

<b>BSC1.03</b>	<b>External Insulin Infusion Pump</b>		
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<b>Section:</b>	1.0 Durable Medical Equipment	<b>Page:</b>	Page 1 of 22

## Policy Statement

- I. A first-time external insulin infusion pump with or without continuous glucose monitoring (CGM), low glucose suspend or automatic adjustment of basal insulin rate capability, may be considered **medically necessary** for insulin-requiring diabetic patients when **all** of the following criteria are met:
  - A. The device requested is age appropriate as approved by the U.S. Food and Drug Administration (FDA) (see Policy Guidelines)
  - B. Documented clinical presentation of at least **one** of the following:
    1. Glycohemoglobin level (HbA1c) greater than 7%
    2. History of recurrent severe hypoglycemia/hypoglycemia unawareness (typically a blood glucose less than 50 mg/dL) or severe glycemc excursions
    3. History of recurrent diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization
    4. Wide fluctuations in blood glucose before mealtime
    5. Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL
    6. Beta cell antibody positive or 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 and a concurrently obtained fasting glucose less than 225mg/dL
    7. Renal insufficiency with a creatinine clearance less than or equal to 50 ml/minute and a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory measurement
    8. Patients with insulin-requiring type 2 diabetes mellitus whose diabetes is poorly controlled (including unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis), despite documented compliance (i.e., a log) with a regimen of four or more finger sticks and insulin adjustments each day
  - C. Documented diabetes management demonstrated by **all** of the following for first time pump users:
    1. Seen by a medical provider three times within the last year
    2. Completion of a comprehensive diabetes education program
    3. Insulin injections greater than or equal to three times a day with self-adjusted dose changes for at least six months prior to the initiation of an insulin pump
    4. A log showing blood glucose testing and insulin dosing adjustments greater than or equal to three times a day during the past month
- II. An external insulin infusion pump may be considered **medically necessary** for preconception or pregnant diabetic women who meet **both** of the following criteria:
  - A. Insulin injections greater than or equal to three times a day
  - B. Failure to meet glycemc control goals
- III. Replacement of an external insulin infusion pump may be considered **medically necessary** for patients who meet **all** of the following criteria:
  - A. Currently on an external insulin pump
  - B. Replacement (with or without upgrades) is needed because the current device is not working, cannot be repaired and is out of warranty
  - C. Documentation of malfunction is provided (e.g., repair logs, MD note)
  - D. The device requested is age appropriate as approved by the U.S. Food and Drug Administration (FDA)

- E. The request is NOT for additional software or hardware for downloading data to a personal computer to aid in self-management of diabetes mellitus

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

Disposable durable medical equipment (DME) supplies such as sensors and transmitters are only covered when the external insulin infusion device has also been approved. Supplies for units purchased by the patient without prior authorization are not covered.

Examples of FDA-approved external insulin pumps discussed in this policy include, but are not limited to:

- Standard external insulin infusion pumps (Stand-alone units e.g., Animas®, Medtronic MiniMed Paradigm 511)
- Integrated or combined external insulin infusion pumps (e.g., MiniMed Paradigm® REAL-Time System)
- Disposable external insulin pump with wireless communication capability to a hand-held control unit and standard finger-stick blood glucose monitoring system (e.g., Omnipod®)
- "Artificial pancreas" device system (subcategory: threshold suspend device system) which integrates a continuous glucose monitor and insulin pump and includes a low-glucose suspend (LGS) feature (e.g., Medtronic MiniMed® 530G and 630G)\*  
**\*Note:** The MiniMed® 530G and 630G devices are FDA approved only for use in patients 16 years and 14 years or older respectively
- A hybrid closed-loop insulin delivery system which consists of an insulin pump, a glucose meter, and a transmitter, linked by a proprietary algorithm and, the SmartGuard Hybrid Closed Loop. The system includes an LGS feature that suspends insulin delivery; either suspend on low or suspend before low and have an optional alarm. Additionally, the system involves semiautomatic insulin-level adjustment to preset targets (e.g., Medtronic MiniMed® 670G).\*  
**\*Note:** The MiniMed® 670G device is FDA approved only for use in patients 7 years and older, and also carries a black box warning to advise providers that it is contraindicated for children under age 7 and patients who require less than a total daily insulin dose of 8 units.

### Coding

Disposable External Insulin Pump (e.g., Omnipod®) CPT codes include:

- **A9274:** External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
- **E0784:** External ambulatory infusion pump, insulin

CPT code 99091 might also be used for this monitoring:

- **99091:** Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days

HCPCS codes are available specifically for continuous glucose monitoring systems:

- **A9276:** Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
- **A9277:** Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)

- **A9278:** Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)

The following HCPCS codes are specific to the “artificial pancreas” system:

- **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

#### Notes:

- Intensive diabetic management in any form, including the use of external insulin infusion pump, is contraindicated for patients (or for children, their caregivers) who, for any reason are unwilling or unable to participate actively in intensive glucose management and to acquire the cognitive and technical skills required by their regimen
- Supplies required for the proper use of a medically necessary external insulin pump or continuous glucose monitor (integrated or stand-alone), including custom-designed batteries, power supplies, and sensors and transmitters are considered medically necessary durable medical equipment (DME)
- A back-up pump is not required in advance (in case it fails) because the patient can revert to multiple daily injections (MDI) until the pump is repaired or replaced
- External insulin infusion pump warranty is four years

### Description

An external insulin infusion pump, also known as a continuous subcutaneous insulin infusion (CSII) pump, ambulatory pump, or mini-infuser, is a portable device used to deliver insulin to manage diabetic patients unable to control their diabetes with multiple daily insulin injections. The battery-operated pump contains an insulin filled cartridge or syringe (worn at the waist) connected to a catheter that is inserted into the patient's subcutaneous tissue, usually in the abdomen. The pump is programmed to deliver a predetermined amount of insulin to meet the patient's insulin requirements and allows programming of different basal and bolus infusion rates as needed. The purpose of the pump is to provide an accurate, continuous controlled delivery of insulin to achieve intensive glucose control.

Tight glucose control in patients with diabetes has been associated with improved health outcomes. Several continuous glucose monitor devices are available to measure glucose levels automatically and frequently (e.g., every 5-10 minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to traditional self-monitoring of blood glucose levels. Devices can be used on an intermittent (short-term) basis or a continuous (long-term) basis.

A hybrid closed-loop insulin delivery system links a glucose monitor to an insulin infusion pump that automatically takes action (e.g., suspends or adjusts insulin) based on the glucose monitor reading. These devices are proposed to improve glycemic control in patients with insulin-dependent diabetes, in particular, control of nocturnal hypoglycemia.

### Related Policies

- Chronic Intermittent Intravenous Insulin Therapy

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

### Continuous Glucose Monitoring Systems

Several CGM systems have been approved by U.S. Food and Drug Administration (FDA) through the premarket approval process (see Table 1).

**Table 1. CGM Systems Approved by the Food and Drug Administration**

Device	Manufacturer	Approval	Indications
Continuous Glucose Monitoring System (CGMS <sup>®</sup> )	MiniMed	1999	3-d use in physician's office
GlucoWatch G2 <sup>®</sup> Biographer		2001	Not available since 2008
Guardian <sup>®</sup> -RT (Real-Time) CGMS	MiniMed (now Medtronic)	2005	
Dexcom <sup>®</sup> STS CGMS system	Dexcom	2006	
Paradigm <sup>®</sup> REAL-Time System (second generation called Paradigm Revel System)	MiniMed (now Medtronic)	2006	Integrates a CGM with a Paradigm insulin pump
FreeStyle Navigator <sup>®</sup> CGM System	Abbott	2008	
Dexcom <sup>®</sup> G4 Platinum	Dexcom	2012 2014	Adults $\geq 18$ y; can be worn for up to 7 d Expanded to include patients with diabetes 2-17 y
Dexcom <sup>®</sup> G5 Mobile CGM	Dexcom	2016 <sup>a</sup>	Replacement for fingerstick blood glucose testing in patients $\geq 2$ y. System requires at least 2 daily fingerstick tests for calibration purposes, but additional fingersticks are not necessary because treatment decisions can be made based on device readings <sup>5</sup>
Freestyle Libre <sup>®</sup> Pro Flash Glucose Monitoring System	Abbott	2017	Adults $\geq 18$ y. Readings are only made available to patients through consultation with a health care professional. Does not require user calibration with blood glucose values

CGM: continuous glucose monitoring.

<sup>a</sup> As a supplement to the G4 premarketing approval.

FDA product codes: MDS, PQF.

### "Artificial Pancreas" Device Systems (Subcategory: Threshold Suspend Device System)

In 2013, the MiniMed<sup>®</sup> 530G System (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P120010). This system integrates an insulin pump and glucose meter and includes a low-glucose suspend (LGS) 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 device is approved only for use in patients 16 years and older.

In 2016, the MiniMed® 630G System with SmartGuard™ (Medtronic) was approved through the premarket approval process (P150001). It is also for use in patients 16 years and older. The system is similar to the 530G but offers updates to the system components including waterproofing. The threshold suspend feature is the same as in the 530G. FDA product code: OZO.

In 2016, the MiniMed® 670G System (Medtronic), a hybrid closed-loop insulin delivery system, was approved by the FDA through the premarket approval process (P160017). It consists of an insulin pump, a glucose meter, and a transmitter, linked by a proprietary algorithm and, the SmartGuard Hybrid Closed Loop. The system includes an LGS feature that suspends insulin delivery; either suspend on low or suspend before low and have an optional alarm. Additionally, the system involves semiautomatic insulin-level adjustment to preset targets. As a hybrid system; basal insulin levels are automatically adjusted, but the patient needs to administer premeal insulin boluses. The system is approved for patients with type 1 who are 7 years and older, and also carries a black box warning to advise providers that it is contraindicated for children under age 7 and patients who require less than a total daily insulin dose of 8 units.

FDA product code: OZP.

## Rationale

### Background

Diabetes mellitus is a worldwide epidemic that has created a crisis for the health care system and society. It is the fourth leading cause of death in the United States and affects nearly 21 million Americans. Within the past few years, "intensive therapy" for diabetes management has gained favor as it seems to offer the greatest hope of preventing diabetic complications. Intensive therapy refers to frequent delivery of exogenous insulin (usually by injection greater than three times a day or alternatively by continuous infusion) to obtain tight control in the normal blood glucose range.

Management of diabetes involves maintenance of blood glucose levels near normal range. Exogenous insulin replacement is the basis of treatment for patients with Type 1 diabetes (T1DM). Management of Type 2 and gestational diabetes is more varied. For some, diet, exercise, and/or various medications can control the blood glucose level. If these measures fail in patients with gestational or Type 2 diabetes mellitus (T2DM), insulin therapy may be needed. When insulin is required, frequent glucose monitoring and adjustment of insulin is necessary until an appropriate insulin regimen is established.

When diabetes is poorly controlled, accelerated vascular disease characterized by both large and small artery disease predisposes individuals to a number of late secondary complications. These complications include heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, nerve damage and impotence. Improved glycemic control has been shown to slow the onset or progression of the major neuropathic and microvascular complications.

The 1993 Diabetes Control and Complications Trial (DCCT) offered compelling evidence that intensive treatment achieving tight glycemic control reduces the occurrence of microvascular and neuropathic complications in patients treated before the development of advanced disease.<sup>1</sup> This trial involved 1,441 Type 1 diabetics at 29 medical centers. Subjects were randomly assigned to the experimental group receiving intensive therapy or the control group receiving conventional therapy. The study's results were so convincing of the benefits of intensive therapy that the independent data monitoring committee recommended early termination of the trial. As the evidence favoring intensive therapy accumulated, investigators could no longer legitimately encourage subjects to remain in the less

effective conventional therapy group. Patients were followed for an average of 6.5 years (range three to nine years). The study's principal outcome measure was retinopathy, but it also included data regarding renal, neurologic, cardiovascular, and neuropsychological complications as well as the adverse effects from treatment.

The advent of blood glucose monitors for use by patients in the home revolutionized the management of diabetes. Using fingersticks, patients can monitor their blood glucose levels both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight glucose control, defined as a strategy involving frequent glucose checks and a target hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) level in the range of 7%, is now considered standard of care for diabetic patients. Randomized controlled trials assessing tight control have demonstrated benefits for patients with type 1 diabetes in decreasing microvascular complications. The impact of tight control on type 1 diabetes and macrovascular complications such as stroke or myocardial infarction is less certain. The Diabetes Control and Complications Trial (2002) demonstrated that a relative HbA<sub>1c</sub> level reduction of 10% is clinically meaningful and corresponds to approximately a 40% decrease in risk for progression of diabetic retinopathy and 25% decrease in risk for progression of renal disease.<sup>2</sup>

Due to an increase in turnover of red blood cells during pregnancy, HbA<sub>1c</sub> is slightly lower in women with a normal pregnancy compared with nonpregnant women. The target A<sub>1c</sub> in women with diabetes is also lower in pregnancy. The American Diabetes Association recommends that, if achievable without significant hypoglycemia, the A<sub>1c</sub> should range between 6.0 to 6.5%; an A<sub>1c</sub> less than 6% may be optimal as the pregnancy progresses.<sup>3</sup>

Tight glucose control requires multiple daily measurements of blood glucose (i.e., before meals and at bedtime), a commitment that some patients may be unwilling or unable to meet. Also, the goal of tight glucose control has to be balanced with an associated risk of hypoglycemia. Hypoglycemia is known to be a risk in patients with type 1 diabetes. While patients with insulin-treated type 2 diabetes may also experience severe hypoglycemic episodes, there is a lower relative likelihood of severe hypoglycemia compared with patients who had type 1 diabetes.<sup>4,5</sup> An additional limitation of periodic self-measurements of blood glucose is that glucose levels are seen in isolation, and trends in glucose levels are undetected. For example, while a diabetic patient's fasting blood glucose level might be within normal values, hyperglycemia might be undetected postprandially, leading to elevated HbA<sub>1c</sub> values.

### **External Insulin Infusion Pump**

The external insulin infusion pump is a programmable, battery-powered mechanical syringe regulated by a miniature computer. Typically, the syringe has a two to three-day insulin capacity and is connected to an infusion set attached to a small needle or cannula which the patient inserts into the subcutaneous tissue. The syringe is activated by the pump programmed to deliver a steady "basal" amount of insulin and release a "bolus" dose at meals and at programmed intervals. The pump is the size of a pager and weighs about three ounces, and can be worn on a belt or a pocket. It contains a cartridge reservoir filled with fast acting insulin. The pump connects to narrow flexible plastic tubing that ends with a needle inserted just under the skin near the abdomen. The user sets the pump to give a basal amount of insulin continuously throughout the day. The pump gives an additional bolus dose of insulin at meals and at times when blood sugar is too high based on the user's input. Frequent blood glucose monitoring is essential to determine insulin dosages and to ensure that insulin is delivered appropriately.

External insulin pumps are approved by the FDA as 510(k) Class II devices for the continuous infusion of insulin. Examples of approved devices include but are not limited to:

- Medtronic MiniMed Paradigm Model 511 Insulin Pump (Medtronic MiniMed, Northridge, CA)
- One Touch® Ping™ Insulin Pump (Animas Corp., Frazer, PA)
- Dana Diabecare® II Insulin Pump (Sooil Development Co., Ltd., North Attleboro, MA)

A number of technological advances have been made in insulin infusion pumps over the past several years. New models are introduced periodically with improved programming, safety features, and decreased size and weight. Patients using a continuous subcutaneous insulin infusion (CSII) pump may want to upgrade to newer devices however there is no information currently available in the medical/scientific literature that indicate additional health benefits. Wireless connectivity to separate parts of the pump device or to other types of devices such as glucose meters and continuous glucose monitoring systems are also part of new technology.

Some external insulin pumps are integrated or combined with continuous glucose monitoring technology. Examples of combination systems approved by the US Food and Drug Administration (FDA) include:

- iXL-II Diabetes Management System with Blood Glucose Measurement (Insulet Corporation, Boston, MA) marketed as OmniPod™ Insulin Management System, FDA approved January 3, 2005.
- Deltec Cozmo® Insulin Infusion Pump with CoZmonitor™ Glucose Monitor (Smiths Medical MD Inc., St. Paul, MN), FDA approved on May 27, 2004.
- Medtronic MiniMed Paradigm® Models 515 and 715 Insulin Pumps (Medtronic MiniMed, CA) used in conjunction with BD Paradigm Link Glucose Monitor (Becton Dickinson & Co.), FDA approved on May 21, 2004, and May 19, 2004, respectively

In 2008, a 510(k) approval was issued by the FDA for the Symphony Glucose Management System (trade name).<sup>6</sup> The system consists of an Animas external insulin pump that wirelessly communicates with a LifeScan blood glucose meter-remote. The system is a predicate device to the Paradigm Model 512 Insulin Pump and the Paradigm Link Glucose Monitor. Bidirectional wireless communication occurs between the glucose meter and the insulin pump and allows the individual to remotely operate insulin dosing using the glucose meter-remote.

The MiniMed Paradigm® REAL-Time Insulin Pump is currently the only device that includes a continuous glucose monitor as opposed to the standard glucose meter. The insulin pump is used in conjunction with the Guardian RT® Continuous Glucose Monitoring System (in this system, the continuous glucose sensor-transmitter wirelessly transmits interstitial glucose concentration data to the pump unit, which displays it in "real time"). However, this still requires blood glucose measurements.

Another type of external insulin pump is the Insulet Omnipod® which involves two separate devices with wireless radiofrequency connection. The "Pod", is a disposable self-adhesive unit that incorporates an insulin reservoir, a microcomputer controlled insulin pump, and a cannulation device. The Pod can be worn for up to 72 hours and then replaced. The second part of the device is the Personal Diabetes Manager (PDM) which is a hand-held control that communicates wirelessly with the Pod to control basal-rate and bolus infusion. The system also incorporates the FreeStyle™ blood glucose meter which works similar to a standard (non-continuous) blood glucose meter. The proposed advantages of the Omnipod® include a disposable system that is watertight (allowing swimming), tubeless, weighs less than 1.2 ounces, and requires no assembly.

### **Continuous Glucose Monitoring System**

Recently, measurements of glucose in the interstitial fluid have been developed as a technique to measure glucose values automatically throughout the day, producing data that show the trends in glucose levels. Although devices measure glucose in the interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).

Several devices have received approval from the U.S. Food and Drug Administration (FDA). The first approved devices were the Continuous Glucose Monitoring System (MiniMed), which uses an implanted temporary sensor in the subcutaneous tissues, and the GlucoWatch G2 Biographer, an

external device worn like a wristwatch that measures glucose in interstitial fluid extracted through the skin by electric current (referred to as reverse iontophoresis).

Devices subsequently approved include those for pediatric use and those with more advanced software, more frequent measurements of glucose levels, or more sophisticated alarm systems. Devices initially measured interstitial glucose every 5 to 10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured ranges from every 1 to 2 minutes to 5 minutes, and most provide measurements in real-time directly to patients. While CGM potentially eliminates or decreases the number of required daily fingersticks, it should be noted that, according to the FDA labeling, monitors are not intended as an alternative to traditional self-monitoring of blood glucose levels but rather as adjuncts to monitoring, supplying additional information on glucose trends not available from self-monitoring. Also, devices may be used intermittently (i.e., for periods of 72 hours) or continuously (i.e., on a long-term basis).

In addition to stand-alone continuous glucose monitors, several insulin pump systems have a built-in CGM.

### **"Artificial Pancreas" Device Systems (Subcategory: Threshold Suspend Device System)**

According to the U.S. Food and Drug Administration (FDA), an artificial pancreas is a medical device that links a glucose monitor to an insulin infusion pump, and the pump automatically reduces and increases subcutaneous insulin delivery according to measured subcutaneous glucose levels using a control algorithm. Because control algorithms can vary significantly, there are a variety of artificial pancreas device systems currently under development. These systems span a wide range of designs from a low-glucose suspend (LGS) device systems to the more complex bihormonal control-to-target systems.

FDA has described 3 main categories of artificial pancreas device systems<sup>7</sup>: threshold suspend device, control-to-range, and control-to-target systems. With threshold suspend device systems, also called LGS systems, the delivery of insulin is suspended for a set time when 2 glucose levels are below a specified low level indicating hypoglycemia. With control-to-range systems, the patient sets his or her own insulin dosing within a specified range, but the artificial pancreas device system takes over if glucose levels outside that range (higher or lower). Patients using this type of system still need to check blood glucose levels and administer insulin as needed. With control-to-target systems, the device aims to maintain glucose levels near a target level (e.g., 100 mg/dL). Control-to-target systems are automated and do not require user participation except to calibrate the continuous glucose monitoring system. Several device subtypes are being developed: those that deliver insulin-only, bihormonal systems, and hybrid systems.

## **Literature Review**

### **External Insulin Infusion Pump**

Controlled trials comparing multiple daily injections (MDI) and external insulin pumps demonstrate that in most patients overall blood glucose control is the same or slightly improved with insulin pump treatment. However, in diabetics treated with insulin pumps, hypoglycemia is less frequent and nocturnal glucose control is improved. The American Association of Clinical Endocrinologists (AACE) states that insulin pump therapy is an effective alternative to MDI's, improving overall glucose control, reducing hypoglycemia episodes and hypoglycemia unawareness, reducing the incidence of dawn phenomenon and increasing lifestyle flexibility for diabetic patients including children, adolescents, and Type 2 diabetics. The AACE further advises that insulin pump therapy should be tailored to each patient's individual needs to obtain and maintain glycemic goals and reduce adverse events.<sup>8</sup>

Clinical evidence in the peer-reviewed literature supports the safety and efficacy of CSII in Type 1 diabetics non-responsive to insulin administration by multiple daily injections as demonstrated by persistent glycosylated hemoglobin (HbA1c) levels greater than 7.0%, recurring hyper- or



hypoglycemic episodes, wide fluctuations in blood glucose levels, dawn phenomenon, and/or history of severe glycemic excursions. Benefits are seen in long-term control as shown by lowered HbA1c levels.<sup>9,10,11</sup>

There are few published clinical trials regarding the safety and efficacy of CSII in Type 2 diabetics and the benefits of intensive insulin therapy delivered via MDI injections or external pump are not as well established. Professional organizations differ on their recommendations for CSII in T2DM.

Guidelines from the AACE state that consideration of the use of CSII in insulin-treated patients should be given.<sup>12</sup> The American Diabetes Association (ADA) advises that both CSII and MDI injections are effective means of implementing intensive diabetes management with a goal of achieving near-normal levels of blood glucose and improved lifestyle flexibility. While the ADA includes insulin as a treatment option for T2DM in order to reach and maintain HbA1c goals of less than 7% and as close to 6% as possible, they do not discuss the use of pumps compared to daily injections.<sup>13</sup> The 2008 guidelines from the National Institute for Clinical Excellence (NICE), do not recommend use of CSII in persons with T2DM. The Institute for Clinical Systems Improvement (ICSI) states that insulin pump therapy may be helpful for patients who "are interested in more intensified management of blood sugars, want more flexibility, or if pregnancy is desired." They also advise that the patient's understanding and self-care knowledge should be assessed by the physician. Additionally, insulin pumps may be used by some Type 2 diabetics.<sup>14</sup>

Some proposed indications for insulin therapy in Type 2 diabetics include a short intensive course to achieve glycemic control, which may lead to better long-term maintenance, severe hyperglycemic episodes or insulin deficiency (insulinopenia), a HbA1c greater than 10%, severe ketonuria, and short-term use after diet and exercise have failed.<sup>15,16</sup>

The Center for Medicare and Medicaid Services (CMS) reviewed nine scientific studies investigating the use of C-peptide levels to differentiate between T1DM and T2DM diabetes. The CMS advised that Type 2 diabetics who would benefit from CSII could be determined by the C-peptide level. C-peptide is a polypeptide of 31 amino acids and a byproduct of insulin production. The level of C-peptide in the blood can be used to help determine how much insulin the patient's pancreas is still producing. Type 1 diabetics have low C-peptide levels and typically Type 2 diabetics have normal or high C-peptide levels. However, C-peptide levels can lower with long-term beta cell damage in certain T2DM patients. C-peptide levels can also find the causes of hypoglycemia. The CMS review concluded that a fasting C-peptide level less than or equal to 110% of the lower limit of normal of the laboratory's measurement method and a concurrently obtained fasting glucose of less than or equal to 225 milligrams/deciliter (mg/dL) was indicative of insulinopenic T2DM. In patients with compromised renal function, a creatinine clearance less than or equal to 50 milliliters (mL)/minute, and a fasting C-peptide level that was less than or equal to 200% of the lower limit of normal was also indicative of insulinopenia.<sup>17,18</sup>

There is no consensus regarding the lowest age when CSII is appropriate, however most experts agree that children under the age of two should not undergo CSII because of the risk of hypoglycemic events. The majority of studies agree that children and adolescents should be assessed and considered potential candidates for CSII.<sup>19</sup> Careful consideration by the physician and parents with realistic expectations of CSII are required. The NICE guideline for the treatment of T1DM children (less than 11 years) lists CSII as a treatment option for young people who are committed, have the ability to use the device, and have failed multiple dose insulin therapy.<sup>20</sup>

The need for insulin during pregnancy increases because of a reduction in insulin action. Type 1 pregnant diabetics may require increasing insulin dosages. Type 2 diabetics who were taking oral hypoglycemics need to discontinue these drugs during pregnancy. The Type 2 and gestational diabetic may require insulin to achieve and maintain glycemic control. Poor glycemic control during pregnancy can lead to congenital abnormalities, miscarriage, stillborns, and unusually large babies.

External insulin pump therapy has been proposed as an alternative to MDI injections for the treatment of women with gestational diabetes.

The Pregestational Diabetes guideline from the American College of Obstetricians and Gynecologists (ACOG) lists insulin injections or CSII as a treatment option for pregnant women with diabetes. They also warn that if delivery of insulin is interrupted or impaired by battery failure or infusion site infection, diabetes ketoacidosis may develop rapidly, which is a potential harm.<sup>21</sup>

The 2008 NICE Clinical Guidelines on the management of diabetes from pre-conception to postnatal care state that clinical trials have shown no advantages or disadvantages regarding the use of an insulin pump compared to MDI injections in pregnancy.<sup>22</sup> However, the authors advised that the CSII may be indicated in insulin-treated women if adequate glycemic control is not achieved by MDI. The 2009 NICE Technology Assessment on CSII stated that the criteria for use of CSII with pregnant women should not be different than for other adults.<sup>23</sup>

Of mention, modern external infusion pumps appear safe and reliable, and studies reviewed in the writing of this policy did not indicate a need for a "back-up" pump. If an insulin pump fails, a patient can and should revert to daily multiple injections until the pump is repaired or replaced.

### **Continuous Glucose Monitoring System Randomized Controlled Trials**

The largest and most recent studies are also briefly summarized in the following paragraphs. The studies were conducted in North America, Europe, and Asia. Baseline HbA<sub>1c</sub> levels were between 8.5% and 9.0% in the RCTs, with participants having a mean baseline age range in the mid-50s and early-60s. The RCTs used a mixed of intermittent and continuous, real-time monitoring.

Ehrhardt and colleagues published 2 reports (2011, 2012) from an RCT evaluating the largest sample (N=100) in the Poolsup et al (2013) systematic review (accounting for 45% of the weight in the pooled analysis of HbA<sub>1c</sub> levels).<sup>24,25</sup> The trial evaluated the intermittent use of a CGM device in adults with type 2 diabetes treated with diet/exercise and/or glycemia-lowering medications but not prandial insulin who had an initial HbA<sub>1c</sub> level of at least 7% but not more than 12%. The trial compared real-time CGM with the Dexcom device used for four, 2-week cycles (2 weeks on and 1 week off) with SMBG. The primary efficacy outcome was mean change in HbA<sub>1c</sub> levels. Mean HbA<sub>1c</sub> levels in the CGM group were 8.4% at baseline, 7.4% at 12 weeks, 7.3% at 24 weeks, and 7.7% at 52 weeks. In the SMBG group, these values were 8.2% at baseline, 7.7% at 12 weeks, 7.6% at 24 weeks, and 7.9% at 52 weeks. During the trial, the reduction in HbA<sub>1c</sub> levels was significantly greater in the CGM group than in the SMBG group (p=0.04). After adjusting for potential confounders (e.g., age, sex, baseline therapy, whether the individual started taking insulin during the study), the difference between groups over time remained statistically significant (p<0.001). The investigators also evaluated SMBG results for both groups. The mean proportions of SMBG tests less than 70 mg/dL were 3.6% in the CGM group and 2.5% in the SMBG group (p=0.06).

The RCT by Sato et al (2016) included 34 patients with type 2 diabetes who were at least 20 years old and on insulin injection therapy, had HbA<sub>1c</sub> levels between 6.9% and 11.0% during the previous 3 months, with HbA<sub>1c</sub> fluctuations within 0.5%.<sup>26</sup> All patients conducted SMBG and used CGM devices that do not have data available in real-time (i.e., data were viewed retrospectively by physicians). Devices were used for 4 to 5 days before each of 3 clinic visits, 2 months apart. At clinic visits, patients were evaluated, and suggestions made to improve glucose control by lifestyle changes and by changing medication doses. In the intervention group, but not the control group, patients and physicians had access to CGM data at the clinic visits. The primary end point was change in HbA<sub>1c</sub> levels from baseline, which did not differ significantly between groups at the end of the trial, between the first and second visits, or between the second and third visits. HbA<sub>1c</sub> levels changed little in either group. In the intervention group, the mean baseline HbA<sub>1c</sub> level was 8.2%, and the mean final HbA<sub>1c</sub> level was also 8.2%. Comparable percentages in the control group were 8.2% and 7.9%. In this trial,

conducted in Japan, decisions on medication doses were made only by the physician at clinic visits, and practices may differ in other countries.

The largest RCT, Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes (DIAMOND), was reported by Beck et al (2017).<sup>27</sup> DIAMOND was performed at 25 endocrinology practices in North America (22 in the United States, 3 in Canada) and enrolled adults with type 2 diabetes receiving multiple daily injections of insulin. One-hundred fifty-eight patients were randomized into 2 groups, CGM and usual care (n=79 in each group). Patients compliant during a run-in period were eligible for randomization. Patients in both groups were given a blood glucose meter. Participants in the CGM group were given a Dexcom G4 Platinum CGM System (Dexcom) and instructions on use. Change in HbA<sub>1c</sub> level from baseline to 24 weeks was the primary outcome. Analyses were adjusted for baseline HbA<sub>1c</sub> levels and clinic were performed using intention-to-treat analysis with missing data handling by multiple imputation. At baseline, the mean total daily insulin dose was 1.1 U/kg/d. Week 24 follow-up was completed by 97% of the CGM group and 95% of the control group. Mean CGM use was greater than 6 d/wk at 1 month, 3 months, and 6 months. The adjusted difference in mean change in HbA<sub>1c</sub> level from baseline to 24 weeks was -0.3% (95% CI, -0.5% to 0.0%; p=0.022) favoring CGM. The adjusted difference in the proportion of patients with a relative reduction in HbA<sub>1c</sub> level of 10% or more was 22% (95% CI, 0% to 42%; p=0.028) favoring CGM. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. The treatment groups did not differ in any of the quality of life measures.

### **"Artificial Pancreas" Device Systems (Subcategory: Threshold Suspend Device System)**

#### **Low-Glucose Suspend Devices**

In 2015, Agrawal et al retrospectively analyzed use of the threshold suspend feature associated with the Paradigm Veo System in 20,973 patients, most of whom were treated outside of the United States.<sup>28</sup> This noncontrolled descriptive analysis provides information on the safety of the device when used in a practice setting. The threshold suspend feature was enabled for 100% of the time by 14,673 (70%) patients, 0% of the time by 2249 (11%) patients, and the remainder used it intermittently. The mean (SD) setting used to trigger suspension of insulin was a sensor glucose level of 62.8 (5.8) mg/dL. On days when the threshold suspend feature was enabled, there was a mean of 0.82 suspend events per patient-day. Of these, 56% lasted for 0 to 5 minutes, and 10% lasted the full 2 hours. (Data on the length of the other 34% of events were not reported.) On days when the threshold suspend feature was on, sensor glucose values were 50 mg/dL or less 0.64% of the time compared with 2.1% of sensor glucose values 50 mg/dL or less on days when the feature was off. Reduction in hypoglycemia was greatest at night. Sensor glucose percentages equivalent to 17 minutes per night occurred when the threshold suspend feature was off vs glucose percentages equivalent to 5 minutes per night when the threshold suspend feature was on. Data on the use of the device has suggested fewer and shorter hypoglycemic episodes. The length and severity of hypoglycemic episodes were not fully discussed in this article.

#### **Hybrid Closed-Loop Insulin Delivery Systems**

The MiniMed 670G, which uses a combination of control-to-range and control-to-target strategies, was approved by FDA in September 2016. In 2016, Bergenstal et al published a prospective single-arm study on the safety of the system in patients with type 1 diabetes.<sup>29</sup> It included 124 patients ages 14-to-75 years old who had type 1 diabetes for at least 2 years, had HbA<sub>1c</sub> levels less than 10.0%, and who had used an insulin pump for at least 6 months. There was an initial run-in period at baseline for patients to learn how to use the device followed by a 3-month period of device use. The study period included a 6-day hotel stay with a 1-day period of frequent sampling of venous blood glucose levels to verify device accuracy. The primary safety end points were the incidence of severe hypoglycemia and diabetic ketoacidosis and the incidence of device-related and serious adverse events.

There were no episodes of severe hypoglycemia or ketoacidosis during the study. A total of 28 device-related adverse events occurred, all of which could be resolved at home. There were 4 serious adverse events, 1 case each of appendicitis, bacterial arthritis, worsening rheumatoid arthritis, and

*Clostridium difficile* diarrhea. There were also a number of predefined descriptive end points (but no statistically powered efficacy end points). The device was in closed-loop mode for a median of 97% of the study period. Mean (SD) HbA<sub>1c</sub> levels were 7.4% (0.9%) at baseline and 6.9% (0.6%) at the end of the study, and the percentage of sensor glucose values within the target range was 66.7% at baseline and 72.2% at the end of the study. This trial and a related study in children are ongoing (NCT02463097, NCT02660827; see the Ongoing and Unpublished Clinical Trials section).

A 2017 multicenter pivotal trial published by Garg et al evaluated the safety of Medtronic's hybrid closed-loop system, using methods similar to those of Bergenstal and employing the same device (MiniMed 670G).<sup>30</sup> Of 129 subjects, 124 completed the trial; 30 were adolescents (age range, 14-21 years) and 94 were adults (age range, 22-75 years), all of whom had type 1 diabetes for at least 2 years before the study, and used insulin pump therapy for 6 months or more. As with Bergenstal et al, a 3-month study period was preceded by a run-in period for subjects to be more familiar with the equipment, and the sensor glucose values were confirmed by an extended hotel stay (6-day/5-night with daily exercise). In both the adolescent and adult cohorts, the trial found improvements during the study phase over the run-in phase, with an increased percentage of glucose values in the favorable range (for adults, a mean improvement of 68.8% to 73.8%; for adolescents, a mean improvement of 60.4% to 67.2%;  $p < 0.001$  for both cohorts). Similarly, the authors reported a decrease in percentage of values outside of the target range ( $< 70$  mg/dL or  $> 180$  mg/dL): for adults, time spent below the target range decreased from 6.4% to 3.4% ( $p < 0.001$ ); time above the range decreased from 24.9% to 22.8% ( $p = 0.01$ ). For both cohorts, HbA<sub>1c</sub> levels showed a significant reduction between baseline and the end of study: for adults, the mean decreased from 7.3% to 6.8% ( $p < 0.001$ ), while for adolescents, the mean decreased from 7.7% to 7.1% ( $p < 0.001$ ). Secondary outcomes, which included a reduction of nocturnal hyperglycemia and hypoglycemia, increase in mean overall body weight, and a reduction of basal insulin, were favorable for the study phase, compared with the run-in phase; measurements from the hotel stay verified the in-home glucose values. However, there were several limitations in the trial, including its nonrandomized design, the exclusion of individuals who had recently experienced diabetic ketoacidosis or severe hypoglycemia, and the interaction between subjects and site personnel. Additionally, most of the adult cohort were already using continuous glucose monitoring, and baseline HbA<sub>1c</sub> levels were lower than average for both cohorts; both baseline characteristics potentially limit the generalizability of the results.

## Summary of Evidence

### External Insulin Infusion Pump

In summary, the need for tight glycemic control is necessary regardless of whether diabetes is gestational, Type 1 or Type 2. The literature supports the efficacy of the external insulin infusion pump for properly trained diabetics who are not well controlled on intensive, multi-dose insulin therapy.

## Continuous Glucose Monitoring System

### Type 1 Diabetes

For individuals who have type 1 diabetes who are willing and able to use the device, and have adequate medical supervision, who receive long-term CGM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Systematic reviews have generally found that at least in the short-term, long-term CGM resulted in significantly improved glycemic control for adults and children with type 1 diabetes, particularly highly compliant patients. A 2017 individual patient data analysis, pooling data from 11 RCTs, found that reductions in HbA<sub>1c</sub> levels were significantly greater with real-time CGM than with a control intervention. Two RCTs in patients who used multiple daily insulin injections and were highly compliant with CGM devices during run-in phases found that CGM was associated with a larger reduction in HbA<sub>1c</sub> levels than previous studies. One of the 2 RCTs prespecified hypoglycemia-related outcomes and reported that time spent in hypoglycemia was significantly less in the CGM group. One RCT in pregnant women with type 1 diabetes, which compares real-time CGM with self-monitoring of blood glucose, has also reported a difference in change in HbA<sub>1c</sub> levels, an increased percentage of time in the recommended glucose control target range, a smaller proportion of infants who were

large for gestational age, a smaller proportion of infants who had neonatal intensive care admissions lasting more than 24 hours, a smaller proportion of infants who had neonatal hypoglycemia requiring treatment, and reduced total length of hospital stay all favoring CGM. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have type 1 diabetes who receive short-term (intermittent) glucose monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. The evidence for intermittent short-term monitoring on glycemic control is mixed, and there was no definite improvement in HbA<sub>1c</sub> levels. Studies have not shown an advantage for intermittent glucose monitoring in reducing severe hypoglycemia events, but the number of events reported is generally small and effect estimates imprecise. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Type 2 Diabetes**

For individuals who have type 2 diabetes who receive long-term, real-time CGM, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Only the DIAMOND RCT (N=158) has used continuous, real-time CGM in type 2 diabetes. Selected patients were highly compliant during a run-in phase. The difference in change in HbA<sub>1c</sub> levels from baseline to 24 weeks was -0.3% favoring CGM. The difference in the proportion of patients with a relative reduction in HbA<sub>1c</sub> level by 10% or more was 22% favoring CGM. There were no differences in the proportions of patients with an HbA<sub>1c</sub> level less than 7% at week 24. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. The treatment groups did not differ in any of the quality of life measures. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who have type 2 diabetes who receive short-term, intermittent CGM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Systematic reviews of 3 to 4 RCTs have found statistically significant benefits from CGM regarding glycemic control. However, the degree of HbA<sub>1c</sub> reduction and the difference in HbA<sub>1c</sub> reductions between groups may not be clinically significant. Also, the small number of RCTs and variability among interventions make it difficult to identify an optimal approach to CGM or a subgroup of type 2 diabetes patients who might benefit. Moreover, studies of CGM in patients with type 2 diabetes have generally not addressed the clinically important issues of severe hypoglycemia and diabetic complications. Very few pregnant women with type 2 diabetes have been included in RCTs. The evidence is sufficient to determine the effects of the technology on health outcomes.

### **"Artificial Pancreas" Device Systems (Subcategory: Threshold Suspend Device System)**

#### **Low-Glucose Suspend Devices**

Several RCTs have evaluated the first FDA-approved artificial pancreas device, which includes an LGS feature, or a similar device used outside of the United States. Two RCTs were conducted in-home settings. The RCT, limited to adults showed an improvement in the primary outcome (AUC for nocturnal hypoglycemic events). AUC is not used for assessment in clinical practice. However, the magnitude of reduction for hypoglycemic events in this population, which was a secondary outcome, is likely to be clinically significant.

#### **Hybrid Closed-Loop Insulin Delivery Systems**

Several studies have been published on a hybrid closed-loop insulin delivery system, but only 2 uncontrolled studies used a device approved in the United States. The single-arm study using the FDA-approved device focused on safety outcomes. There were no episodes of severe hypoglycemia, diabetic ketoacidosis during the study, and no device-related severe adverse events. The analysis was not designed to evaluate the impact of the device on glycemic control and did not include a comparison intervention; this study is ongoing. A 2017 pivotal trial of the same device likewise evaluated its safety, rather than comparing it with another intervention. Among studies on a similar

device used outside of the United States, 2 crossover RCTs found significantly better outcomes (i.e., more time spent in the glycemic range and less time spent <70 mg/dL) in the artificial pancreas group than in the control group. Published data are needed on the efficacy of the semiautomatic insulin adjustment feature in the new FDA-approved device, specifically studies comparing glycemic control outcomes using the new device to glycemic control with currently used systems.

### Supplemental Information

#### Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 1 physician specialty society and 4 academic medical centers in 2008. Input concurred that continuous glucose monitoring, particularly intermittent glucose monitoring, was helpful in a subset of patients with diabetes. Reviewers commented that this monitoring can improve diabetes care by reducing glucose levels (and improving hemoglobin A<sub>1c</sub> levels) and/or by reducing episodes of hypoglycemia. Reviewers argued that there is persuasive data from case reports to demonstrate the positive impact of intermittent glucose monitoring.

### Practice Guidelines and Position Statements

#### American Diabetes Association

The 2017 American Diabetes Association position statement on diabetes included the following recommendations on CGM (see Table 22).<sup>31</sup>

**Table 2. Recommendations on Diabetes Care**

Recommendations	LOE <sup>a</sup>
"When used properly, continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens is a useful tool to lower A1C in selected adults (aged ≥25 years) with type 1 diabetes."	A
"Although the evidence for A1C lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device."	B
"CGM may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes."	C

LOE: level of evidence.

<sup>a</sup> LOE: A: clear evidence from well-conducted, generalizable RCTs that are adequately powered; B: supportive evidence from well-controlled cohort studies; C: supportive evidence from poorly controlled or uncontrolled studies. The Association also recommended that physicians assess individual readiness prior to prescribing CGM and that education, training, and support were needed for optimal CGM device implementation.

#### Endocrine Society

In 2016, the Endocrine Society published clinical practice guidelines that included the following recommendations on CGM<sup>32</sup>:

6. Real-time continuous glucose monitors in adult outpatients
  - 6.1 We recommend real-time continuous glucose monitoring (RT-CGM) devices for adult patients with T1DM [type 1 diabetes mellitus] who have A<sub>1c</sub> levels above target and who are willing and able to use these devices on a nearly daily basis.
  - 6.2 We recommend RT-CGM devices for adult patients with well-controlled T1DM who are willing and able to use these devices on a nearly daily basis.
- Use of continuous glucose monitoring in adults with type 2 diabetes mellitus [T2DM]
- 6.3 We suggest short-term, intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A<sub>1c</sub> levels ≥7% and are willing and able to use the device.

#### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

In January 2017, the Centers for Medicare & Medicaid Services issued a ruling that CGM devices approved by the Food and Drug Administration that can be used to make treatment decisions are considered durable medical equipment.<sup>33</sup> To date, 1 device has met these criteria, the Dexcom G5.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

**Table 3. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT03263494	CGM Intervention in Teens and Young Adults with T1D (CITY): A Randomized Clinical Trial to Assess the Efficacy and Safety of Continuous Glucose Monitoring in Young Adults 14- <25 With Type 1 Diabetes	200	Jul 2019
NCT02838147	Effect of a Continuous Glucose Monitoring on Maternal and Neonatal Outcomes in Gestational Diabetes Mellitus: A Randomized Controlled Trial	200	Jul 2019
<b>Unpublished</b>			
NCT01787903 <sup>a</sup>	The Effects of Real-time Continuous Glucose Monitoring on Glycemia and Quality of Life in Patients with Type 1 Diabetes Mellitus and Impaired Hypoglycemia Awareness)	52	Apr 2016 (completed)
NCT02671968 <sup>a</sup>	Real-Time Continuous Glucose Monitoring (RT-CGM) in Patients with Type 1 Diabetes at High Risk for Low Glucose Values Using Multiple Daily Injections (MDI) in Germany (HYPODE-STUDY)	141	Oct 2017 (completed)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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## Documentation for Clinical Review

### Please provide the following documentation:

#### Initial Request for External Insulin Pump:

- Documentation of completion of a comprehensive diabetic education program
- Documentation of glucose self-testing an average of at least three times a day during the past month prior to initiation of the pump
- History and physical and/or consultation reports and three diabetes management related chart notes within the last year, and documentation that patient has required multiple daily injections of insulin (i.e., at least three injections per day), with self-adjusted dose changes for at least six months
- Laboratory report including: HbA1c, glucose levels, C-peptide (if applicable)
- Reason for requesting an External Insulin Pump, including but not limited to difficulties in maintaining stable or acceptable blood glucose levels

#### Patients on an External Insulin Pump prior to Enrollment:

- Documentation of use of external insulin infusion pump (including model) prior to enrollment

#### Any Requests for External Insulin Pump Repair or Replacement:

- Documentation of (All):
  - Description of pump failure or pump problem (i.e., MD notes)
  - Pump warranty expiration date
  - Repair history

### Post Service (in addition to the above, please include the following):

- Results/reports of additional tests performed
- Procedure report(s) if applicable

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	99091	Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
HCPCS	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
	A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
	A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
	A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
	A9278	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
	E0784	External ambulatory infusion pump, insulin
	J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units
	K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service <b>(Deleted code effective 1/1/2023)</b>
	K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system <b>(Deleted code effective 1/1/2023)</b>
	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
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)	

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
11/01/1981	BCBSA Medical Policy adoption
06/01/1995	Policy Revision
08/01/2002	Coding Update
10/15/2007	Policy Review
09/25/2009	Policy revision with position change
07/31/2015	Coding update
12/04/2015	Policy revision without position change
11/01/2016	Policy revision without position change
11/01/2017	Policy revision without position change
12/01/2018	Policy revision without position change
11/01/2019	Policy revision without position change
03/01/2020	Administrative update. Policy statement clarification.
08/01/2020	Annual review. No change to policy statement.
08/01/2021	Annual review. No change to policy statement.
08/01/2022	Annual review. No change to policy statement.
08/01/2023	Annual review. No change to policy statement. Policy guidelines updated. Coding update.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an

authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p><b>External Insulin Infusion Pump BSC1.03</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. A first-time external insulin infusion pump with or without continuous glucose monitoring (CGM), low glucose suspend or automatic adjustment of basal insulin rate capability, may be considered <b>medically necessary</b> for insulin-requiring diabetic patients when <b>all</b> of the following criteria are met:                     <ol style="list-style-type: none"> <li>A. The device requested is age appropriate as approved by the U.S. Food and Drug Administration (FDA) (see Policy Guidelines)</li> <li>B. Documented clinical presentation of at least <b>one</b> of the following:                             <ol style="list-style-type: none"> <li>1. Glycohemoglobin level (HbA1c) greater than 7%</li> <li>2. History of recurrent severe hypoglycemia/hypoglycemia unawareness (typically a blood glucose less than 50 mg/dL) or severe glycemc excursions</li> <li>3. History of recurrent diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization</li> <li>4. Wide fluctuations in blood glucose before mealtime</li> <li>5. Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL</li> <li>6. Beta cell antibody positive or 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 and a concurrently obtained fasting glucose less than 225mg/dL</li> <li>7. Renal insufficiency with a creatinine clearance less than or equal to 50 ml/minute and a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory measurement</li> <li>8. Patients with insulin-requiring type 2 diabetes mellitus whose diabetes is poorly controlled (including unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent</li> </ol> </li> </ol> </li> </ol>	<p><b>External Insulin Infusion Pump BSC1.03</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. A first-time external insulin infusion pump with or without continuous glucose monitoring (CGM), low glucose suspend or automatic adjustment of basal insulin rate capability, may be considered <b>medically necessary</b> for insulin-requiring diabetic patients when <b>all</b> of the following criteria are met:                     <ol style="list-style-type: none"> <li>A. The device requested is age appropriate as approved by the U.S. Food and Drug Administration (FDA) (see Policy Guidelines)</li> <li>B. Documented clinical presentation of at least <b>one</b> of the following:                             <ol style="list-style-type: none"> <li>1. Glycohemoglobin level (HbA1c) greater than 7%</li> <li>2. History of recurrent severe hypoglycemia/hypoglycemia unawareness (typically a blood glucose less than 50 mg/dL) or severe glycemc excursions</li> <li>3. History of recurrent diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization</li> <li>4. Wide fluctuations in blood glucose before mealtime</li> <li>5. Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL</li> <li>6. Beta cell antibody positive or 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 and a concurrently obtained fasting glucose less than 225mg/dL</li> <li>7. Renal insufficiency with a creatinine clearance less than or equal to 50 ml/minute and a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory measurement</li> <li>8. Patients with insulin-requiring type 2 diabetes mellitus whose diabetes is poorly controlled (including unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent</li> </ol> </li> </ol> </li> </ol>

POLICY STATEMENT

(No changes)

BEFORE	AFTER
<p>diabetic ketoacidosis), despite documented compliance (i.e., a log) with a regimen of four or more finger sticks and insulin adjustments each day</p> <p>C. Documented diabetes management demonstrated by <b>all</b> of the following for first time pump users:</p> <ol style="list-style-type: none"> <li>1. Seen by a medical provider three times within the last year</li> <li>2. Completion of a comprehensive diabetes education program</li> <li>3. Insulin injections greater than or equal to three times a day with self-adjusted dose changes for at least six months prior to the initiation of an insulin pump</li> <li>4. A log showing blood glucose testing and insulin dosing adjustments greater than or equal to three times a day during the past month</li> </ol> <p>II. An external insulin infusion pump may be considered <b>medically necessary</b> for preconception or pregnant diabetic women who meet <b>both</b> of the following criteria:</p> <ol style="list-style-type: none"> <li>A. Insulin injections greater than or equal to three times a day</li> <li>B. Failure to meet glycemic control goals</li> </ol> <p>III. Replacement of an external insulin infusion pump may be considered <b>medically necessary</b> for patients who meet <b>all</b> of the following criteria:</p> <ol style="list-style-type: none"> <li>A. Currently on an external insulin pump</li> <li>B. Replacement (with or without upgrades) is needed because the current device is not working, cannot be repaired and is out of warranty</li> <li>C. Documentation of malfunction is provided (e.g., repair logs, MD note)</li> <li>D. The device requested is age appropriate as approved by the U.S. Food and Drug Administration (FDA)</li> <li>E. The request is NOT for additional software or hardware for downloading data to a personal computer to aid in self-management of diabetes mellitus</li> </ol>	<p>diabetic ketoacidosis), despite documented compliance (i.e., a log) with a regimen of four or more finger sticks and insulin adjustments each day</p> <p>C. Documented diabetes management demonstrated by <b>all</b> of the following for first time pump users:</p> <ol style="list-style-type: none"> <li>1. Seen by a medical provider three times within the last year</li> <li>2. Completion of a comprehensive diabetes education program</li> <li>3. Insulin injections greater than or equal to three times a day with self-adjusted dose changes for at least six months prior to the initiation of an insulin pump</li> <li>4. A log showing blood glucose testing and insulin dosing adjustments greater than or equal to three times a day during the past month</li> </ol> <p>II. An external insulin infusion pump may be considered <b>medically necessary</b> for preconception or pregnant diabetic women who meet <b>both</b> of the following criteria:</p> <ol style="list-style-type: none"> <li>A. Insulin injections greater than or equal to three times a day</li> <li>B. Failure to meet glycemic control goals</li> </ol> <p>III. Replacement of an external insulin infusion pump may be considered <b>medically necessary</b> for patients who meet <b>all</b> of the following criteria:</p> <ol style="list-style-type: none"> <li>A. Currently on an external insulin pump</li> <li>B. Replacement (with or without upgrades) is needed because the current device is not working, cannot be repaired and is out of warranty</li> <li>C. Documentation of malfunction is provided (e.g., repair logs, MD note)</li> <li>D. The device requested is age appropriate as approved by the U.S. Food and Drug Administration (FDA)</li> <li>E. The request is NOT for additional software or hardware for downloading data to a personal computer to aid in self-management of diabetes mellitus</li> </ol>