Implantable Infusion Pumps

**Origination:** January 8, 1990  
**Review Date:** March 18, 2015  
**Next Review:** March 2017

**DESCRIPTION OF PROCEDURE OR SERVICE**  
An implantable pump is intended to provide long-term continuous or intermittent drug infusion. Possible routes of administration include intravenous, intra-arterial, subcutaneous, intraperitoneal, intrathecal, epidural, and intraventricular. The pump is surgically placed in a subcutaneous pocket under the infraclavicular fossa or in the abdominal wall, and a catheter is threaded into the desired position. A drug is infused over an extended period of time, and the drug reservoir may be refilled as needed by an external needle injection through a self-sealing septum in the infusion pump.

**POLICY STATEMENT**  
Coverage will be provided for implantable infusion pumps when it is determined to be medically necessary, as outlined in the below guidelines and medical criteria.

**BENEFIT APPLICATION**  
Please refer to the member’s individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations, if the criteria are met.

Coverage decisions will be made in accordance with:
- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member’s particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

**CRITERIA REQUIRED FOR COVERAGE APPROVAL**  
Preauthorization by the Plan is required: Implantable infusion pumps are considered eligible for coverage when used to deliver drugs having Food and Drug Administration (FDA) approval for this route of access and for the treatment of the following:
A. Chemotherapy
Primary liver cancer (Intrahepatic artery injection of chemotherapeutic agents). The implantable infusion pump is covered for intra-arterial infusion of 5-FUdR for the treatment of liver cancer for members with primary hepatocellular carcinoma or Duke’s Class D colorectal cancer, in whom the metastases are limited to the liver, and where:
1. the disease is unresectable, or
2. The member refuses surgical excision of the tumor.

B. Treatment of severe, chronic intractable pain
An implantable infusion pump is covered when used to administer opioid drugs (e.g., morphine) intrathecally or epidurally for the treatment of severe chronic intractable pain of malignant or nonmalignant origin in members who have a life expectancy of at least 3 months, and who have proven unresponsive to less invasive medical therapy as determined by the following:

1. The member’s history must indicate that he/she would not respond adequately to noninvasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain). For the terminally ill patient, the progression from non-invasive pain control methods to using a pump may occur more rapidly with less emphasis on behaviorally approaches to pain control.

2. A preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and the degree of side effects (including effects on the activities of daily living) and member acceptance.

C. Severe spasticity: The Implantable infusion pumps may be medically necessary for:
1. The infusion of anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in members who are unresponsive to less invasive medical therapy as indicated by the following criteria:
   a. at least a 6-week trial on noninvasive methods of spasm control, such as oral anti-spasmodic drugs; and
   b. Prior to pump implantation, the member must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.

D. Coverage of Other Uses of Implanted Infusion Pumps
1. Determinations may be made on coverage of other uses of implanted infusion pumps if:
   a. The drug is reasonable and necessary for the treatment of the individual member;
b. It is medically necessary that the drug be administered by an implanted infusion pump; **and**

c. The FDA-approved labeling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.

**WHEN COVERAGE WILL NOT BE APPROVED**

The implantation of an infusion pump is contraindicated in the following members and diseases:

1. Members with a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.)
2. Members who have an infection
3. Members whose body size is insufficient to support the weight and bulk of the device; **and**
4. Members with other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.
5. Thromboembolic Disease - there is insufficient published clinical data to support the safety and effectiveness of the heparin implantable pump.
6. Diabetes - Implanted infusion pumps for the infusion of insulin to treat diabetes are not covered. The data does not demonstrate that the pump provides effective administration of insulin.

**BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION**

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

**Applicable codes:** 36260, 36261, 36262, 62350, 62351, 62355, 62361, 62362, 62365, 62367, 62368, 62369, 62370, 95990, 95991, 95992, 95993, E0782, E0783, E0785, E0756, J0475, J2274, J2278, J7799, J9200, A4220, E0786.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all **specific** information needed to make a medical necessity determination is included.

**References:**

2. LCD Implantable Infusion Pump; L31790; Effective 10/30/2014: Accessed via Internet site [www.cms.gov/medicare-coverage-database on 03/06/2013, 2/20/15](http://www.cms.gov/medicare-coverage-database on 03/06/2013, 2/20/15).

**Policy Implementation/Update Information:**

- **Revision Date:** January 14, 1991; April 26, 1999; February 18, 2004; November 30, 2005
- **Revision Date:** November 28, 2007: No criteria changes made
- **Revision Date:** September 2009: Re-worded section B on chronic pain to mirror CMS language.
- **Revision Date:** December 15, 2010; Coverage criteria updated under section C. for severe spasticity, to remain current with CMS language/guidelines. Baclofen is only listed as an example of a drug used for infusion in NCD 280.14, under this section, policy language revised to mirror NCD. Added code per Sr. Coding Analyst – see 2nd inserted document. Code 80101 is a drug screen and is no longer covered. Code 80101 has been replaced by Code G0431.
- **Revision Date:** 03/20/2013: Minor edits for clarification, # B under Criteria.
Revision Date: 2/20/15: No updates to coverage criteria, only revision were coding updates.

Approval Dates:
Medical Coverage Policy Committee: March 18, 2015

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