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TRICARE
MANAGEMENT ACTIVITY

MB&RB

**CHANGE 131
6010.54-M
NOVEMBER 3, 2010**

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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 - OCTOBER 2010

CONREQ: 15220

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.

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Acting Chief, Medical Benefits and
Reimbursement Branch**

**ATTACHMENT(S): 19 PAGE(S)
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WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT.

CHANGE 131
6010.54-M
NOVEMBER 3, 2010

REMOVE PAGE(S)

CHAPTER 1

Section 2.1, pages 3 through 5

Section 3.1, pages 1 and 2

CHAPTER 4

Section 6.1, page 3

Section 9.1, pages 1, 2, 5, and 6

CHAPTER 7

Section 3.13, pages 1 through 3

CHAPTER 8

Section 2.3, pages 1 through 4

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Section 2.1, pages 3 through 5

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Section 9.1, pages 1, 2, 5, and 6

Section 3.13, pages 1 through 3

Section 2.3, pages 1 through 4

pages 7 and 8

SUMMARY OF CHANGES

CHAPTER 1

1. Section 2.1. Eye Movement Desensitization and Reprocessing (EMDR) removed from the unproven list.
2. Section 3.1. External Infusion Pumps (EIPs) for insulin may be considered for cost-sharing when the diagnosis is Cystic Fibrosis-Related Diabetes (CFRD) with fasting hyperglycemia. Effective January 21, 2009.

CHAPTER 4

3. Section 6.1. Total hip resurfacing for treatment of degenerative hip disease is unproven and added as an exclusion.
4. Section 9.1.
 - a. Endovenous Radiofrequency Ablation (RFA)/obliteration and endovenous laser ablation/therapy for the treatment of saphenous venous reflux with symptomatic varicose veins is covered under certain conditions.
 - b. Endovenous RFA for the treatment of incompetent perforator veins is unproven and is added as an exclusion. Endovenous laser ablation/therapy for the treatment of incompetent perforator veins is excluded on the basis that this is off-label use of a device and is unproven.

CHAPTER 7

5. Section 3.13. Eye Movement Desensitization and Reprocessing (EMDR) is covered for the treatment of Post-Traumatic Stress Disorder (PTSD) in adults, effective April 16, 2007.

CHAPTER 8

6. Section 2.3. Added coverage for Insulin for Cystic Fibrosis-Related Diabetes (CFRD) under the rare disease policy as described in Chapter 1, Section 3.1.

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7. Added EMDR.

TRICARE POLICY MANUAL 6010.54-M, AUGUST 1, 2002

CHAPTER 1, SECTION 2.1

UNPROVEN DRUGS, DEVICES, MEDICAL TREATMENTS, AND PROCEDURES

l. The following is a partial list of drugs, devices, medical treatments, or procedures considered to be unproven. Other drugs, devices, medical treatments, or procedures also considered to be unproven are listed as specific exclusions in relevant sections of the TRICARE Policy Manual. For example, Cardiomyoplasty for treatment of heart failure is considered unproven and is listed as a specific exclusion in [Chapter 4, Section 9.1](#) (Cardiovascular System). Neither the partial list below nor the exclusions cited in other sections of the TRICARE Policy Manual provide an all inclusive list of unproven drugs, devices, medical treatments, or procedures. Other unproven drugs, devices, medical treatments, or procedures are also excluded although they do not appear in the TRICARE Policy Manual.

1. Adoptive immunotherapy using either Tumor-Infiltrating Lymphocytes (TIL) or Lymphokine-Activated Killer (LAK) cells, activated in vitro by recombinant or natural IL-2 or other lymphokines, for the treatment of cancer.

2. Adrenal tissue transplant to brain.

3. Autolymphocyte Therapy (ALT).

4. Calcium EAP/calcium orotate and selenium (also known as Nieper therapy) - involves inpatient care and use of calcium compounds and other non-FDA approved drugs and special diets. Used for cancer, heart disease, diabetes, multiple sclerosis -- Not a proven treatment for any indication.

5. Canaloplasty in the treatment of glaucoma is unproven.

6. Services related to the candidiasis hypersensitivity syndrome, yeast syndrome, or gastrointestinal candidiasis are unproven (i.e., allergenic extracts of *Candida albicans* for immunotherapy and/or provocation/neutralization). Disseminated systemic candidiasis (ICD-9-CM 112.5) is a recognized diagnosis, and medically necessary treatment is covered.

7. Cellular therapy (HCPCS procedure code M0075).

8. Chelation therapy, except when using FDA-approved chelators for FDA-approved indications.

9. Diaphanography (Transillumination Light Scanning).

10. Dynamic Posturography (both static and computerized) (CPT¹ procedure code 92548).

11. Electric reflex salivary stimulation (Salitron® Electrostimulation System) in the treatment of xerostomia (dry mouth) secondary to Sjogren's syndrome (HCPCS procedure code E0755).

12. Growth factor, including platelet-derived growth factors, for treating non-healing wounds. This includes Procuren®, a platelet-derived wound-healing formula.

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CHAPTER 1, SECTION 2.1

UNPROVEN DRUGS, DEVICES, MEDICAL TREATMENTS, AND PROCEDURES

13. Hand transplant from a cadaver donor.
14. Histamine therapy.
15. Holding therapy - involves holding the patient in an attempt to achieve interpersonal contact, and to improve the patient's ability to concentrate on learning tasks.
16. Hyperosmotic blood-brain barrier disruption produced by infusion of Mannitol to increase drug delivery to brain tumors.
17. Hyperventilation Provocation Test (HVPT) for diagnosing hyperventilation syndrome.
18. Immunotherapy for malignant disease except when using drugs approved by the FDA for this purpose.
19. Intracavitary administration of cisplatin for malignant disease is unproven, except for patients with optimally debulked Stage III ovarian cancer and pseudomyxoma peritonei resulting from appendiceal carcinoma.
20. Iridology (links flaws in eye coloration with disease elsewhere in the body).
21. Light therapy for Seasonal Depression (also known as seasonal affective disorder (SAD)). This therapy uses varying degrees of light to treat depression.
22. Neurofeedback.
23. All organ transplants not listed as covered in the TRICARE Policy Manual or [32 CFR 199.4\(e\)\(5\)](#).
24. Portable nocturnal hypoglycemia monitors.
25. Pupillometry.
26. Sensory Afferent Stimulation (SAS) devices for relief of nausea (e.g., Relief Band®).
27. Spinoscopy. Use of a Spinoscope with skin markers to assess the function of the spine.
28. Synaptic 2000 for acute and chronic pain.
29. Tinnitus Masker.
30. Transdermal nicotine therapy used to treat ulcerative colitis.
31. Transfer Factor (TF). This is a Dialyzable Leukocyte Extract (DLE) used to transfer delayed hypersensitivity from an immune to a nonimmune subject and is considered unproven.

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CHAPTER 1, SECTION 2.1

UNPROVEN DRUGS, DEVICES, MEDICAL TREATMENTS, AND PROCEDURES

NOTE: See [Chapter 1, Section 3.1](#) for policy on Rare Diseases.

NOTE: See [Chapter 7, Section 24.1](#) for policy on cancer clinical trials.

NOTE: See [Chapter 8, Section 5.1](#) for policy on Medical Devices, including coverage of Humanitarian Use Devices and a FDA-approved Investigational Device Exemption (IDE) categorized by the FDA as non-experimental/investigational (FDA Category B).

NOTE: See [Chapter 8, Section 9.1](#) for policy on off-label use of drugs.

- END -

RARE DISEASES

ISSUE DATE: May 18, 1994

AUTHORITY: 32 CFR 199.2(b) and 32 CFR 199.4(g)(15)

I. DESCRIPTION

TRICARE defines a rare disease as any disease or condition that affects less than 200,000 persons in the United States.

II. POLICY

A. Coverage for treatment of rare diseases may be considered on a case-by-case basis. Case-by-case review is not required for drugs, devices, medical treatments, and procedures that have already been established as safe and effective for treatment of rare diseases.

B. In reviewing the case, any or all of the following sources may be used to determine if the proposed benefit is considered safe and effective.

1. Trials published in refereed medical literature.
2. Formal technology assessments.
3. National medical policy organization positions.
4. National professional associations.
5. National expert opinion organizations.

C. If case review indicates that the proposed benefit for a rare disease is safe and effective for that disease, benefits may be allowed. If benefits are denied, an appropriate appealing party may request an appeal.

D. Off-label use of rituximab may be considered for cost-sharing for the treatment of recurrent nodular CD20 positive lymphocyte predominant Hodgkin's disease. The effective date is January 1, 2003.

E. Off-label use of rituximab may be considered for cost-sharing in reducing proteinuria for the treatment of Immunoglobulin A (IgA) nephropathy (proliferative glomerulonephritis). The effective date is May 1, 2007.

F. Effective May 13, 2009, Intraperitoneal Hyperthermic Chemotherapy (IPHC) (CPT¹ procedure codes 77600, 77605, and 96445) in conjunction with cytoreductive surgery or peritonectomy for treatment of pseudomyxoma peritonei resulting from appendiceal carcinoma may be covered on a case-by-case basis for adult patients when all of the following criteria are met:

1. There is no evidence of distant metastasis.
2. There is evidence of low histological aggressiveness of the disease.
3. The patient has not undergone preoperative systemic chemotherapy.
4. The patient's condition does not preclude major surgery.
5. The chemotherapeutic agents used are Mitomycin C, Cisplatin (also known as Cisplatinum), or Fluorouracil.

G. External Infusion Pumps (EIPs) for insulin may be considered for cost-sharing when the diagnosis is Cystic Fibrosis-Related Diabetes (CFRD) with fasting hyperglycemia. See Chapter 8, Section 2.3 for policy regarding EIPs. Effective January 21, 2009.

III. EXCLUSION

Intracranial angioplasty with stenting (CPT¹ procedure code 61635) of the venous sinuses for treatment of pseudotumor cerebri (also known as idiopathic intracranial hypertension and benign intracranial hypertension) is unproven.

- END -

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CHAPTER 4, SECTION 6.1

MUSCULOSKELETAL SYSTEM

M. Osteochondral allograft of the humeral head with meniscal transplant and glenoid microfracture in the treatment of shoulder pain and instability is unproven.

N. Thermal Intradiscal Procedures (TIPs) (CPT³ procedure codes 22526, 22527, 62287, and HCPCS code S2348) are unproven. TIPs are also known as: Intradiscal Electrothermal Annuloplasty (IEA), Intradiscal Electrothermal Therapy (IDET), Intradiscal Thermal Annuloplasty (IDTA), Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT), Coblation Percutaneous Disc Decompression, Nucleoplasty (also known as percutaneous radiofrequency (RF) thermomodulation or percutaneous plasma discectomy), Radiofrequency Annuloplasty (RA), Intradiscal Biacuplasty (IDB), Percutaneous (or Plasma) Disc Decompression (PDD), Targeted Disc Decompression (TDD), Cervical Intradiscal RF Lesioning.

O. Total hip resurfacing (HCPCS code S2118) for treatment of degenerative hip disease is unproven.

VI. EFFECTIVE DATES

- A. February 6, 2006, for percutaneous vertebroplasty and balloon kyphoplasty.
- B. May 1, 2008, for Total Ankle Replacement (TAR).
- C. May 1, 2008, for core decompression of the femoral head.

- END -

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CARDIOVASCULAR SYSTEM

ISSUE DATE: August 26, 1985

AUTHORITY: 32 CFR 199.4(c)(2) and (c)(3)

I. CPT¹ PROCEDURE CODES

33010 - 33130, 33140, 33141, 33200 - 37186, 37195 - 37215, 37250 - 37785, 92950 - 93272, 93303 - 93581, 93600 - 93745, 93770, 93797 - 93799, 0075T, 0076T

II. DESCRIPTION

The cardiovascular system involves the heart and blood vessels, by which blood is pumped and circulated through the body.

III. POLICY

A. Medically necessary services and supplies required in the diagnosis and treatment of illness or injury involving the cardiovascular system are covered.

B. Ventricular Assist Devices (VADs).

1. VADs (external and implantable) are covered if the device is Food and Drug Administration (FDA) approved and used in accordance with FDA approved indications.

2. VADs as destination therapy (CPT¹ 33979) are covered if they have received approval from the FDA for that purpose and are used according to the FDA-approved labeling instructions. Benefits are authorized when the procedure is performed at a TRICARE-certified heart transplantation center, a TRICARE-certified pediatric consortium heart transplantation center, or a Medicare facility which is approved for VAD implantation as destination therapy, for patients who meet all of the following conditions:

a. The patient has chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than two years).

b. The patient is not a candidate for heart transplantation.

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CHAPTER 4, SECTION 9.1

CARDIOVASCULAR SYSTEM

- c. The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including a dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors (if tolerated) for at least 60 of the last 90 days.
- d. The patient has Left Ventricular Ejection Fraction (LVEF) less than 25%.
- e. The patient has demonstrated functional limitation with a peak oxygen consumption of less than 12 ml/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion.
- f. The patient has the appropriate body size (by device per FDA labeling) to support the VAD implantation.

C. Gamma and beta intracoronary radiotherapy (brachytherapy) is covered for the treatment of in-stent restenosis in native coronary arteries.

D. Transmyocardial Revascularization (TMR) (CPT² procedure codes 33140 and 33141).

1. Coverage is available for patients with stable class III or IV angina which has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages. In addition, the angina symptoms must be caused by areas of the heart not amenable to surgical therapies such as percutaneous transluminal coronary angioplasty, stenting, coronary atherectomy or coronary bypass.

2. Coverage is limited to those uses of the laser used in performing the procedure which have been approved by the FDA for the purpose for which they are being used.

E. TMR as an adjunct to Coronary Artery Bypass Graft (CABG) is covered for patients with documented areas of the myocardium that are not amenable to surgical revascularization due to unsuitable anatomy.

F. FDA approved IDE clinical trials. See [Chapter 8, Section 5.1, paragraph D.](#) and [F.](#) for policy.

G. Endovenous Radiofrequency Ablation (RFA)/obliteration (CPT² procedure codes 36475 and 36476) and endovenous laser ablation/therapy (CPT² procedure codes 36478 and 36479) for the treatment of saphenous venous reflux with symptomatic varicose veins is covered when:

1. One of the following indications is present:

a. Persistent symptoms interfering with activities of daily living in spite of conservative/non-surgical management. Symptoms include aching, cramping, burning, itching and/or swelling during activity or after prolonged standing.

b. Significant recurrent attacks of superficial phlebitis.

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5. The use of a distal embolic protection device is required. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted due to the risks of CAS without distal embolic protection.

6. The degree of CAS shall be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the beneficiary's medical records. If the stenosis is measured by ultrasound prior to the procedure, then the degree of stenosis must be confirmed by angiography at the start of the procedure. If the stenosis is determined to be less than 70% by angiography, then CAS should not proceed.

7. All procedures are performed in a Centers for Medicare and Medicaid Services (CMS) approved facility that has been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes.

IV. EXCLUSIONS

A. Thermogram; cephalic (CPT⁵ procedure code 93760); peripheral (CPT⁵ procedure code 93762) are unproven.

B. Percutaneous Myocardial Laser Revascularization (PMR) is unproven.

C. Cardiomyoplasty (Cardiac Wrap) for treatment of heart failure is unproven.

D. Minimally Invasive CABG surgery to include Minimally Invasive Direct Coronary Artery Bypass (MIDCAB) and Port Access Coronary Artery Bypass (PACAB) are unproven.

E. Percutaneous Transluminal Angioplasty (PTA) in the treatment of obstructive lesions of the vertebral and cerebral arteries is unproven. PTA of the carotid artery without stenting is unproven. PTA of the carotid artery with stenting but without embolic protection (CPT⁵ procedure code 37216) is unproven.

F. Signal-Average Electrocardiography (CPT⁵ procedure code 93278) is unproven.

G. Percutaneous transluminal mechanical thrombectomy vein(s) including intraprocedural pharmacological thrombolytic injections and fluroscopic guidance (CPT⁵ procedure code 37187) is unproven.

H. Percutaneous transluminal mechanical thrombectomy, vein(s) including intraprocedural pharmacological thrombolytic injections and fluroscopic guidance, repeat treatment on subsequent day during course of thrombolytic therapy (CPT⁵ procedure code 37188) is unproven.

I. Intracranial angioplasty with stenting (CPT⁵ procedure code 61635) of the venous sinuses for treatment of pseudotumor cerebri (also known as idiopathic intracranial hypertension and benign intracranial hypertension) is unproven.

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CHAPTER 4, SECTION 9.1

CARDIOVASCULAR SYSTEM

J. Endovenous RFA (CPT⁶ procedure codes 36475 and 36476) for the treatment of incompetent perforator veins is unproven. Endovenous laser ablation/therapy (CPT⁶ procedure codes 36478 and 36479) for the treatment of incompetent perforator veins is excluded on the basis that this is off-label use of a device and is unproven.

V. EFFECTIVE DATES

A. March 1, 2001, for gamma and beta intracoronary radiotherapy (brachytherapy).

B. January 1, 2002, for TMR.

C. October 1, 2003, for VADs as destination therapy.

D. December 1, 2003, for endovenous RFA/obliteration.

E. January 1, 2005, for ABPM.

F. March 17, 2005, for PTA of the carotid artery with stenting in beneficiaries at high risk for CEA.

G. March 21, 2006, for percutaneous transluminal mechanical thrombectomy for acute limb ischemia.

H. January 1, 2007, for pulmonary vein isolation/ablation.

I. January 1, 2009, for endovenous laser ablation/therapy.

- END -

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PSYCHOTHERAPY

ISSUE DATE: December 5, 1984

AUTHORITY: [32 CFR 199.4\(c\)\(3\)\(ix\)](#)

I. CPT¹ PROCEDURE CODE RANGE

90804 - 90857

II. DESCRIPTION

Psychotherapy is the treatment for mental illness and behavioral disturbances in which the clinician establishes a professional contact with the patient and, through definitive therapeutic communication, attempts to alleviate the emotional disturbances, reverse or change maladaptive patterns of behavior, and encourage personality growth and development.

III. POLICY

A. Benefits are available for inpatient and outpatient psychotherapy that is medically or psychologically necessary to treat a covered mental disorder.

B. Individual psychotherapy for patients with a mental disorder (DSM IV) that coexists with an alcohol and other drug abuse disorder is a covered benefit.

C. Charges for outpatient psychotherapy are not covered when the patient is an inpatient in an institution. Claims for outpatient psychotherapy must be denied for the entire period during which the beneficiary is an inpatient in the institution.

D. Employees of institutional providers are not authorized to bill for services rendered as part of that employment. Such services billed by the employee must be denied.

E. Eye Movement Desensitization and Reprocessing (EMDR) is **covered for the treatment of Post-Traumatic Stress Disorder (PTSD) in adults.**

F. Psychotherapy is not a Health and Behavior Assessment/Intervention. See [Chapter 7, Section 16.2](#).

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IV. POLICY CONSIDERATIONS

A. Maximum duration of psychotherapy sessions:

1. Inpatient or outpatient individual psychotherapy (CPT² procedure codes 90806, 90807, 90818, 90819) approximately 45 to 50 minutes; or (CPT² procedure codes 90804, 90805, 90816, 90817) approximately 20 to 30 minutes.

2. Inpatient or outpatient group, conjoint or family psychotherapy: 90 minutes (CPT² procedure codes):

90846 - FAMILY PSYTX W/O PATIENT

90847 - FAMILY PSYTX W/ PATIENT

90849 - MULTIPLE FAMILY GROUP PSYTX

90853 - GROUP PSYCHOTHERAPY

3. Crisis intervention (CPT² procedure codes):

90808 - PSYTX, OFFICE, 75-80 MIN

90809 - PSYTX, OFF, 75-80, W/E&M

90821 - PSYTX, HOSP, 75-80 MIN

90822 - PSYTX, HOSP, 75-80 MIN W/E&M

B. Frequency of psychotherapy sessions.

NOTE: Beginning October 1, 1993, the mental health benefit year is changed from a calendar year to fiscal year. A patient is not automatically entitled to a designated number of sessions, and review can be more frequent when determined necessary.

1. The frequency limitations on outpatient psychotherapy apply to any psychotherapy performed on an outpatient basis, whether by an individual professional provider or by staff members of an institutional provider.

2. Treatment sessions may not be combined, i.e., 30 minutes on one day added to 20 minutes on another day and counted as one session, to allow reimbursement and circumvent the frequency limitation criteria.

3. Multiple sessions the same day: If the multiple sessions are of the same type--two individual psychotherapy sessions or two group therapy sessions--payment may be made only if the circumstances represent crisis intervention and only according to the restrictions applicable to crisis intervention. A collateral session not involving the identified patient on the same day the patient receives a therapy session does not require review.

4. Collateral visits (CPT² procedure code 90887). Collateral visits are payable when medically or psychologically necessary for treatment of the identified patient. A collateral visit is considered to be a psychotherapy session for purposes of reviewing the duration or frequency of psychotherapy.

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5. Psychoanalysis (CPT³ procedure code 90845). Psychoanalysis is covered when provided by a graduate or candidate of a psychoanalytic training institution recognized by the American Psychoanalytic Association and when preauthorized by the contractor.

6. Play therapy. Play therapy is a form of individual psychotherapy which is utilized in the diagnosis and treatment of children with psychiatric disorders. Play therapy is a benefit, subject to the regular points of review and frequency limitations applicable to individual psychotherapy.

7. Marathon therapy. Marathon therapy is a form of group therapy in which the therapy sessions last for an extended period of time, usually one or more days. Marathon therapy is not covered since it is not medically necessary or appropriate.

8. Inpatient psychotherapy and medical care. The allowable charge for inpatient psychotherapy includes medical management of the patient. A separate charge for hospital visits rendered by the provider on the same day as he/she is rendering psychotherapy is not covered. Payment is authorized only for medically necessary hospital visits billed on a day that psychotherapy was not rendered. If the provider who is primarily responsible for treatment of the mental disorder is not a physician, charges for medical management services by a physician are coverable, but only if the physician is rendering services that the non-physician provider is prohibited from providing. Concurrent inpatient care by providers of the same or different disciplines is covered only if second or third level review determines that the patient's condition requires the skills of multiple providers.

9. Physical examination. A physical examination is an essential component of the workup of the psychiatric patient, and for all admissions should be performed either by the attending psychiatrist or by another physician. The examination may lead to confirmation of a known psychiatric diagnosis or consideration of other unsuspected psychiatric or medical illness. When not performed by the attending psychiatrist, payment may be made to another physician for performance of the initial physical examination. Any additional concurrent care provided by a physician other than the attending psychiatrist may be covered only if it meets the criteria under inpatient concurrent care.

V. EFFECTIVE DATES

A. November 13, 1984.

B. April 16, 2007, for EMDR for the treatment of PTSD in adults.

- 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 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 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):

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.

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.

TRICARE POLICY MANUAL 6010.54-M, AUGUST 1, 2002

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EXTERNAL AND IMPLANTABLE INFUSION PUMP

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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