CHAPTER 8
SECTION 2.3

EXTERNAL AND IMPLANTABLE INFUSION PUMP

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III. DESCRIPTION

A. An External Infusion Pump (EIP) is a device designed to deliver measured amounts of a drug through injection over a period of time into a patient in a controlled manner.

B. An Implantable Infusion Pump (IIP) system delivers therapeutic plasma levels of active drug to a target organ or body compartment for prolonged periods of time. The bulk flow of drug is generated either by fluorocarbon propellant (nonprogrammable IIP) or direct electromechanical action powered by a battery (programmable IIP). The pump is surgically implanted in a subcutaneous pocket and connects to a dedicated catheter that has been placed in the appropriate compartment. Constant or variable-rate infusions are possible over long periods of time (several weeks to years) with minimal human intervention (refilling or reprogramming) while retaining the capability for external control of rate and volume of primary and supplemental drug delivery. In addition to the pump itself, dependent on the type of pump used, the components of the system may include any of the following: reservoir, optional access port, connectors, various size catheters, micropore filter, hand-held programmer, and a variety of accessories.

IV. POLICY

A. External Infusion Pump (EIP)

1. Claims may be reimbursed for medically necessary U.S. Food and Drug Administration (FDA)-approved EIPs when used according to label specifications in delivering continuous or intermittent drug therapy on an inpatient or outpatient basis.

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2. Supplies for the effective use of the EIP. must be FDA approved. Such supplies include those drugs and biologicals prescribed for usage directly into the EIP in order to achieve the therapeutic benefit of the EIP, or to assure the proper functioning of the equipment.

3. EIPs and otherwise covered medical supplies required in the administration of the drug therapy performed in the home are covered.

4. Other medical conditions requiring the use of an infusion of medicine from a FDA-approved EIP may be cost shared when medical review determines the treatment to be medically necessary and generally accepted medical practice. Examples of covered medical conditions requiring the use of FDA-approved EIPs.

a. Cancer chemotherapy agents.

b. Morphine when used in the treatment of intractable pain.

c. Desferoxamine.

d. Insulin: When the diagnosis is insulin dependent Type 1 diabetes mellitus and there is documentation by the physician of poor diabetic control; or for Cystic Fibrosis-Related Diabetes (CFRD) under the rare diseases policy as described in Chapter 1, Section 3.1.

e. Antibiotic therapy.

f. Heparin therapy in treatment of thromboemobolic disease.

5. EIPs are cost shared as Durable Medical Equipment (DME). (See the TRICARE Reimbursement Manual (TRM), Chapter 1, Section 11 for more information on reimbursement of DME.)

B. Implantable Infusion Pump (IIP)

Claims may be reimbursed for services and supplies related to the use of medically necessary, FDA-approved IIPs when used according to pump label specifications. This may include but is not limited to implantation, refilling, servicing, maintenance, and removal of the pump and/or accessories. Uses may include but are not limited to the following (please note "EXCEPTIONS" and "EFFECTIVE DATES" listed below):

1. Treatment of primary liver cancer or metastatic colorectal liver cancer where the metastases are limited to the liver with continuous hepatic artery infusions of chemotherapeutic agents (e.g., floxuridine, doxorubicin hydrochloride, cisplatin, methotrexate, with bacteriostatic water or physiologic saline and/or heparin);

2. Treatment of osteomyelitis with administration of antibiotics (e.g., clindamycin);

3. Treatment of chronic intractable pain of malignant or nonmalignant origin by administration of opioid drugs (e.g., morphine) intrathecally or epidurally in patients who

have a life expectancy of at least 3 months and who have not responded to less invasive medical therapy. Documentation of the following must be provided in order for TRICARE to consider a claim for payment:

a. Inadequate response to noninvasive methods of pain management such as systemic opioids, including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain, and

b. A preliminary trial of intraspinal opioid with a temporary intrathecal/ epidural catheter to evaluate pain relief, side effects, and patient acceptance.

4. Treatment of chronic intractable spasticity with administration of anti-spasmodic drugs (e.g., baclofen) in patients who have proven unresponsive to less invasive medical therapy. The following must be provided in order to consider a claim for payment:

a. Documentation of inadequate control of spasticity or intolerable side effects resulting from at least a 6-week trial of noninvasive methods of spasm control with drugs such as oral antispasmodics alone or combined with anticonvulsants (depending on the disease progression and the patient' symptoms), and

b. Documentation of a favorable response to a trial intrathecal dose of the antispasmodic drug prior to pump implantation;

5. Second level review is required for all other IIP uses. Reimbursement may be considered for other uses of IIPs (not specifically excluded in "EXCEPTIONS" below) with documentation of the following:

a. The medical necessity of the drug;

b. The medical necessity and appropriateness of an IIP to deliver the drug; and

c. The IIP use adheres to the FDA-approved labeling for the pump and the drug.

V. POLICY CONSIDERATIONS

A. FDA-approved IIPs are labeled for specific drugs and routes of administration, e.g., intravenous fluorouracil (5-FU), intra-arterial floxuridine, epidural morphine sulfate, intrathecal morphine sulfate, and intrathecal baclofen. Payments of claims may be considered for IIPs used according to label specifications.

B. Reimbursement will follow the appropriate methodology for the place where the services are delivered, i.e., services provided in a hospital will be reimbursed according to the appropriate inpatient reimbursement methodology; reimbursement for physician's office services will follow appropriate outpatient reimbursement procedures. When the implantation is performed on an inpatient basis, charges for the pump and the related equipment, supplies, and drugs will be included in the hospital charges. If services performed in the physician's office are primarily for maintenance and refilling of the infusion system, reimbursement is limited to the charges for the maintenance and refilling services; no allowance may be made for an office visit.

C. In addition to IIPs, implanted access ports and pulsatile pumps forming a self-sealing patent access portal for the administration of intravenous medications (e.g., Port-a cath, Medi-port and Infusiport systems) may be cost-shared. These systems are distinguished from IIPs by the method of controlling the drug delivery rate. Access ports deliver drugs by passive diffusion. Pulsatile pumps deliver drugs when the patient manually compresses the device. Drug delivery rates in IIPs are controlled by vapor pressure or by direct electromechanical action.

VI. EXCLUSIONS

A. TRICARE currently classifies the use of implantable infusion pumps in the treatment of thromboembolic disease and diabetes as unproven. TRICARE may not, therefore, reimburse charges for the use of IIPs for these indications.

B. IIP labels include specific contraindications. Claims for IIPs and related services and supplies for pumps not used in accordance with FDA-approved label specifications may not be reimbursed.

VII. EFFECTIVE DATES

A. Chemotherapy for malignancies: March 14, 1988

B. Antibiotics for osteomyelitis: February 2, 1989

C. Opioids for chronic intractable pain of malignant origin: July 25, 1991

D. Opioids for chronic intractable pain of nonmalignant origin: October 28, 1991

E. Antispasmodics for chronic intractable spasticity: August 12, 1992

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