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**CHANGE 127  
6010.57-M  
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**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL  
FOR  
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**The TRICARE Management Activity has authorized the following addition(s)/revision(s).**

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**SUMMARY OF CHANGE(S): See page 3.**

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**ATTACHMENT(S): 4 PAGE(S)  
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**CHANGE 127**  
**6010.57-M**  
**JANUARY 12, 2015**

**REMOVE PAGE(S)**

**CHAPTER 8**

Section 2.3, pages 3 and 4

**CHAPTER 11**

Section 12.1, pages 5 and 6

**INSERT PAGE(S)**

Section 2.3, pages 3 and 4

Section 12.1, pages 5 and 6

**SUMMARY OF CHANGES**

**CHAPTER 8**

1. Section 2.3. This change clarifies that off-label uses of External and Implantable Infusion Pumps (EIPs/IIPs) may be cost-shared when provided in accordance with TPM Chapter 8, Section 5.1. Effective Date: 07/27/2012.

**CHAPTER 11**

2. Section 12.1. This change clarifies that for technicians who do not have a National Provider Identifier (NPI), the NPI of the ordering/supervising physician or non-physician practitioner is required on the claim form. Effective Date: 02/12/2015.



**4.2.3** 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 three 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:

**4.2.3.1** 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

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

**4.2.4** 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:

**4.2.4.1** Documentation of inadequate control of spasticity or intolerable side effects resulting from at least a six 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

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

**4.2.5** Second level review is required for all other IIP uses. Reimbursement may be considered for other uses of IIPs (not specifically excluded in [paragraph 6.0](#)) with documentation of the following:

**4.2.5.1** The medical necessity of the drug;

**4.2.5.2** The medical necessity and appropriateness of an IIP to deliver the drug; and

**4.2.5.3** The IIP use adheres to the FDA approved labeling for the pump and the drug.

### **4.3 Off-Label Uses for EIPs and IIPs**

Effective July 27, 2012, when provided in accordance with [Section 5.1](#), EIPs and IIPs, including related services and supplies, provided for off-label uses may be cost-shared unless such use is specifically excluded by TRICARE statute, regulation, or policy.

## **5.0 POLICY CONSIDERATIONS**

**5.1** 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.

**TRICARE Policy Manual 6010.57-M, February 1, 2008**

Chapter 8, Section 2.3

External And Implantable Infusion Pump (IIP)

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**5.2** 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.

**5.3** 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.

**6.0 EXCLUSIONS**

**6.1** 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.

**6.2** 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.

**7.0 EFFECTIVE DATES**

**7.1** Chemotherapy for malignancies: March 14, 1988.

**7.2** Antibiotics for osteomyelitis: February 2, 1989.

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

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

**7.5** Antispasmodics for chronic intractable spasticity: August 12, 1992.

**7.6** External insulin infusion pumps for Type 2 diabetes mellitus: August 1, 2010.

- END -

**2.4.3** The contractor will verify that the provider meets TRICARE authorization criteria through the collection and review of applicable Medicare, Joint Commission, and state and national board certificates/licenses requests on the corporate services provider application form.

**2.4.4** The authorization process is streamlined (simplified) in that the individual authorization of professional providers employed by or under contract with a corporate entity will not be required as part of the authorization process.

**2.4.4.1** Instead, the responsibility for ensuring all individuals meet TRICARE requirements is placed on the corporate entity itself.

**2.4.4.2** This assurance is further strengthened by requiring Medicare approval for payment as a condition of authorization under TRICARE, since Medicare also relies on the delegation of certification of individual professional and allied health care providers to the corporate entity.

**2.4.4.3** Although the actual provider of care will still have to be identified on the claim form, verification of the qualifications of employed and contracted individual providers will not be required by the contractors. **In the case where the individual (e.g., technician) providing the service does not have a National Provider Identifier (NPI), the NPI of the ordering/supervising physician, non-physician practitioner, or billing entity is required on the claim form.**

**2.4.4.4** Reliance on Medicare approval for payment - or when Medicare approved status is not required, accreditation by a qualified accrediting organization - is administratively expeditious and cost effective for both TRICARE and providers qualifying for authorization under the new provider category.

**2.4.5** The effective date of authorization will be the date the provider met the "Conditions for Coverage/Authorization" as prescribed in [paragraph 2.3](#) or June 8, 1999, whichever is later. Retroactive authorization will apply to both network providers (providers that have entered into negotiated network contracts) and non-network providers (those providers authorized under the application process) subject to the effective date of June 8, 1999, appearing in the Corporate Services Provider Final Rule published in the **Federal Register** on March 10, 1999.

## **2.5 Approval Process For New Provider Categories Seeking Authorization Under the Corporate Services Provider class**

**2.5.1** While contractors will use the "Conditions for Coverage/Authorization" under [paragraph 2.3](#) for initial review/screening of all new provider categories seeking authorization status under the Corporate Services Provider class, final approval will be reserved for TMA.

**2.5.2** The contractors should only submit those provider categories who on initial analysis appear to meet the criteria for inclusion under the Corporate Services Provider class. The submission should include all supporting documentation, along with the contractor's rationale for recommending authorization status under the Corporate Services Provider class.

**2.5.3** If TMA concurs with the contractor's recommendation, a new provider specialty code will be added.

**TRICARE Policy Manual 6010.57-M, February 1, 2008**

Chapter 11, Section 12.1

Corporate Services Provider Class

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**2.5.4** A notice of the agency's determination, along with supporting documentation (a copy of the package seeking final approval status of the provider category), will be sent out to all the regional contractors for appropriate action.

**2.5.5** Requests for final approval status should be submitted to TMA through the contractor's Contracting Officer Representative (COR).

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