Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/24**
(See policy history boxes for previous effective dates)

Title: Continuous Subcutaneous Insulin Infusion (CSII) (Insulin Pumps) and Transdermal Insulin Delivery Systems

Description/Background

According to the 2017 surveillance figures from the Centers for Disease Control, the total prevalence of diabetes in the United States for all ages was 30.3 million people, which is 9.4% of the population. Of those 30.3 million, there are 23.1 million diagnosed and 7.2 million people do not realize they have the disease. Approximately 132,000 children and adolescents younger than age 18 were diagnosed with diabetes of which around 17,900 had type I diabetes.

External Insulin Pumps
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. An external insulin infusion pump is a programmable, battery-powered mechanical syringe/reservoir device controlled by a microcomputer to deliver a continuous subcutaneous insulin infusion (CSII) into the body. Typical devices have a two to three day supply of insulin connected to an infusion set attached to a small needle or cannula programmed to deliver a steady basal amount of insulin and release a bolus dose at meals and at programmed intervals. The purpose of an insulin pump is to provide an accurate, continuous, controlled delivery of insulin, which can be regulated by the user to achieve intensive glucose control and prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis.

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 also contains an integrated blood glucose meter.

Transdermal Insulin Delivery Systems
The Valeritas V-Go Disposable Insulin Delivery Device is a mechanical (no electronics), self-contained, sterile, patient fillable, single-use disposable insulin delivery device with an integrated stainless steel subcutaneous needle. It is designed for the subcutaneous delivery of insulin for the management of diabetes mellitus in persons requiring insulin. After filling the V-Go with insulin using the EZ Fill, the device is secured to the patient's skin over the infusion site with an adhesive-backed foam pad, which is attached to the back of the pump. Once activated, the V-Go delivers a continuous infusion of insulin at a fixed rate. The device also allows the user to initiate bolus injections to supplement their daily basal insulin requirements. Three device models (20, 30 and 40 Units/day) are available to address the different basal and bolus requirements of each patient. A window in the top of the pump allows the user to see into the reservoir to check the drug and to monitor the progress of the infusion.

Regulatory Status:

Various manufacturers have received FDA approvals for insulin pumps.

The V-Go device (Models V-Go20, V-Go 30, V-Go40) received a second FDA 510(k) clearance (**K103825**) on February 23, 2011. The Device Description and Intended Use listed in this clearance are identical to those listed in the **K100504** clearance. The statement regarding **Substantial Equivalence** in the second clearance is as follows: "…The Valeritas V-Go Insulin Delivery Device is substantially equivalent to the predicate device, the Valeritas V-Go Insulin Delivery Device, cleared by this center on 1 December 2010 (**K100504**). The Valeritas V-Go device has the same intended use and performance characteristics. The primary difference qualifies the use of NovoLog in the device in addition to Humalog…"

Medical Policy Statement

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

Transdermal insulin delivery systems (e.g., V-Go Transdermal Basal-Bolus Insulin Delivery Device) are experimental/investigational. There is insufficient evidence in medical literature to determine if the use of these devices result in improved patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

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 ($HbA1_c$) > 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
- Transdermal insulin delivery devices (e.g., V-Go)

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	A4225	A4230	A4231	A4232	A4230
A9274	E0784	E2102	J1817	K0601	K0602
K0603	K0604	K0605			

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

99091 E1399 S9145

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.

Transdermal Insulin Delivery Systems

A proposed new method of insulin delivery is a transdermal, mechanical insulin delivery system. A patch-like device is filled with insulin and placed on the skin. The devices deliver a continuous low dose of basal insulin through the skin and/or deliver bolus insulin upon demand. Other than the device worn on the skin, there are no additional components or separate control devices that manage or monitor the insulin dosage. Overall, this technology is proposed for type 2 diabetics. An example of this type of device is the V-Go Disposable Insulin Delivery Device (Valeritas, Inc., Bridgewater, NJ). Proposed advantages of these systems include not having to perform intermittent subcutaneous injections, ease of use, improved safety due to reduction in needle handling, and improved acceptance and compliance by the patients. However, the systemic blood levels of delivering insulin in this manner have generally proven to be inadequate for management of the diabetic patient.[1]

V-Go is a basal-bolus insulin delivery device proposed for use by type 2 adult diabetics. The device, which uses the h-Patch™ delivery technology, is used for subcutaneous delivery of 24 hours of U-100 fast-acting insulin (i.e., Humalog® [insulin lispro] and Novolog® [insulin aspart].

V-Go is filled with insulin using the EZ Fill device and then applied to the body (e.g., arm or abdomen). By pushing a button, a microneedle is subcutaneously inserted into the body and insulin delivery begins at a continuous preset basal rate. When needed, a bolus can be delivered by pushing the bolus button. A window with a grey indicator allows visualization of the reservoir to monitor the progress of the infusion. The reservoir is replaced every 24 hours and discarded after use. V-Go is a fully mechanical device using a compressed spring and does not require electronics, batteries or software. Different preset basal rates are available (i.e., V-Go 20, V-Go 30, V-Go 40). The device is only available with a prescription for a 30-day supply (one kit). Two vials of insulin are required for the V-Go 20 and three vials for the V-Go 30 and V-Go 40.[9,10]

The advantages of transdermal drug delivery of insulin by devices such as the V-Go include convenience, good patient compliance, prolonged therapy, and avoidance of both the liver's first-pass metabolism and degradation in the gastrointestinal tract.

In 2008, Kapitza et al. reported on a study of basal–prandial insulin delivery in type 2 diabetes mellitus via the V-Go.[7] The aim of this proof-of-concept study was to evaluate the clinical functionality, safety, and pharmacodynamics of the V-Go delivering insulin aspart and redistributing a single basal dose of insulin glargine as a constant basal infusion supplemented with prandial insulin in subjects with type 2 diabetes mellitus. In six subjects receiving once-daily subcutaneous (SC) injections of insulin glargine (≥15 U/day) with or without concomitant oral antidiabetic drugs, glargine was discontinued following a 3-day baseline phase. The V-Go was then applied to the lower abdomen of the subjects once daily for 7 days (days 1–3 inpatient, days 4–7 outpatient). Each V-Go provided a continuous 24-hour preset basal infusion rate of insulin aspart (0.6 U/h) and up to three daily prandial doses at mealtimes. Capillary blood glucose concentrations were measured at 11 time points per day during the baseline and inpatient phases and at 4 time points per day during the outpatient phase. Additionally, glucose profiles were measured continuously on all days.

Results: The V-Go was well tolerated and operated as anticipated. The mean ± SEM pre-study daily dose of SC insulin glargine was 33.3 ± 13.8 U; the mean daily total insulin aspart dose infused with the V-Go was 31.5 ± 7.5 and 32.3 ± 7.8 U for the inpatient and outpatient periods, respectively. Fasting blood glucose values were similar to those observed at baseline throughout the study, with nonsignificant (NS) reductions in readings collected during the outpatient phase before lunch (-35 ± 27 mg/dl) and before dinner (-38 ± 25 mg/dl). The 2-hour postprandial glucose trended lower from 231 to 195 mg/dl (NS) at breakfast, 234 to 166 mg/dl (NS) at lunch, and 222 to 171 mg/dl (NS) at dinner. Bedtime blood glucose decreased (mean change from baseline -52 ± 21 mg/dl; $P = 0.0313$), as did nighttime (3:00 AM) measurements (-20 ± 9 mg/dl; $P = 0.0313$). Overall glycemic control tended to improve, as shown by continuous glucose monitoring changing from 173 to 157 mg/dl ($P = 0.063$, NS) and 156 mg/dl ($P = 0.219$) during inpatient and outpatient periods, respectively. Glycemic variability assessed by the M value similarly tended to decrease from 33 ± 9 to 25 ± 4 (NS) and 21 ± 4 (NS) for inpatient and outpatient periods, respectively. The V-Go appears to be a safe and reliable method for the delivery of basal and prandial insulin, with the potential to facilitate more consistent insulin delivery and provide better control of fasting and postprandial glycemia, which may improve long-term metabolic control. Additional studies of the V-Go in larger numbers of subjects are required to refine the practical benefit of this novel device.

The V-Go is approved by the FDA as a Class II, 510(k) external insulin infusion pump. The system is indicated for continuous subcutaneous infusion of insulin in one 24-hour time period and on-demand bolus dosing in two-unit increments in adult patients requiring insulin. V-Go 20 delivers 20 units of insulin in one 24-hour time period (0.83 U/hr), V-Go 30 delivers 30 units of insulin in one 24-hour time period (1.25U/hr) and V-Go 40 delivers 40 units of insulin in one 24-hour time period (1.67U/hr). Each device can also deliver on-demand bolus dosing in two-unit increments (up to 36 units per one 24-hour time period). Per the FDA, no clinical performance data were required to validate the intended uses or user needs of the system.[11]

There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of V-Go. Published studies include a case series of six type 2 diabetics who used V-G for seven days[7] and a retrospective review with data collected by 22 type 2 diabetics and one type 1 diabetic using a patient questionnaire.[9]

Government Regulations

National:

National Coverage Determination (NCD) for Infusion Pumps (Manual section 280.14), effective 12/17/2004.

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
1e. External Infusion Pumps

1. 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 ($HbAl_c$) > 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.

Other Uses of CSII
The Centers for Medicare & Medicaid Services will continue to allow coverage of all other uses of CSII in accordance with the Category B investigational device exemption clinical trials regulation (42 CFR 405.201) or as a routine cost under the clinical trials policy (Medicare National Coverage Determinations Manual 310.1).

(Medicare does not address coverage for the transdermal insulin delivery device)

Local:

Local Coverage Determination (LCD) -National Government Services L33794, Effective on or after 07/18/21, effective 7/1/2023 . External Infusion Pumps.
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 beneficiary 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 ($HbA1_C$) 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.

(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
- Hemoglobin $A1_c$ Home Device
- Chronic intermittent intravenous insulin therapy (CIIIT)

References

1. Anhalt H, Bohannon N. “Insulin Patch Pumps: Their Development and Future in Closed-Loop Systems. Diabetes Techn & Thera. 2010;12(1): 51-58.

2. 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.
3. Center for Medicare and Medicaid Services. National Coverage Determination. Infusion Pumps (280.14). Effective date 12/17/2004, last reviewed February 2005. Available at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&CoverageSelection=National&KeyWord=Infusion+Pumps&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAAA%3d%3d&. Accessed August 2023.
4. HAYES Medical Technology Directory, “Insulin Pumps, External,” Lansdale, PA: HAYES, Inc., February 11, 2003, update search March 28, 2008. Archived November 2014.
5. HAYES Search and Summary, “OmniPod® Insulin Management System (Insulet Company),” Lansdale, PA: HAYES, Inc., August 27, 2010.
6. HAYES Search and Summary, “V-Go™ Disposable Insulin Delivery Device (Valeritas Inc.),” Lansdale, PA: HAYES, Inc., July 1, 2013. Archived August 2014.
7. Kapitza C, Fein S, Heinemann L, Schleusener D, Levesque S, Strange P. Basal-prandial insulin delivery in type 2 diabetes mellitus via the V-Go: a novel continuous subcutaneous infusion device. J Diabetes Sci Technol. 2008 Jan; 2(1):40-6.
8. National Government Services, Inc., LCD, DME MAC Jurisdiction B, “External Infusion Pumps,” #L33794 (Rev. Eff. 1/1/14). Available at http://www.ngsmedicare.com/ngs/portal/ngsmedicare/l27215/!ut/p/a1/tVJBb4IwGP0rXDiaflAKeiROjSiaSJYJl6W0BWugIDZk-_cD3ZIdprgs6-1r3-t738tDCdqjRNFW5lTLStGinxP3FTb4yZ8TByAiBJYz2Hlh5NngWB0g7gFBNL0CwgnA0nej-WIBeLuxh_gvKEEJU7rWBxSr_FwKLhltBKuUFkqb8O3OBFa1oqG5MLjQoimluvg04YoojLogJHs3WMcUjQmF7dkW6RXqjsTFWebqMjHJUQwWTTEDcDikxMFsIng2yZhnWV5qYSBfu904PvwxG_JQNgPpXgF3LN4V2ZIBwBgPeSAo7tb0bv6wslH0i8yDB0KVx9Mp8bva9B1502j_T73ppOwmnIZ53x99GEmVVWj_-RgMJf8zm5fCKGtmjAzKtGwFqsvncnzMVmt3N9uNAZOiXWfh2f8Atv9yEA!!/dl5/d5/L2dBISEvZ0FBIS9nQSEh/ accessed August 2023.
9. Rosenfeld CR, Bohannon NJ, Bode B, Kelman AS, Mints SN et al. The V-Go insulin delivery device used in clinical practice: patient perception and retrospective analysis of glycemic control. Endocr Pract. 2012 Sep-Oct; 18(5):660-7.
10. U.S. Food and Drug Administration (FDA), Centers for Devices and Radiological Health, new device approval, “V-Go® Disposable Insulin Delivery Device”. Approval date: December 2010. Available at Https://www/valeritas.com/news-room/newsletter.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through August 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective BCBSM	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.”
11/1/14	8/19/14	8/19/14	Added information on transdermal insulin delivery systems as experimental/investigational. References and rationale updated.
3/1/16	12/10/15	12/10/15	Routine policy maintenance. No change in policy status.
1/1/17	10/11/16	10/11/16	Routine policy maintenance. No changes in policy status.
1/1/18	10/19/17	10/19/17	Routine policy maintenance. No change in policy status.
1/1/19	10/16/18	10/16/18	Routine policy maintenance. Deleted Medicaid section. No change in policy status.
1/1/20	10/15/19		Routine policy maintenance. No change in policy status.
1/1/21	10/20/20		Routine policy maintenance. No change in policy status.
1/1/22	10/19/21		Routine policy maintenance. No change in policy status.
1/1/23	10/18/22		Routine policy maintenance, added code E2102 as established, no change in policy status.
1/1/24	10/17/23		Routine policy maintenance, no change in policy status. Vendor managed: Northwood (ds)

Next Review Date: 4th Qtr. 2024

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) AND TRANSDERMAL INSULIN DELIVERY SYSTEMS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply. Transdermal insulin delivery systems (e.g., V-Go) are not covered.
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

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.