



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS

16401 EAST CENTRETECH PARKWAY
AURORA, COLORADO 80011-9066

TRICARE
MANAGEMENT ACTIVITY

MB&RB

**CHANGE 141
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**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
FOR
TRICARE POLICY MANUAL (TPM), AUGUST 2002**

The TRICARE Management Activity has authorized the following addition(s)/revision(s).

CHANGE TITLE: EVOLVING PRACTICES - MAY 2011

CONREQ: 15379

PAGE CHANGE(S): See page 2.

SUMMARY OF CHANGE(S): See page 3.

EFFECTIVE AND IMPLEMENTATION DATE: As indicated, otherwise upon direction of the Contracting Officer.

Ann N. Fazzini

**Ann N. Fazzini
Chief, Medical Benefits and
Reimbursement Branch**

ATTACHMENT(S): 10 PAGE(S)
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REMOVE PAGE(S)

CHAPTER 4

Section 8.1, pages 1 and 2

Section 18.5, pages 1 and 2

CHAPTER 7

Section 14.1, pages 1 and 2

CHAPTER 8

Section 2.3, pages 1 - 4

INSERT PAGE(S)

Section 8.1, pages 1 and 2

Section 18.5, pages 1 and 2

Section 14.1, pages 1 and 2

Section 2.3, pages 1 - 4

SUMMARY OF CHANGES

CHAPTER 4

1. Section 8.1. Nitric oxide expired gas determination (CPT procedure code 95012) for asthma is unproven.
2. Section 18.5.
 - a. Added HCPCS Procedure Code S2404 to the range, and added coverage for prenatal surgical repair of myelomeningocele when the gestational age of the fetus is 19.0 to 25.9 weeks and myelomeningocele is present with an upper boundary located between T1 through S1 with evidence of hindbrain herniation. Prenatal fetal surgery in the treatment of myelomeningocele is proven, effective February 9, 2011.
 - b. Noted that enrollment in the In-Utero Fetal Surgical Repair of Myelomeningocele Clinical Trial Demonstration Project terminated on December 7, 2010.
 - c. Added to EXCLUSIONS: The in-utero surgical repair of myelomeningocele in patients who have one or more of the following: (1) fetal anomaly unrelated to myelomeningocele; (2) severe kyphosis; (3) risk of pre-term birth (e.g., short cervix or previous pre-term birth); or (4) maternal body mass index of 35 or more.

CHAPTER 7

3. Section 14.1. CPT Procedure Code Ranges clarified as follows: 95004-95010, 95015-95199. Nitric oxide expired gas determination for asthma is unproven and added to the EXCLUSIONS listing.

CHAPTER 8

4. Section 2.3. Added coverage for the use of FDA-approved External Infusion Pumps (EIPs) for Type 2 diabetes mellitus when there is documentation by the physician of poor diabetic control and the patient has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI). External insulin infusion pumps for Type 2 diabetes mellitus are proven, effective August 1, 2010.

RESPIRATORY SYSTEM

ISSUE DATE: August 26, 1985
AUTHORITY: [32 CFR 199.4\(c\)\(2\)](#)

I. CPT¹ PROCEDURE CODES

30000 - 32488, 32491, 32500 - 32999, 96570, 96571

II. DESCRIPTION

The respiratory system is comprised of the tubular and cavernous organs and structures by means of which pulmonary ventilation and gas exchange between ambient air and the blood are brought about.

III. POLICY

A. Services and supplies required in the diagnosis and treatment of illness or injury involving the respiratory system are covered.

B. Resection of pneumatoceles is a covered procedure.

C. Lung Volume Reduction Surgery (LVRS) is a covered procedure, see [Chapter 4, Section 8.2](#).

D. Endoscopic thoracic sympathectomy (CPT¹ procedure code 32664) is covered for treatment of severe primary hyperhidrosis when appropriate nonsurgical therapies have failed and the hyperhidrosis results in significant functional impairment.

IV. EXCLUSIONS

A. Pillar palatal implant system for the treatment of Obstructive Sleep Apnea (OSA) is unproven.

B. Uvulopalatopharyngoplasty (UPPP) (CPT¹ procedure code 42145) for the treatment of Upper Airway Resistance Syndrome (UARS) is unproven.

C. Nitric oxide expired gas determination (CPT¹ procedure code 95012) for asthma is unproven.

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V. EFFECTIVE DATE

December 1, 2006, for endoscopic thoracic sympathectomy for severe primary hyperhidrosis.

- END -

FETAL SURGERY

ISSUE DATE:

AUTHORITY: [32 CFR 199.4\(c\)\(2\)\(i\)](#)

I. HCPCS PROCEDURE CODES

S2401 - S2405, S2411

II. DEFINITION

Fetal surgery is defined as an intervention consisting of opening of the gravid uterus (by either a traditional cesarean surgical incision or through single or multiple fetoscopic port incisions), surgically correcting a fetal abnormality, and either returning the fetus to the uterus (or restoring uterine closure, if the intervention has been accomplished without removal of the fetus) for completion of gestational development.

III. POLICY

A. Fetal surgery is covered for the following indications:

1. Prenatal surgical intervention consisting of vesicoamniotic shunting in fetuses with hydronephrosis due to bilateral urinary tract obstruction together with evidence of progressive oligohydramnios and evidence of adequate renal function as generally defined by normal urinary electrolytes, and with no other lethal abnormalities or chromosomal defects.

2. Prenatal intervention of either an open in-utero resection of malformed pulmonary tissue or placement of a thoraco-amniotic shunt in cases of hydrothorax or large cystic lesions for fetuses congenital cystic adenomatoid malformation or extralobar pulmonary sequestration, who are of less than 32 weeks' gestation and who have evidence of progressive hydrops, placentomegaly and/or the beginnings of maternal mirror syndrome.

3. Twin-twin transfusion syndrome, gestation age of less than 25 weeks' gestation at the time of diagnosis.

4. Sacrococcygeal teratoma in the presence of fetal hydrops and/or placentomegaly in fetuses with less than 28 weeks of gestation.

5. Prenatal surgical repair of myelomeningocele when the gestational age of the fetus is 19.0 to 25.9 weeks and myelomeningocele is present with an upper boundary located between T1 through S1 with evidence of hindbrain herniation.

B. Other conditions when determined by medical review to be medically necessary and appropriate treatment for the patient's medical condition and that reliable evidence has established in-utero surgery as safe and effective treatment.

IV. CONSIDERATIONS

A. The enrollment into the Department of Defense (DoD) In-Utero Fetal Surgical Repair of Myelomeningocele Clinical Trial Demonstration Project terminated on December 7, 2010, based on clear evidence of efficacy in the prenatal surgery group.

B. For dates of services on or after October 1, 2009, coverage for prenatal surgical intervention of temporary tracheal occlusion of Congenital Diaphragmatic Hernia (CDH) for fetuses with a prenatal diagnosis of CDH (CPT¹ procedure code S2400), shall be determined on a case-by-case basis, based on the Rare Disease policy. Procedural guidelines for review of rare disease are contained in Chapter 1, Section 3.1.

V. EXCLUSIONS

A. The in-utero surgical repair of myelomeningocele in patients who have one or more of the following:

1. Fetal anomaly unrelated to myelomeningocele.
2. Severe kyphosis.
3. Risk of pre-term birth (e.g., short cervix or previous pre-term birth).
4. Maternal body mass index of 35 or more.

B. The in-utero repair for aqueductal stenosis (HCPCS S2409) and procedures performed in-utero, not otherwise classified.

C. In-utero surgery for other conditions for which the safety and effectiveness has not been established.

VI. EFFECTIVE DATE

Prenatal surgical repair of myelomeningocele is covered, effective February 9, 2011.

- END -

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ALLERGY TESTING AND TREATMENT

ISSUE DATE: April 19, 1983

AUTHORITY: [32 CFR 199.4\(c\)\(2\)\(iv\)](#)

I. CPT¹ PROCEDURE CODE RANGES

95004 - 95010, 95015 - 95199

II. DESCRIPTION

The testing and treatment of conditions related to allergies.

III. POLICY

Services and supplies required in the diagnosis and treatment of allergies are covered.

IV. EXCLUSIONS

A. Unproven allergy testing. The following are examples of unproven allergy testing. This list is NOT intended to be all-inclusive:

1. In vitro histamine release.
2. Provocative and neutralization testing for food, environmental chemicals, inhalant allergens, and endogenous hormones.
3. Sublingual testing.
4. Cytotoxic leukocyte test for food and inhalant allergies.
5. Reback skin window test.
6. Passive transfer (Prausnitz-Kustner) test.
7. Serial skin-test end point titration for routine testing.
8. Kinesiology testing. This test involves muscle strength measurements after food ingestion or sublingual application of food extracts.

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9. Reaginic Pulse test. This test measures the increase of pulse rates after ingestion of a suspected allergic food substance.

10. ELISA - Enzyme-linked immunoabsorbent assay.

11. Electrodermal diagnosis.

12. Chemical analysis of body tissue.

13. Recall skin tests.

14. In vitro lymphocyte proliferation.

15. Food challenge testing performed in connection with clinical ecology programs.

16. Nitric oxide expired gas determination (CPT² procedure code 95012) for asthma is unproven.

B. Unproven allergy treatment. The following are examples of unproven allergy treatment. This list is NOT intended to be all-inclusive:

1. Sublingual antigen therapy.

2. Sublingual neutralization therapy for food and inhalant allergy.

3. Urine autoinjection (autogenous urine immunization).

4. Intracutaneous (intradermal) and subcutaneous neutralization therapy for food allergies.

5. Immunotherapy involving any injection of a food antigen.

6. Chemical exposure avoidance, special diet therapy, drug therapy and neutralization therapy for environmental allergies.

7. Total serum IgE concentration in cord blood.

- END -

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EXTERNAL AND IMPLANTABLE INFUSION PUMP

Issue Date: February 26, 1986

Authority: [32 CFR 199.4\(d\)\(1\)](#)

I. CPT¹ PROCEDURE CODES

36260 - 36262, 36530 - 36535, 62350 - 62368, 96530

II. HCPCS PROCEDURE CODES

Level II Codes E0780, E0784, Q0081, Q0084-Q0085

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 patient has one of the following indications (list is all-inclusive):**

(1) When the diagnosis is insulin dependent Type 1 diabetes mellitus and there is documentation by the physician of poor diabetic control; **OR**

(2) For Cystic Fibrosis-Related Diabetes (CFRD) under the rare diseases policy as described in [Chapter 1, Section 3.1.](#); **OR**

(3) For Type 2 diabetes mellitus when there is documentation by the physician of poor diabetic control **AND** the patient has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI) therapy

e. Antibiotic therapy.

f. Heparin therapy in treatment of thromboembolic 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):

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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's 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.

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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.
- F. External insulin infusion pumps for Type 2 diabetes mellitus: August 1, 2010.

- END -