

Evidence Based Guideline

Implantable Infusion Pumps

File Name: implantable_infusion_pumps
Guideline Number: EBG.DME0150
Origination: 4/1981
Last Review: 3/2005

Active guideline, no longer scheduled for routine literature review.

Description of Procedure or Service

An implantable pump (IP) 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 IP 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 IP. [Bacteriostatic](#) water or physiological saline is often used to dilute therapeutic drugs. A heparinized saline solution may also be used during an interruption of drug therapy to maintain catheter patency.

The driving mechanisms of the implantable infusion pumps may include peristalsis, fluorocarbon propellant, osmotic pressure, piezoelectric disk benders, or the combination of an osmotic pressure with an oscillating piston.

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Implantable infusion pumps may be appropriate when used to deliver drugs having Food and Drug Administration (FDA) approval for this route of access and for the related indication for treatment of the following:

A. Chemotherapy

1. Primary liver cancer ([Intrahepatic](#) artery injection of [chemotherapeutic](#) agents)
2. [Metastatic](#) colorectal cancer where metastases are limited to the liver ([Intrahepatic](#) artery injection of [chemotherapeutic](#) agents)
3. Head/neck cancers ([intra-arterial](#) injection of [chemotherapeutic](#) agents)

B. Treatment of severe, chronic, or intractable pain: Implantable Infusion Pumps, specifically [intravenous](#) or [epidural](#) administration of narcotics may be medically necessary for the treatment of bone pain, tissue injury, colicky pain of some intestinal disorders, and/or pressure pain when **all of the following** criteria are met:

1. The patient must have demonstrable pathology, such as objective findings for pain complaints **AND**
2. All conservative therapy has failed **AND**
3. Further surgical interventions are not indicated **AND**
4. No severe drug addiction problems are documented or suspected **AND**

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5. For **epidural** pumps, the patient must successfully pass a trial period of Spinal Administered Narcotics (SAN) as listed below.
 - a. The device is placed for a trial period of at least a week
 - b. The patient spends the first 23 hours in the hospital so the device can be programmed to afford pain relief. This also affords the ability to observe for signs of infection or other possible complications.
 - c. The next seven to ten days are on an outpatient basis
 - d. Clinicians want between 50 and 70% pain relief from the trial before permanent implantation.

OR

6. For **intrathecal** pumps, the patient must successfully pass a trial period of Spinal Administered Narcotics (SAN) as listed below.
 - a. The device is placed for a trial period of at least a week
 - b. The patient is admitted inpatient
 - c. Clinicians want between 50 and 70% pain relief from the trial before permanent implantation.

AND

7. The patient must have behavioral clearance stating patient is appropriate candidate for the device as noted below. The following psychological-behavioral factors may exclude a patient for an implantable device:
 - a. Active Psychosis
 - b. Active suicidality
 - c. Active homicidality
 - d. Untreated major depression or mood disturbance
 - e. Somatization disorder complaints inconsistent with exam or diagnostic workup
 - f. Alcohol dependency
 - g. Drug dependency
 - h. Unresolved compensation or litigation
 - i. Lack of appropriate social support
 - j. Compromised reasoning, judgement or memory

The evaluation must conclude that the patient is or is not an appropriate candidate for an implantable device.

The requesting physician must supply a copy of a comprehensive psychological evaluation from a licensed psychiatrist or psychologist familiar with the management of chronic pain.

- C. **Severe spasticity:** Implantable infusion pumps may be medically necessary for baclofen infusion in patients with severe spasticity of spinal cord origin or cerebral origin in patients who are unresponsive to or who cannot tolerate oral baclofen therapy.

Medical Evidence regarding Implantable Infusion Pumps indicates it is not recommended in the following situations:

Implantable infusion pumps are not recommended for any use other than those listed above. For example, the use of heparin for **thromboembolic** disease, insulin for diabetes, antibiotics for osteomyelitis, would be

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considered investigational uses for implantable infusion pumps. BCBSNC does not cover investigational services.

Benefits Application

Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: E0782, E0783, E0786

Medical Term Definitions

Bacteriostatic

inhibiting the growth or multiplication of bacteria.

Chemotherapeutic

a drug or drugs that have a specific toxic effect upon cancerous tissue.

Epidural

situated within the spinal canal, on or outside the dura mater (tough membrane surrounding the spinal cord).

Intra-arterial

within the artery.

Intractable

resistant to cure, relief, or control.

Intrahepatic

within the liver.

Intraperitoneal

within the abdomen, area that contains the abdominal organs.

Intrathecal

into the subarachnoid space of the spinal column.

Intravenous

within the vein.

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Intraventricular

within a ventricle.

Metastatic

transfer of disease from one organ or part of the body to another not directly connected with it.

Spasticity

increased muscle tone with heightened deep tendon reflexes.

Subcutaneous

under the skin.

Thromboembolic

a condition where there is an obstruction of a blood vessel with thrombotic material (clot).

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual - 3/96

Krames ES. Intraspinal Opioids: Selection Criteria for Patients with Nonmalignant Pain. *Journal of Pain and Symptom Management* Vol II. June 1996; 338.

Nelson, et al. Psychological Selection Criteria for Implantable Devices. *Pain Forum*. 1996;5(2):93-127

MEDLINE - 7/21/99

Medical Policy Advisory Group - 3/1/2001

ECRI. Spinal Infusion of Pain Medication for Chronic Pain from Nonmalignant Conditions. Retrieved 5/18/01, from World Wide Web: http://www.ecri.org/207.252.160.123/members/_Elements/Exec_Brief/oexb65.txt

Specialty Matched Consultant Advisory Panel - 9/2002

Specialty Matched Consultant Advisory Panel - 4/2003

BCBSA Medical Policy Reference Manual - 7.01.41, 4/15/02

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.41, 11/9/04.

Policy Implementation/Update Information

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|------|---|
| 4/81 | Original Policy |
| 7/82 | Reaffirmed: Generally accepted medical practice for heparin in severe thromboembolic disease; experimental/investigative for hepatic artery chemotherapy. |
| 3/83 | Reaffirmed: Generally accepted medical practice for heparin in severe thromboembolic disease experimental/investigative for hepatic artery chemotherapy |
| 3/84 | Reaffirmed: Experimental/investigative for hepatic artery chemotherapy |
| 6/84 | Reaffirmed: Experimental/investigative for hepatic artery chemotherapy and severe thromboembolic disease |
| 3/85 | Reversed: Generally accepted medical practice for hepatic artery chemotherapy; experimental/investigative in severe thromboembolic disease |

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- 12/85 Evaluated: Generally accepted medical practice for hepatic artery chemotherapy; experimental/investigative in severe thromboembolic disease and for any route of delivery other than intravascular (epidural, intrathecal, intraventricular, or spinal) regardless of the drug used or the condition being treated.
- 8/88 Evaluated: Eligible for coverage in treatment of primary liver cancer; colorectal cancer limited to liver metastases; head/neck cancers; and the management of severe, chronic, and intractable pain. All other uses are investigational.
- 8/99 Reformatted, Medical Term Definitions added.
- 10/00 System coding changes.
- 12/00 2001 HCPCS code E0786 added to policy. System coding changes.
- 3/01 Medical Policy Advisory Group review. Typographical errors corrected. Slight change in psychological-behavioral factors criteria. Approve.
- 5/01 Clarified criteria for severe spasticity. Typographical errors corrected. Added new source reference. Coding Format change.
- 6/02 Policy section on when an implantable infusion pump is covered was reformatted for clarity. Codes reviewed. No change.
- 10/02 Specialty Matched Consultant Advisory Panel review. Added information regarding intrathecal pumps in When Implantable Infusion Pump is covered.
- 1/03 Added code 95990 to policy. System coding changes.
- 7/03 Specialty Matched Consultant Advisory Panel review. No change to policy criteria. Added code 96530 to policy. Reaffirm.
- 9/03 Removed codes E0785, 36260, 36261, 36262, 36530, 36531, 36532, 61215, 62350, 62351, 62355, 62360, 62361, 62362, 62365, 62367, 62368, 95990 from the policy. Code 96530 was not added to the policy.
- 4/04 Billing/Coding section updated for consistency.
- 4/7/05 Specialty Matched Consultant Advisory Panel [MPAG] review on 3/10/05. No changes made to policy criteria. References added. Policy status changed to: "Active policy, no longer scheduled for routine literature review."
- 10/02/06 Medical Policy changed to Evidence Based Guideline.

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.