Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/13**
(See policy history boxes for previous effective dates)

Title: Continuous Subcutaneous Insulin Infusion (CSII) (Insulin Pumps)

Description / Background

According to the 2005 surveillance figures from the Centers for Disease Control, the total prevalence of diabetes in the United States for all ages was 20.8 million people, which is 7.0% of the population. Of those 20.8 million, there are 14.6 million diagnosed and 6.2 million people do not realize they have the disease. One in 400 to 600 children and adolescents have diabetes with the number increasing rapidly with the obesity epidemic. As of 2005, it is estimated that 7.87% or 593,200 persons (range: 560,000 to 635,000) age 18+ in Michigan have been diagnosed with diabetes.

With the publication and acceptance of the Diabetes Control and Complications Trial, tighter control of glucose has become the standard of care. One method that has proven beneficial and effective in achieving tight control of glucose is the use of continuous subcutaneous insulin infusion (CSII), also known as an insulin pump. The pump contains both a syringe and a tiny computer chip with memory to store instructions. After the syringe is filled with short-acting insulin and placed in the pump, the computer commands the syringe to deliver hundreds of tiny "micro-shots" of insulin per day according to programmed instructions.

The syringe is connected to the patient by a thin plastic tube called an infusion set. At the end of the infusion set is a small needle or soft cannula, which is inserted into the subcutaneous tissue. Insulin pump therapy not only results in improved metabolic control but also the total daily amount of insulin used can be decreased as much as 20%-25% in all age groups. Insulin pump therapy has also proven beneficial for pregnant diabetics to maintain their blood sugars in a near normal state, reducing the number of miscarriages and birth defects.

Newer pumps have been developed which offer some advantages in terms of patient convenience, comfort, ease of use and preference. One such pump is the OmniPod. The OmniPod features a pod, which contains a lightweight, watertight, self-enclosed insulin pump

with automated cannula insertion. The pod is disposable and delivers insulin according to preprogrammed instructions transmitted wirelessly from the personal diabetes manager (PDM), a hand-held device that programs the pump with customized insulin instructions. The PDM not only monitors the operation of the pump and performs suggested bolus calculations but contains an integrated blood glucose meter.

Regulatory Status:

Various manufacturers have received FDA approvals for insulin pumps.

Medical Policy Statement

The safety and effectiveness of external insulin pumps have been established for patients meeting specific patient selection criteria. They are a useful therapeutic option when indicated.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:
External infusion pumps and related drugs/supplies are established in the home setting for the treatment of diabetes in the following situations, if determined to be medically necessary and prescribed by an allopathic or osteopathic physician.

*Patients must meet all the following criteria:

- The patient must complete a comprehensive diabetes education program
- The patient has been on a regime of at least three injections daily with frequent self-adjustments for at least six months prior to the initiation of the pump
- The patient has documented the frequency of glucose self-testing on average at least four times per day during the two months prior to initiation of the insulin pump
- The patient also meets one of the following criteria on a multiple daily injection regimen:
  - Glycosylated hemoglobin level (HbA1c) > 7.0 percent
  - History of recurring hypoglycemia
  - Wide fluctuations in blood glucose before mealtime
  - “Dawn” phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
  - History of severe glycemic excursions

*For gestational diabetics, only the following criteria must be met to qualify for insulin pump therapy:

- Insulin injections are required greater than or equal to 3 times per day; and
- The patient cannot be controlled by the use of intermittent dosing

Exclusions:

- Patients with major psychiatric disorders such as psychosis and severe depression
- Patients with eating disorders
- Young children who cannot tolerate the cannula or refrain from changing pump settings

- Patients who fail to comply with treatment regimen
- Patients who, in the judgment of the diabetic specialist, are non-responsive to a trial of insulin pump therapy

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CPT / HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

A4222	A4230	A4231	A4232	A9274	E0784
J1817	K0552	K0601	K0602	K0603	K0604
K0605					

Other codes (investigational, not medically necessary, etc.):

99091

Rationale

The tight control of glucose in the management of diabetes is the current standard of care. The basis of this standard is the landmark NIDDK-supported Diabetes Control and Complications Trial (DCCT). This trial demonstrated that intensive control of blood glucose levels is extremely effective in preventing complications affecting the eyes, kidneys and nerves. Long-term results from the follow-up study from the DCCT now show that intensive therapy also dramatically reduces the risk of heart disease, which is the leading cause of death in people with diabetes. Results also showed that a finite period of good glucose control provides benefits years down the road. Thus, patients and physicians are advised to start intensive therapy as early as possible following diagnosis.

Prevention efforts are having dramatic and positive effects on rates of diabetic kidney disease in people with insulin-dependent diabetes. The incidence rate of end-stage renal disease in Caucasians less than 30 years of age with diabetes, most of whom have insulin-dependent diabetes, is about half the rate seen in the late 1980s and early 1990s. Credit for recent gains likely goes to implementation of strategies to prevent kidney disease, including improved management of diabetes.

Newer pumps have been developed which offer some advantages in terms of patient convenience, comfort, ease of use and preference. One such pump is the OmniPod. The OmniPod features a pod, which contains a lightweight, watertight, self-enclosed insulin pump with automated cannula insertion. The pod is disposable and delivers insulin according to preprogrammed instructions transmitted wirelessly from the personal diabetes manager (PDM), a hand-held device that programs the pump with customized insulin instructions. The PDM monitors the operation of the pump, performs suggested bolus calculations and contains an integrated blood glucose meter.

Government Regulations

National:

National Coverage Determination (NCD) for Infusion Pumps (280.14), effective 2005:

Item/Service Description
A. General
Infusion pumps are medical devices used to deliver solutions containing parenteral drugs under pressure at a regulated flow rate.

Indications and Limitations of Coverage
B. Nationally Covered Indications
The following indications for treatment using infusion pumps are covered under Medicare:

External Infusion Pumps

1. Iron Poisoning (Effective for Services Performed On or After September 26, 1984) when used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload, only external infusion pumps are covered.
2. Thromboembolic Disease (Effective for Services Performed On or After September 26, 1984) when used in the administration of heparin for the treatment of thromboembolic disease and/or pulmonary embolism, only external infusion pumps used in an institutional setting are covered.
3. Chemotherapy for Liver Cancer (Effective for Services Performed On or After January 29, 1985). The external chemotherapy infusion pump is covered when used in the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable; OR, where the patient refuses surgical excision of the tumor.
4. Morphine for Intractable Cancer Pain (Effective for Services Performed On or After April 22, 1985). Morphine infusion via an external infusion pump is covered when used in the treatment of intractable pain caused by cancer (in either an inpatient or outpatient setting, including a hospice).
5. Continuous Subcutaneous Insulin Infusion (CSII) Pumps (Effective for Services Performed On or after December 17, 2004). Continuous subcutaneous insulin infusion (CSII) and related drugs/supplies are covered as medically reasonable and necessary in the home setting for the treatment of diabetic patients who: (1) either meet the updated fasting C-Peptide testing requirement, or, are beta cell autoantibody positive; and, (2) satisfy the remaining criteria for insulin pump therapy as described below. Patients must meet either Criterion A or B as follows:

   Criterion A: The patient has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin doses for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen:
   a. Glycosylated hemoglobin level (HbAlc) > 7.0 percent;
   b. History of recurring hypoglycemia;
   c. Wide fluctuations in blood glucose before mealtime;
   d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl; or,
   e. History of severe glycemic excursions.

   Criterion B: The patient with diabetes has been on a pump prior to enrollment in

Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

General CSII Criteria
In addition to meeting Criterion A or B above, the following general requirements must be met:

The patient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or, as an alternative, must be beta cell autoantibody positive.

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

Continued coverage of the insulin pump would require that the patient be seen and evaluated by the treating physician at least every 3 months.

The pump must be ordered by and follow-up care of the patient must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators and dietitians who are knowledgeable in the use of CSII.

Local:
Local Coverage Determination (LCD) -National Government Services, revision 4/1/11.
Conventional continuous subcutaneous insulin infusion pumps (CSII) (Effective for Services Performed On or after 4/1/2000).--
An external infusion pump and related drugs/supplies are covered as medically necessary in the home setting for the treatment of diabetes. In order to be covered, patients must meet criterion A or B:

Administration of continuous subcutaneous insulin for the treatment of diabetes mellitus (ICD-9 codes 249.00–250.93) if criterion A or B is met and if criterion C or D is met:
A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:
   1. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.
   2. For patients with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 per cent of the lower limit of normal of the laboratory’s measurement method.
   3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.
B. Beta cell autoantibody test is positive.
C. The patient has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with

frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria (1–5) while on the multiple injection regimen:

1. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
2. History of recurring hypoglycemia
3. Wide fluctuations in blood glucose before mealtime
4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
5. History of severe glycemic excursions

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

If criterion A or B is not met, the pump and related accessories, supplies, and insulin will be denied as not reasonable and necessary. If criterion C or D is not met, the pump and related accessories, supplies and insulin will be denied as not reasonable and necessary.

Continued coverage of an external insulin pump and supplies requires that the patient be seen and evaluated by the treating physician at least every 3 months. In addition, the external insulin infusion pump must be ordered and follow-up care rendered by a physician who manages multiple patients on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.

Subcutaneous insulin is administered using ambulatory infusion pump E0784. Claims for usage of infusion pumps other than E0784 will be denied as not reasonable and necessary.

Michigan Department of Community Health:

Insulin pumps are covered when other methods to control blood glucose levels have been ineffective and one of the following applies:

- Blood glucose levels demonstrate poor glycemic control despite monitoring at least four times per day and multiple daily insulin injections with a persistently elevated glycosylated hemoglobin level greater than seven percent.
- There is a history of severe glycemic excursions, brittle diabetes, hypoglycemic/hyperglycemic reaction, nocturnal hypoglycemia, any extreme insulin sensitivity and/or very low insulin requirements.
- There is evidence of the "dawn" phenomenon where fasting blood glucose level often exceeds 200 mg/dl.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Intermittent or Continuous Invasive Glucose Monitoring
- Hemoglobulin A1c Home Device

- Chronic intermittent intravenous insulin therapy (CIIIT)

References

1. Blue Cross Blue Shield Association, "External Infusion Pumps," *Medical Policy Review Manual*, # 1.01.08, Issue 1: 2003, last review April 2003, no further review scheduled.
2. Brunton, Stephen, MD, "Insulin Delivery Systems: Reducing Barriers to Insulin Therapy and Advancing Diabetes Mellitus Treatment," *The American Journal of Medicine*, Volume 121, Number 6A, June 2008, pp. 535-541.
3. Fatourechi, Mitra M., et al., "Hypoglycemia with Intensive Insulin Therapy: A Systematic Review and Meta-Analyses of Randomized Trials of Continuous Subcutaneous Insulin Infusion *versus* Multiple Daily Injections," *J Clin Endocrinol Metab,* March 2009, Volume 94, Number 3, pp. 729–740.
4. *HAYES Medical Technology Directory,* "Insulin Pumps, External," Lansdale, PA: HAYES, Inc., February 11, 2003, update search March 28, 2008.
5. *HAYES Search and Summary,* "OmniPod® Insulin Management System (Insulet Company)," Lansdale, PA: HAYES, Inc., August 27, 2010.
6. Michigan Department of Community Health, "External Infusion (Insulin) Pump and Related Supplies," *Medicaid Provider Manual*, Section 2.14, April 1, 2011 update.
7. National Government Services, Inc., LCD, DME MAC Jurisdiction B, "External Infusion Pumps," #EIP V12 (Rev. Eff. 1/1/09).
8. White, Russell D., MD, FAAFP, FACSM, AACE, "Insulin Pump Therapy (Continuous Subcutaneous Insulin Infusion)," *Prim Care Clin Office Pract*, Volume 34, 2007, pp. 845–871.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 9/11/12, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/3/05	5/3/05	5/31/05	Joint policy established
5/1/08	2/18/08	5/1/08	Routine maintenance, code updates
9/1/09	7/28/09	6/16/09	Routine maintenance
9/1/11	6/21/11	6/21/11	Routine maintenance
1/1/13	10/16/12	10/16/12	Routine maintenance; changed “type 1 diabetes” to “insulin dependent diabetes.”

Next Review Date: 4th Qtr, 2013

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 11/25/97	Revised: 4/20/00, 8/20/01
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII)
(INSULIN PUMPS)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	Conventional insulin pumps are covered. Disposable insulin pumps (A9274) are not a covered benefit as of 1/1/08. Disposable insulin pumps are not covered.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
Blue Cross Complete of Michigan	Conventional insulin pumps are covered when other methods to control blood glucose levels have been ineffective and one of the following applies: • Blood glucose levels demonstrate poor glycemic control despite monitoring at least four times per day and multiple daily insulin injections with a persistently elevated glycosylated hemoglobin level greater than seven percent. • There is a history of severe glycemic excursions, brittle diabetes, hypoglycemic/hyperglycemic reaction, nocturnal hypoglycemia, any extreme insulin sensitivity and/or very low insulin requirements. • There is evidence of the "dawn" phenomenon where fasting blood glucose level often exceeds 200 mg/dl. Documentation must be less than 90 days old and include: • Diagnosis/medical condition pertaining to the need for the pump. • Lab values of blood glucose levels. • Medical history documenting the need for the pump. • Any medical complications experienced by the beneficiary related to the need for blood glucose monitoring. CSHCS (Children's Special Health Care Services) requires a prescription from an appropriate pediatric subspecialist. Preauthorization is not required if the Standards of Coverage are met, and: • The beneficiary is over the age of 16 and has one of the diagnoses indicated

	• below: • Diabetes Mellitus without Complication • Diabetes with Ketoacidosis • Diabetes with Hyperosmolarity • Diabetes with Other Coma • Diabetes with Renal Manifestations • Diabetes with Ophthalmic Manifestations • Diabetes with Neurological Manifestations • Diabetes with Peripheral Circulatory Disorders • Diabetes with Other Specified Manifestations • Diabetes with Unspecified Complication • Diabetes Mellitus Complicating Pregnancy The beneficiary is under the age of 16, has one of the diagnoses above, and the pump is ordered by a pediatric endocrinologist. Exclusions: • Items for a beneficiary who is non-compliant with a physician's plan of care (or) items ordered for the purpose of solving problems related to noncompliance (e.g., insulin pump) • **Disposable insulin pumps (A9274) are non-covered.**

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.