVERAGE POLICY: /COVERAGE DETERMINATION:

Use of Continuous Glucose Monitoring systems for the treatment of diabetes is considered MEDICALLY NECESSARY for Type 1 diabetics who:

- Have episodes of hypoglycemia unawareness,

  OR

- Fail to achieve: (Adequate glycemic control appropriate to the patient,

  OR  (Appropriate A1C levels,

  despite frequent self-monitoring of blood glucose levels by finger stick and insulin adjustments.
Use of an External (Ambulatory) Insulin Pump, including programmable, disposable external insulin pumps, for the treatment of diabetes is considered MEDICALLY NECESSARY for Type 1 diabetics who:

- Fail to achieve:  
  - Adequate glycemic control appropriate to the patient,  
  - OR  
  - Appropriate A1C levels,

despite frequent self-monitoring of blood glucose levels by finger stick and insulin adjustments.

NOT MEDICALLY NECESSARY

1. Use of a personal CGM device by individuals with type 2 diabetes or for pregnant women with gestational diabetes is NOT MEDICALLY NECESSARY.

2. Closed-Loop Systems, also called Artificial Pancreas Device Systems (APDS), that combine continuous glucose monitoring (CGM) with a combination pump and display unit are considered EXPERIMENTAL AND INVESTIGATIONAL and are not a Covered Health Service due to lack of clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature. This includes but is not limited to the following devices:
   - Paradigm® REAL-Time System,
   - MiniMed 530G System with Enlite Sensor

3. Implantable Insulin Pumps (IIP) for the treatment of diabetes are considered EXPERIMENTAL AND INVESTIGATIONAL and are not a Covered Health Service due to lack of clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature.

4. Use of a GlucoWatch® Automatic Glucose Biographer is NOT MEDICALLY NECESSARY.

Clinical Considerations:

Definitive patient selection criteria for CGM systems have not been established. However, there is sufficient evidence of benefit to support the use of CGM in adult patients with type 1 diabetes who have not achieved adequate glycemic control despite frequent self-monitoring of fingerstick blood glucose levels. The use of a CGM system is not recommended for patients with impaired vision or hearing that would not allow full recognition of the device signals and alarms and who do not have a caregiver who can perform this function for them.

Definitive patient selection criteria for insulin pump therapy for treatment of diabetes have not been established. However, insulin pumps should be used only in individuals who have demonstrated ability to consistently and accurately monitor blood glucose at least 3 times per day and adjust insulin dosing accordingly and in those who have adequate access to medical personnel trained in insulin pump therapy.

Contraindications:

Contraindications reported in the literature for intensive insulin therapy provided by either multiple daily injection or pump include the following (Ziegler et al., 1992; DCCT Research Group, 1993; Steinberg, 1993; Wredling et al., 1993; Campbell and May, 1995; Pickup and Keen, 2002):

- Severe neuropathy
• A history of hypoglycemic unawareness
• Other major medical or emotional illness
• Cardiovascular disease
• Advanced renal failure or severe retinopathy
• Uncorrected endocrine abnormality
• Cognitive impairment
• Chronic alcohol abuse
• Age < 2
• Failure to comply with all components of conventional insulin therapy
• Employment involving heavy work and frequent showers
• “Brittle” diabetes accompanied by recurrent ketoacidosis and apparent insulin resistance
• Inadequate body size to support the bulk of an implanted pump in subcutaneous tissues

Insulin pump therapy, or any form of intensive insulin therapy, is associated with a 2 to 3 times increased risk of severe hypoglycemia, compared with conventional insulin therapy.

Possible Complications:
• Weight gain
• Transient worsening of retinopathy
• Severe hypoglycemia
• Infection and inflammation at infusion site
• Catheter blockage
• Chronic subcutaneous infection
• Local erythema
• Abdominal pain
• Bladder pressure
• Low-grade fever

Ketoacidosis can develop due to pump defect, catheter leakage or blockage, or by a disconnection of the catheter from the skin (Reichel et al., 1998). The incidence of device malfunction due to catheter obstruction or breakage or premature battery failure is high. Catheter obstruction has been reported to occur at rates ranging from 45% to 86% over a 3-year period (Selam et al, 1992a; Renard et al., 1995; Dunn et al., 1997). Pump site infections have been reported in up to 4% of patients receiving implantable insulin pump therapy (Udelsman et al., 2000; Gin et al., 2003).

BACKGROUND:

Diabetes mellitus is a chronic disorder involving impaired metabolism of carbohydrates, proteins, and fats. It is characterized by increased blood glucose levels, or hyperglycemia, and is caused by impaired pancreatic insulin secretions or by inefficient use of insulin by the body. Diabetes cannot be cured. Medical management is based on controlling glucose levels to maintain long-term normoglycemia. Patients with type 1 diabetes are dependent on exogenous insulin for adequate glycemic control. Patients with type 2
diabetes may be able to control glucose levels with diet or oral antidiabetic agents, although they may also benefit from insulin therapy.

Several methods of administering insulin are available, including the conventional needle and syringe, insulin infusion pumps, pen injectors, and jet injectors. Many patients have difficulty complying with a regimen of daily subcutaneous (SC) injections because of pain, inconvenience, or fear of injections. The reluctance to administer multiple injections every day can lead to suboptimal glycemic control, resulting in a higher risk of complications. An injection-free system could assist patients in achieving better control (Valla, 2010; CDC, 2011).

**Continuous glucose monitoring (CGM) systems** use a small, flexible glucose oxidase sensor inserted under the skin, usually in the abdomen or arm, to measure interstitial glucose concentrations. A water resistant transmitter on the skin sends glucose readings wirelessly to a receiver which downloads data to a personal computer, generating a glycemic profile. Interstitial glucose concentrations are reported every 5 to 10 minutes; some CGMs are capable of reporting every minute. This enables patients to detect trends and patterns in their glucose levels. Although the information from these monitoring systems allows therapy to be optimized, it requires high levels of attention to and frequent adjustment of insulin doses.

**Closed-Loop Systems**, also called **artificial pancreas device systems (APDS)**, consist of a continuous glucose monitor and a pump system incorporating a computerized algorithm that communicates with both devices. The goal of the APDS is to monitor glucose levels and adjust insulin levels without direct patient interaction. A transmitter connected to the glucose sensor sends data wirelessly to a combination pump and display unit, which can automatically adjust insulin infusion to provide continuous control of glucose levels. The pump will also sound and show alarms when glucose levels are too high or too low.

**External insulin pumps** have a programmable, battery-powered mechanical syringe precisely regulated by a miniature internal computer. The syringe, which has a 2-day insulin capacity, is filled with short-acting or regular insulin. The syringe is connected by a thin plastic tube, known as an infusion set or infusion line, to a small 27-gauge needle or a soft Teflon cannula. The patient inserts the needle or cannula into subcutaneous tissue, usually in the abdomen. A plunger on the syringe is activated by a lead screw, delivering insulin at the rate programmed into the pump (Stagner, 1992; Strowig, 1993).

The pump delivers insulin in two ways—basal delivery and bolus delivery. Basal delivery is a slow, continuous infusion of insulin delivered at a predetermined rate programmed into the pump to cover background insulin needs, such as protein uptake by cells, release of fats by the liver and fat cells, and balance of other hormones in the blood. Bolus insulin delivers a larger amount of insulin given at a distinct time, such as prior to a meal or a long sedentary period, such as bedtime, or when blood glucose is elevated due to stress, illness, or increased dietary intake. The patient programs in the dose and receives it by pressing a button. In general, the total basal dose received over a 24-hour period comprises 40% to 60% of the patient's total insulin requirements, and the bolus doses comprise the remaining 40% to 60% (Strowig, 1993).

A high level of patient motivation is critical for successful insulin pump therapy. The patient is responsible for refilling the syringe, changing both the injection site and the infusion set every 24 to 48 hours, replacing
batteries every 1 to 3 months, monitoring blood glucose levels several times a day, and adjusting and programming bolus doses. The pump can be worn 24 hours per day during most activities, including sports and sexual intimacy, although they must be removed or protected when bathing. If the pump is removed for longer than 1 hour, manual syringes should be used. The pumps have built-in safety features that prevent the over injection of insulin and an alarm signals low batteries, low insulin levels, blockages, and inappropriate patient usage (Strowig, 1993).

**Implantable insulin pump (IIP) systems** consist of the pump, an intraperitoneal delivery catheter, and a patient-pump communicator used to program the device. Approximately 6000 units of U-400 regular human insulin can be stored in the pump reservoir, which is maintained at a negative atmospheric pressure. This minimizes the potential for life-threatening over-delivery of insulin and allows for passive refilling of the reservoir by a percutaneous route. Current pump models are powered by lithium batteries that have a life of approximately 2.5 years. A polyethylene-lined silicone catheter is attached to a side port of the pump and is designed to deliver insulin directly into the peritoneal cavity. The pump delivers a constant basal rate of insulin supplemented with intermittent boluses (Waxmann et al., 1992; Udelsman et al., 2000; Gin et al., 2003). Insulin rate limits are preprogrammed by the attending physician. The actual amount of insulin released is then regulated by the patient based on frequent blood glucose self-monitoring (Selam et al., 1992a; Gin et al., 2003; Logtenberg et al., 2009a). The pump is refilled transcutaneously every 3 months under local anesthesia.

**REGULATORY STATUS:**

**1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

The following continuous glucose monitoring (CGM) systems have been approved by the FDA: GlucoWatch® G2 Biographer (Animas Corp.); DexCom Seven™ Plus (DexCom Inc.), MiniMed CGMS, MiniMed Guardian® Real-Time System, MiniMed Paradigm® Real-Time System, and iPro Continuous Glucose Monitor (Medtronic MiniMed Inc.); and the FreeStyle® Navigator Continuous Glucose Monitoring System (Abbott Diabetes Care) (CDRH, 2010a; CDRH, 2010b; CDRH, 2010c, CDRH, 2010d).

The GlucoWatch G2 Biographer is indicated for detecting trends and tracking patterns in glucose levels in adults (age 18 years or older) and in children and adolescents (age 7 to 17 years) with diabetes. The device is intended for use as an adjunctive device to supplement, not replace, information obtained from standard home glucose-monitoring devices. The device is indicated for use in the detection and assessment of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of results should be based on the trends and patterns seen with several sequential readings over time (CDRH, 2010a).

The DexCom Seven Plus CGM system is indicated for detecting trends and tracking patterns in diabetic adults age 18 years or older. It is approved as an adjunctive device, but not as a replacement, for standard home glucose-monitoring devices, and is intended to aid in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions (CDRH, 2010c). The device consists of a receiver (a pager-like device...
that is programmed to collect and process data from the sensor and display the results as a glucose value), transmitter, sensor (a device that is inserted underneath the skin to continuously monitor glucose levels), a receiver carrying case, and receiver charger. The glucose levels measured by the sensor are sent by a wireless, low-powered radio frequency to the receiver every 5 minutes for 7 days before a new sensor must be inserted. This particular device must be removed prior to magnetic resonance imaging (MRI). Additionally, use of acetaminophen-containing medications during the time that the sensor is inserted may affect device performance (CDRH, 2010c; DexCom Inc., 2010).

The MiniMed CGMS is intended to continuously record interstitial glucose levels in persons with diabetes. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose-monitoring devices. The information collected by the device may be downloaded and displayed on a computer and reviewed by healthcare professionals; measurements are not displayed to the patient in real time. This information may allow identification of patterns of glucose level excursions above or below the desired range, facilitating therapy adjustments, which may minimize these excursions (CDRH, 2010b).

The MiniMed Guardian Real-Time System with real-time display is indicated for continuous or periodic monitoring of glucose levels in the fluid beneath the skin in diabetic adults 18 years of age or older, and in diabetic children age 7 to 17 years, for the purpose of improving diabetes management. The device provides an alert if the glucose level falls below or rises above preset values. Values are not intended to be used directly for making therapy adjustments, but rather, to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on Guardian values. Glucose data can be further downloaded to personal computer software for analysis of historical glucose values. Approval for the Paradigm RealTime system is similar, although this device is specifically designed to be used in conjunction with an insulin pump (CDRH, 2010b).

iPro Continuous Glucose Monitor (CGM), a prescription-use only CGM device, provides a 3-day evaluation of glucose levels. A subcutaneous sensor records glucose levels every 5 minutes for 3 days, and is designed for occasional use, rather than everyday use. The iPro System is intended to continuously record interstitial glucose levels in diabetic individuals, but the readings are not available directly to patients in real time, and the readings are available for review by physicians after the entire 72-hour recording interval. Available data are designed to identify patterns of glucose level excursions above or below the desired range, facilitating therapy regimen adjustments that may minimize these excursions (CDRH, 2010b).

The FreeStyle Navigator system is a glucose monitoring device indicated for patients age 18 or older with diabetes, and is designed to improve diabetes management. The device consists of an internal blood glucose meter that confirms the continuous glucose result and provides real-time readings, graphs, trends, and glucose alarms to the user. It is intended to be used in a home setting to assist patients with diabetes to predict and detect episodes of hypoglycemia and hyperglycemia, and in clinical settings to assist healthcare professionals to evaluate glucose control (CDRH, 2010d).
The Paradigm REAL-Time System is classified as an invasive glucose sensor and it is regulated by the FDA as a Class III device that is subject to the most rigorous laws enforced by the FDA. This device was initially approved via the Premarket Approval (PMA) process on June 15, 1999 (P980022). According to a supplement (S048) to the PMA approved on April 9, 2009, subcutaneous glucose measurements obtained with the Paradigm System are not intended to guide therapy adjustments directly. Instead, the glucose measurements are intended to help patients decide when blood glucose should be measured using a finger-stick blood sample. The Paradigm system has not been approved for closedloop use.

External Pumps
A search of the FDA Center for Devices and Radiological Health (CDRH) 510(k) database identified a number of insulin infusion pumps that have received premarket approval, including devices from:

- Disetronic Medical Systems, Inc.
- Deltec, Inc.
- Sooli Development Co.
- Nipro Diabetes Systems, Inc.
- Animas Corp.
- Cane SRL
- Medtronic MiniMed • Cardiac Pacemakers, Inc.
- Pharma-Plast USA, Inc.

Internal Insulin Pumps (IIP)
No IIPs have received FDA approval for marketing (CDRH, 2011a).

Artificial Pancreas System with Threshold Suspend Automation
The MiniMed 530g insulin pumps (Medtronic first-generation artificial pancreas system) is the first system approved under the new product classification, "OZO: Artificial Pancreas Device System, Threshold Suspend," created by the U.S. Food and Drug Administration. Threshold Suspend automation automatically stops the delivery of insulin if glucose levels reach a threshold, which can be set by a healthcare provider between 60-90 mg/dL. Once the threshold is met, the MiniMed 530G system will first alert the wearer with an alarm. If the individual is sleeping, unconscious or otherwise unable to react, the system will suspend all insulin delivery for two hours. Insulin delivery can be resumed at any time.

The MiniMed 530G System is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus in persons, sixteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 530G System can be programmed to automatically suspend delivery of insulin when the sensor glucose value falls below a predefined threshold value. The Enlite sensor can be worn for six days. As a condition of approval,
Medtronic will conduct a post-approval study including children ages two and older, will engage in direct patient follow up, and will make certain manufacturing accommodations. (September 27, 2013).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

   Continuous glucose monitoring (CGM) systems
   CMS does not have a National Coverage Determination (NCD) regarding the use of CGM systems (CMS, 2010). In the absence of an NCD, coverage is left to the discretion of local Medicare carriers.

   Continuous glucose monitors (A9276-A9278) are considered precautionary and therefore non-covered under the DME benefit as stated in article A47238 of the LCD for Minnesota.

   Closed-loop glucose control devices
   CMS covers use of closed-loop blood glucose control devices for short-term management of insulin-dependent diabetic inpatients in times of crisis. Potential crises include stress, trauma, surgery, labor and delivery, or wide fluctuations in blood glucose levels. Due to the complications that may occur, patients usually undergo this treatment for only 24 to 48 hours.

   External Insulin Pumps
   CMS has adopted a national coverage policy on Continuous Subcutaneous Insulin Infusion (CSII) Pumps (effective for services performed on or after December 17, 2004):

   Continuous subcutaneous insulin infusion (CSII) and related drugs/supplies are covered as medically reasonable and necessary in the home setting for the treatment of diabetic patients who: (1) either meet the updated fasting C-Peptide testing requirement, or, are beta cell autoantibody positive; and, (2) satisfy the remaining criteria for insulin pump therapy as described below. Patients must meet either Criterion A or B as follows:

   Consideration for inclusion in criterion A:
   • The patient has completed a comprehensive diabetes education program; has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump; has documented frequency of glucose self-testing an average of at least 4 times per day during the 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:
     ◦ Glycated hemoglobin level (HbA1c) > 7.0%
     ◦ History of recurring hypoglycemia
     ◦ Wide fluctuations in blood glucose before mealtime
     ◦ Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
     ◦ History of severe glycemic excursions.

   Consideration for inclusion in criterion B:
Clinical & Quality Management

MEDICAL POLICY

- The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

General CSII Criteria
In addition to meeting Criterion A or B above, the following general requirements must be met: The patient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or, as an alternative, must be beta cell autoantibody positive.

- Insulinopenia is defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method.
- For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) ≤ 50 ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method.
- Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤ 225 mg/dL.
- Levels only need to be documented once in the medical records.

Continued coverage of the insulin pump would require that the patient be seen and evaluated by the treating physician at least every 3 months. The pump must be ordered by and follow-up care of the patient must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII.
**Internal (Implanted) Insulin Pumps**
CMS does not cover implanted infusion pumps for diabetes, stating that the data do not demonstrate that the pump provides effective administration of insulin (CMS, 2011).

**MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**
Recipients with Type 1, Type 2 or Gestational diabetes are eligible for diabetic equipment and supplies. **Continuous glucose monitoring** does not replace traditional home blood glucose monitoring, but may be approved as an adjunct for individuals with type 1 diabetes with a history of severe hypoglycemia less than 50 mg/dL with unawareness due to age or cognitive function. Documentation must show frequent self-monitoring and appropriate modifications to insulin regimen. Authorization is always required for codes A9277 and A9278. Authorization is not required for code A9276.

**Ambulatory Insulin Infusion Pumps** are covered for eligible MHCP recipients age 12 or younger with type 1 diabetes, or for eligible MHCP recipients over age 12 with diabetes who are beta cell autoantibody positive or have a documented fasting serum C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory’s measurement method. Recipients must meet the following criteria for coverage:
- Completion of a comprehensive diabetes education program
- On a program of at least 3 injections of insulin per day, with frequent self-adjustments of dose, for at least 6 months
- Documented self-testing an average of at least 4 times per day
- Has one of the following:
  - Elevated glycosylated hemoglobin level of HbA1c greater than 7.0%
  - History of recurring hypoglycemia less than 60 mg/dL
  - Wide fluctuations in blood glucose before mealtime
  - Dawn phenomenon with fasting blood sugars often over 200 mg/dL
  - History of wide glycemic excursions
  - Otherwise unable to maintain optimal control.

No decision regarding **Implanted Insulin Pumps** or **Closed-Loop Systems** was found.

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**CLINICAL EVIDENCE:**
A number of studies of **continuous glucose monitoring** systems met the criteria for detailed review, including 20 randomized controlled trials (RCTs) or crossover trials and 9 nonrandomized trials. Ten studies involved pediatric patients with type 1 diabetes, while 16 studies enrolled adult patients with either type 1 or type 2 diabetes. Two studies evaluated women with gestational diabetes, and two involved pregnant women with type 1 or type 2 diabetes. Evidence for closed-loop continuous insulin infusion, external
insulin pumps and implanted insulin pumps were identified. Studies using a control group or crossover
design were selected for review. Additional information was obtained from the ADA and the National
Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Web sites. Studies that used a prospective
design and evaluated the safety and/or efficacy of the implantable insulin pump (IIP) in at least 20 patients
were included. Additional information was obtained from MiniMed Inc. and from the National Diabetes Information Clearinghouse (NDIC), a service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

**EXTERNAL SOURCES/ GROUPS POLICY:**

**American Association of Diabetes Educators (AADE):** June 6, 2014, the AADE released a white paper regarding the use of continuous subcutaneous insulin infusion (CSII), which AADE also terms as insulin pump therapy. AADE recommends an assessment of a number of clinical and lifestyle indicators and desired attributes when performing an assessment of whether a person is an appropriate candidate for insulin pump therapy. Clinical indications for insulin pump use are as follows:

- Inadequate glycemic control despite optimized multiple daily injection (MDI) therapy,
- High glucose variability,
- Elevated A1C,
- Recurrent, severe, or unpredictable hypoglycemia,
- Nocturnal hypoglycemia,
- Hypoglycemia unawareness,
- Recurrent hyperglycemia,
- Dawn phenomenon,
- Preconception planning,
- Pregnancy,
- Extreme insulin sensitivity,
- Gastroparesis,
- Early neuropathy or nephropathy,
- Renal transplantation.

Lifestyle indications are as follows:

- Erratic schedule,
- Varied work shifts,
- Frequent travel,
- Desire for flexibility,
- Inconvenience of multiple daily injections (MDI).

**American Diabetes Association (ADA):** In a clinical practice recommendation entitled “Standards of Medical Care in Diabetes,” the ADA recommends that CGM may be useful as an adjunct to self-monitoring blood glucose (SMBG) for select patients to help guide treatment decisions and/or self-management for patients using less frequent insulin injections or noninsulin therapies. When used in conjunction with intensive insulin regimens, CGM is a useful tool to lower A1C in adults (aged≥25 years) with type 1 diabetes. CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. (ADA, 2015).
### American Association of Clinical Endocrinologists (AACE):
The AACE has published a set of medical guidelines for management of diabetes mellitus. The AACE recommends that CGM be arranged for patients with type 1 diabetes with unstable glucose control and for patients who are not able to achieve an acceptable level of glycosylated hemoglobin. The AACE also states that CGM may be valuable for detecting unrecognized nocturnal hypoglycemia and postprandial hyperglycemia (Rodbard et al., 2007).

### National Institute for Health and Clinical Excellence (NICE):
In a set of guidelines published in 2004, NICE recommended the use of CGM systems in adults on insulin therapy who have consistent problems with controlling blood glucose levels. The guidelines also recommend that CGM be available to children and young adults with type 1 diabetes who have persistent problems with impaired awareness of hypoglycemia, or experience repeated hypoglycemia and hyperglycemia (NICE, 2004).

### SUMMARY:
There was relatively little information in the published literature regarding the safety and efficacy of CSII in type 2 diabetics, and the benefits of intensive insulin therapy delivered via either multiple daily injections or external pump are not as well established for type 2 diabetics as for type 1 diabetics.

Although closed-loop insulin management was associated with better maintenance of glucose levels in the targeted range, only one of the studies reported that this association was statistically significant. Furthermore, this system has only been tested in closed-loop mode for short periods of time in a small number of patients who were receiving high levels of medical care. Therefore, it is not clear whether this treatment will provide long-term benefits for patients under normal conditions.

### Implantable Insulin Pump
The available evidence indicates that IIPs can provide an effective and reasonably safe means of maintaining good glycemic control in individuals with either type 1 diabetes or insulin-requiring type 2 diabetes, although frequent complications due to catheter obstruction, pump function, or infection are reported. IIP therapy, particularly when an IP catheter is used, is associated with a number of benefits compared with intensive insulin therapy via subcutaneous (SC) injection, including less fluctuation in blood glucose, better glycemic control, lower incidence of hypoglycemic events, improved glycosylated hemoglobin levels, less weight gain, and reduced need for antihypertensive medications. A single long-term study suggested that the use of IIPs may delay the onset and slow the progression of the chronic complications of diabetes, such as neuropathy, retinopathy, nephropathy, and vascular disease.

### External Insulin Pump
The DCCT Research Group (1993) demonstrated that, for type 1 diabetics, intensive insulin therapy with MDI or external pump is effective in achieving near-normal blood glucose levels and in delaying the onset and progression of late secondary diabetic complications, including retinopathy, nephropathy, and neuropathy. The research reviewed in this report showed that external insulin pump treatment alone is effective in accomplishing these therapeutic objectives and can provide even greater glycemic control than does multiple daily injection therapy.
APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A4221</td>
<td>Supplies for maintenance of drug infusion catheter, per week (list drug separately)</td>
</tr>
<tr>
<td>K0552</td>
<td>Supplies for external drug infusion pump, syringe type cartridge, sterile, each</td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
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<tr>
<td>A9275</td>
<td>Home glucose disposable monitor, includes test strips</td>
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<tr>
<td>A9276</td>
<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply</td>
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<tr>
<td>A9277</td>
<td>Transmitter; external, for use with interstitial continuous glucose monitoring system</td>
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<tr>
<td>A9278</td>
<td>Receiver (monitor); external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td>E0607</td>
<td>Home blood glucose monitor</td>
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<tr>
<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
</tr>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
<tr>
<td></td>
<td>NOTE: The i-port device is not durable medical equipment (DME) nor does it have a listed code</td>
</tr>
<tr>
<td>S1030</td>
<td>Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)</td>
</tr>
<tr>
<td>S1031</td>
<td>Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)</td>
</tr>
<tr>
<td>S1034</td>
<td>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</td>
</tr>
<tr>
<td>S1035</td>
<td>Sensor; invasive (eg, subcutaneous), disposable, for use with artificial pancreas device system, 1 unit = 1 day supply</td>
</tr>
</tbody>
</table>
S1036 Transmitter; external, for use with artificial pancreas device system
S1037 Receiver (monitor); external, for use with artificial pancreas device system

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>250.xx*</td>
<td>Type 1 insulin-dependent diabetes mellitus</td>
</tr>
<tr>
<td>250.xx*</td>
<td>Type 2 non-insulin-dependent diabetes mellitus (adult onset)</td>
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</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>E10</td>
<td>Type 1 diabetes mellitus</td>
</tr>
<tr>
<td>E11</td>
<td>Type 2 diabetes mellitus</td>
</tr>
<tr>
<td>O24.1</td>
<td>Pre-existing diabetes mellitus, non-insulin-dependent</td>
</tr>
<tr>
<td>O24.2</td>
<td>Pre-existing malnutrition-related diabetes mellitus</td>
</tr>
<tr>
<td>O24.3</td>
<td>Pre-existing diabetes mellitus, unspecified</td>
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<tr>
<td>O24.4</td>
<td>Diabetes mellitus arising in pregnancy</td>
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<tr>
<td>O24.9</td>
<td>Diabetes mellitus in pregnancy, unspecified</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>95250</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording</td>
</tr>
<tr>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report</td>
</tr>
</tbody>
</table>

CPT® is a registered trademark of the American Medical Association.

REFERENCES:


22. Chico A, Vidal-Ríos P, Subirà M, Novials A. The continuous glucose monitoring system is useful for detecting
unrecognized hypoglycemias in patients with type 1 and type 2 diabetes but is not better than frequent capillary glucose measurements for improving metabolic control. Diabetes Care. 2003;26(4):1153-1157.


43. Hays, Winifred S. Medical Technology Directory. Continuous Glucose Monitoring Systems. Dec 2010. Annual Review Dec 2013. Available at: https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=1882&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3Dcontinuous%2Cglucose%2Cmonitoring%2Csystem%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3DasearchRelevance. Accessed Mar 3, 2015.


55. Luijf Y. Mader J. Doll W. et al. Accuracy and reliability of continuous glucose monitoring systems: A head-
56. Medtronic Diabetes. Study Comparing Effectiveness of Intraperitoneal Insulin Administration to Subcutaneous


74. Tamborlane WV, Beck RW, Bode BW, et al.; Juvenile Diabetes Research Foundation Continuous Glucose


POLICY HISTORY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>04-23-2015</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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