BSC 1.03  
External Insulin Infusion Pump

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<th>Effective Date:</th>
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<td>November 1, 1981</td>
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<td>1.0 Durable Medical Equipment</td>
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**Policy Statement**

An external insulin infusion pump may be considered **medically necessary** for insulin-requiring diabetic patients when **both** of the following criteria are met:

- Documented clinical presentation of at least **one** of the following:
  - Glycated hemoglobin level (HbA1c) greater than 7%
  - History of recurrent severe hypoglycemia/hypoglycemia unawareness (typically a blood glucose less than 50 mg/dL) or severe glycemic excursions
  - History of recurrent diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization
  - Wide fluctuations in blood glucose before mealtime
  - Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL
  - 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
  - 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

- Documented diabetes management demonstrated by **all** of the following:
  - Seen by a medical provider three times within the last year
  - Completion of a comprehensive diabetes education program
  - 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
  - Blood glucose testing greater than or equal to three times a day during the past month

An external insulin infusion pump may be considered **medically necessary** for preconception or pregnant diabetic women who meet **both** of the following criteria:

- Insulin injections greater than or equal to three times a day
- Failure to meet glycemic control goals

An external insulin infusion pump may be considered **medically necessary** for patients who have been on an external insulin pump prior to enrollment and have documented frequency of glucose self-testing an average of three times a day during the past month.

The following is considered **not medically necessary**:

- Additional software or hardware for downloading data to a personal computer to aid in self-management of diabetes mellitus
- Equipment upgrades or accessories whose sole purpose is to integrate, through communication technology, an insulin pump and interstitial glucose monitor (e.g., patient has a functioning stand-alone insulin pump and a stand-alone continuous glucose monitoring system (CGMS) and requests integration)
- The replacement of an external insulin infusion pump for any of the following situations:
  - Device can be repaired or refurbished
  - Device is under warranty
  - Documentation of malfunction is not provided (e.g., repair logs, MD notes)

**Policy Guidelines**

Examples of 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®)

*Note: If a continuous glucose monitoring system (CGMS) is requested along with the external insulin pump; please refer to the Blue Shield of California Medical Policy: Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid.

Coding
Disposable External Insulin Pump (e.g., Omnipod®) CPT codes include:
• **E0784**: External ambulatory infusion pump, insulin
• **A9274**: External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories. The disposable system should be changed every three days.

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
• Wide fluctuations in plasma blood glucose at mealtime: Preprandial target goals for non-pregnant patients with diabetes are 80-120 mg/dL; changes are suggested when average plasma glucose levels are less than 80 mg/dL or greater than 140 mg/dL
• Supplies required for the proper use of a medically necessary external insulin pump including custom-designed batteries and power supplies are considered medically necessary durable medical equipment (DME)
• If an insulin pump fails, a back-up pump is not required 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.

Related Policies
• Artificial Pancreas Device Systems
• Chronic Intermittent Intravenous Insulin Therapy
• Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

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.

**Rationale**

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. 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 external insulin 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:

- 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). 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. For further detailed information on medical necessity for CGMS please refer to the Blue Shield of California Medical Policy: Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid.

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.

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.1

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.24,220

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.26 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.17 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.11

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.14,15

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.7,8

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. 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.

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, stillbirths, 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.

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. 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.

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.

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.

References


**Documentation for Clinical Review**

Please provide the following documentation (if/when requested):
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)

Patients on an External Insulin Pump prior to Enrollment:
- Documentation of glucose testing an average of three times a day during the past month

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:
- Results/reports of tests performed
- Procedure report(s)

**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. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.
The following services may be considered medically necessary when policy criteria are met. Services may be considered not medically necessary when policy criteria are not met.

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| ICD-10 Diagnosis | All Diagnoses

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**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.
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. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

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.