Medical Policy

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information.

Category: Durable Medical Equipment
***Current Policy Effective Date: 1/1/08**

Title: External Ambulatory Parenteral Infusion Pumps

Procedure Code(s): Multiple

Description / Background

An external infusion pump (EIP) is a portable device intended to provide continuous ambulatory drug infusion therapy over an extended period. The EIP is also known as an external pump, ambulatory pump or a mini-infuser. The EIP is usually the size of a portable cassette player and can be worn on a belt around the patient's waist or from a shoulder harness. They are battery driven devices.

Proposed drug delivery routes using the EIP include the intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural intrathecal and intraventricular routes. A heparinized saline solution may be used during an interruption of drug therapy to maintain catheter patency. The EIP is battery-powered and drug reservoir refilling is non-invasive. A catheter from the pump is attached to the desired access route for drug delivery.

An EIP for the administration of the following drugs may be considered a therapy of choice for selected patients on**:**

- Morphine and other parenteral analgesics for treatment of severe, chronic cancer pain that is resistant to conventional therapy. Acceptable routes are subcutaneous (SC) and intravenous (IV);
- Heparin for treatment of severe thromboembolic disease that cannot be managed conventionally (e.g., complicated pregnancy). Acceptable routes are SC and IV;
- Chemotherapeutics for treatment of cancer. Acceptable routes are stipulated in the drug labeling and might include either IV or intra-arterial (IA).

(*See policy history boxes for any previous effective dates, if applicable)

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- Insulin for treatment of insulin–dependent diabetes mellitus in patients who cannot be controlled by intermittent dosing. Acceptable routes are SC and IV.

External insulin pump therapy may be indicated for type I diabetes who have not achieved adequate glucose control despite multiple daily injections, or who have an active lifestyle or variable schedule and therefore might benefit from continuous subcutaneous insulin infusion (CSII). Intensive insulin therapy has been shown to reduce complications and improve outcomes in pregnant women with type I diabetes; therefore, external insulin pump therapy may provide an alternative to multiply daily injections for these individuals. Since the benefits of intensive insulin therapy in type 2 diabetics have not been conclusively established, no patient selection criteria for CSII in type 2 diabetes have been defined.

CSII should be used only in those individuals who have demonstrated an ability to consistently and accurately monitor blood glucose at least for three (3) times per day and adjust insulin dosing accordingly and in those who have adequate access to medical personnel trained in external insulin pump therapy. Exclusion criteria are consistent with those for intensive insulin therapy, such as the presence of severe life-threatening medical conditions, uncorrected endocrine abnormality, cognitive impairment, chronic alcohol abuse and age < 2, as well as an inability to maintain and operate the pump.

CPT / HCPCS Level II Codes and Description *(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	E0779	E0780
E0781	E0784	E0791			

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

N/A

Diagnoses / Medical Conditions

None specified

Medical Policy Statement

The safety and effectiveness of external infusion pumps (EIP) in the home setting have been established. They may be considered a useful therapeutic option when indicated.

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Rationale

Use of an external infusion pump for the delivery of certain medications in the home setting is cost-effective. The use of the pump will avoid an inpatient hospitalization if the only reason for the hospitalization is the administration of intravenous drugs or therapies. In addition, improved control of the underlying condition (e.g., diabetes, osteomyelitis) might avoid hospitalization.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

The safety and effectiveness of external infusion pumps (EIP) in the home setting have been established. They may be considered a useful therapeutic option when indicated.

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

Patient selection is essential for appropriate utilization of an external ambulatory infusion pump (EIP). Factors relevant to the selection of an EIP candidate include**:**

- The patient's diagnosis indicates a clinically significant, medically necessary need for home infusion via a controlled delivery system to safely administer the medication.
- The patient's treatment can be appropriately delivered on an outpatient basis, with an expected improvement in the quality of life.
- The drug therapy is ongoing and a therapeutic advantage is expected by using continuous (or pulsatile) infusion rather than intermittent injections.
- If not for an EIP, the patient would have to be treated using a conventional infusion pump in an institutional setting.
- Compliance issues make intermittent injection very difficult or ineffective.
- Patient education protocols are documented and emergency support is available if or when an unexpected adverse event occurs.

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Therapies for which an external ambulatory infusion pump may be appropriate include the administration of:

- Morphine or other parenteral analgesics for the treatment of severe, chronic pain that is resistant to conventional therapy.
- Heparin for the treatment of severe thromboembolic disease that cannot be managed conventionally by intermittent dosing (e.g., complicated pregnancy).
- Chemotherapeutics for treatment of cancer. Acceptable routes are stipulated in the drug labeling and might include either intravenous (IV) or intra-arterial (IA) administration.
- Continuous subcutaneous insulin infusion for the treatment of insulin-dependent diabetes mellitus in patients who cannot be controlled by intermittent dosing. The patient must meet all of the following guidelines for insulin pump therapy:
- The patient has completed a comprehensive diabetes education program.
- The patient has been on a program of at least three (3) insulin injections per day with frequent self-adjustments of the insulin dose for at least six (6) months prior to initiation of insulin pump therapy.
- There is a documented frequency of glucose self-testing, a minimum of four (4) times per day, during the two (2) month period prior to initiation of insulin pump therapy.
- The patient has a history of one or more of the following while on a multiple daily subcutaneous insulin injection regimen:
  - A documented glycosylated hemoglobin level (HbA1c)>7.0%
  - A history of recurring hypoglycemia
  - Wide fluctuations in blood glucose before mealtime
  - A history of severe glycemic excursions
  - “Dawn” phenomenon, with fasting blood sugars frequently exceeding 200 mg/dl

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Related Policies

- Implantable Infusion Pumps
- Insulin Pumps
- Total Parenteral Nutrition

Medicare Information

The following indications for treatment using infusion pumps are covered under Medicare:

1. External Infusion Pumps
   a. 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.
   b. Thromboembolic Disease (Effective for Services Performed On or After September 26, 1984)
      When used in the administration of heparin for the treatment of thromboembolic

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disease and/or pulmonary embolism, only external infusion pumps used in an institutional setting are covered.

c. 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.

d. 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).

(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 & Medicaid 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.)

References

- Blue Cross Blue Shield Association, "External Infusion Pumps," *Medical Policy Reference Manual*, #1.01.08, original policy date 3/9/96, last review date April 2003, no further review scheduled.
- Centers for Medicare and Medicaid Services, *National Coverage Determinations,* "Medical and Surgical Supplies Infusion Pumps," section 280.14, Version 2, < http://bcbsm.mediregs.com/cgi-bin/_fd/fetch_doc?rCall=1&db=mre_mr_ncd&doc_id=49499 > (August 9, 2007).
- LeBlanc, Karl A., et al., "Evaluation of Continuous Infusion of 0.5% Bupivacaine by Elastomeric Pump for Postoperative Pain Management after Open Inguinal Hernia Repair," *J Am Coll Surg*, Vol. 200, No. 2, February 2005, pp. 198-202.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through August 10, 2007, the date the research was completed.

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Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
2/6/03	2/6/03	2/14/03	Joint policy established
1/7/05	1/7/05	1/26/05	Routine maintenance, references updated
1/1/08	10/16/07	11/19/07	Routine maintenance, references updated, policy retired

Next Review Date: This policy is established and is no longer subject to periodic review.

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 5/03/91	Revised: 3/14/01 (infusion pumps)
BCN: 11/25/91	Revised: 11/25/97, 4/20/01 (insulin pumps)
BCBSM: 3/31/96	Revised: 8/24/00

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I. Short Description

An external infusion pump (EIP) is a portable device intended to provide continuous ambulatory drug infusion therapy over an extended period. The EIP is also known as an external pump, ambulatory pump or a mini-infuser. The EIP is usually the size of a portable cassette player and can be worn on a belt around the patient's waist or from a shoulder harness. They are battery driven devices.

II. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	The safety and effectiveness of external infusion pumps (EIP) in the home setting have been established. They may be considered a useful therapeutic option when indicated.
BCNA (Medicare Advantage)	Follow Medicare guidelines and BCN coverage.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service. <Exception: If BCN65 member has an "exact-fill" option, BCN may cover the service even if Medicare does not.>
BlueCaid (Medicaid)	A-6. Equipment to support home care Equipment to support home care treatment as an alternative to hospital care may be covered when medically necessary as defined in this certificate. Equipment included under this section must be hospital equipment (e.g., ventilators, dialysis equipment, infusion pumps), monitors and other items that are used in the home as an alternative to hospital care and must require daily technical or professional supervision. Equipment or items under this section must be obtained through a BlueCaid approved provider and ordered by the member's primary care physician or his/her designee and authorized by BlueCaid.

III. 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.

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- Payment is based on BCN payment rules, individual certificate benefits and certificate riders.
- **Appropriate copayments will apply. Refer to individual certificate and riders for amounts.**
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.

IV. Effective Dates:

Policy updated: 2/6/03, 1/1/08
JUMP policy effective date: 3/14/01

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