

**LOCAL MEDICAL POLICY
MARYLAND MEDICARE PART A**

IMPLANTABLE INFUSION PUMP

Description

Medicare considers coverage for implantable infusion pumps for specific conditions associated with:

- Chemotherapy for liver cancer;
- Anti-spasmodic drugs for severe spasticity; and
- Opioid drugs for treatment of chronic intractable pain.

Implantable infusion pumps for administration of heparin in the treatment of thromboembolic disease is considered investigational and therefore, non-covered by Medicare.

Type of Bill

11X, 13X, 18X, 21X, 71X, 83X, 85X

Revenue Codes

- The implantable infusion pump should be billed using Revenue Code 261.
- The procedure to insert the pump may be billed using Revenue Code 360.

Baclofen

- For bill type(s) 13x, 71x, 83x, and 85x, bill using Revenue Code 636 with HCPCS code J0475; and,
- For all other bill types, Baclofen should be billed using Revenue Code 250. HCPCS is not required.

HCPCS Codes

- 36260© Insertion of implantable intra-arterial infusion pump (e.g., for

chemotherapy of liver)

- 36261© Revision of implanted intra-arterial infusion pump
- 36262© Removal of implanted intra-arterial infusion pump
- 36530© Insertion of implantable intravenous infusion pump
- 36531© Revision of implantable intravenous infusion pump
- 36532© Removal of implantable intravenous infusion pump

HCFA's National Policy

Effective January 1, 1994, HCFA changed the status for procedure codes 36530 and 36531 from (A), active to (N), non-covered, by Medicare. Medicare may not at any time pay for procedure codes 36530 or 36531.

Procedure code 36532 was changed from (A) to (R), rarely covered. The Medicare Intermediary (under individual consideration) may consider payment for procedure code 36532 based on Medicare coverage policy. The coverage policy states that "After a beneficiary has been discharged from the hospital stay in which he received a non-covered service, medical and hospital services required to treat a condition or complication that arises as a result of the prior non-covered service, may be covered, when they are reasonable and necessary in all other respects."

National coverage policy for an implantable infusion pump has been revised as follows:

Chemotherapy for liver cancer (Effective for services performed on or after 9/26/84)

The implantable infusion pump is covered for intra-arterial infusion of 5-FUdR, for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where the disease is unresectable **or** the patient refuses surgical excision of the tumor.

Anti-spasmodic drugs (Effective for services performed on or after 3/4/94)

Medicare will consider payment for implantation of infusion pumps when implanted to:

- Administer anti-spasmodic drugs intrathecally (e.g., Baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by the following criteria:
 - § As indicated by at least a six-week trial, the patient cannot be maintained on non-invasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to adequately control

the spasticity or produce intolerable side effects. Prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.

Opioid Drugs (Effective for services performed on or after 3/4/94)

Medicare will consider payment for opioid drugs when administered intrathecally (e.g., morphine) or epidurally for treatment of severe chronic intractable pain of malignant or non-malignant origin in patients with a life expectancy of at least three months. The patient must have proven unresponsive to less invasive medical therapy as determined by the following criteria:

- The patient's history must indicate that he/she would not respond adequately to non-invasive methods of pain control, such as a systemic opioid (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain); and,
- A preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (including effects on the activities of daily living) and patient acceptance.

Coverage of Other Uses of Implanted Infusion Pumps

Determinations may be made on coverage of other uses of implanted infusion pumps if the contractor's medical staff verifies that:

- The drug is reasonable and necessary for the treatment of the individual patient;
- It is medically necessary that the drug be administered by an implanted infusion pump; and,
- 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.

The implantation of an infusion pump is *contraindicated* in the following patients:

- Patients with a known allergy or hypersensitivity to the drug being used (e.g., oral Baclofen, morphine);
 - Patients who have an infection;
- Patients whose body size is insufficient to support the weight and bulk of the device; and,

- Patients with other implanted programmable devices as crosstalk between devices may inadvertently change the prescription.

Note: Payment may also be made for drugs necessary for the effective use of an implantable infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

Indications for Treatment Using Implantable Infusion Pumps Not Covered by Medicare

- Thromboembolic Disease (Effective for services performed on or after 9/26/84)-According to the Public Health Service, there is insufficient published clinical data to support the safety and effectiveness of the heparin implantable pump. Therefore, the use of an implantable infusion pump for infusion of heparin in the treatment of recurrent thromboembolic disease is not covered by Medicare.
- Diabetes –Implanted infusion pumps for the infusion of insulin to treat diabetes is not covered. The data does not demonstrate that the pump provides effective administration of insulin.

Reasons for Denial

The implantation of an infusion pump is **contraindicated** in the following patients:

- Patients with a known allergy or hypersensitivity to the drug being used such as oral Baclofen or morphine;
 - Patients who have an infection;
- Patients whose body size is insufficient to support the weight and bulk of the device; and,
 - Patients with other implanted programmable devices, since crosstalk between devices may inadvertently change the prescription,
 - All other indications not listed in the “Indications and Limitations of Coverage” section of this policy;
- The medical record does not verify that the service described by the HCPCS code was provided; and,
 - The service does not follow the guidelines of this policy.

Indications and Limitations of Coverage and/or Medical Necessity
National policy coverage as outlined above.

ICD-9-CM Codes That Support Medical Necessity

Not applicable at this time.

Non-covered ICD-9-CM Code(s)

Not applicable at this time.

Coding Guidelines

- To report this service, use the appropriate HCPCS code;
- All of the coverage criteria must be met before this service can be reimbursed by Medicare;
- Diagnosis(es) must be present on any claim submitted, and must be coded to the highest level of specificity. The diagnosis code(s) must be representative of the patient's condition.

Documentation Requirements

Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to Medicare upon request.

Documentation in the patient's medical record should support that the patient's spasticity was unresponsive to other treatment methods. The medical record should also indicate that the oral form of Baclofen was ineffective for controlling the spasticity, or that the patient could not tolerate the oral form of the drug.

It must be evident in the patient's medical record that the patient showed a favorable response to the trial dose of Baclofen. Patients who do not respond to a 100 mcg. intrathecal bolus of Baclofen should not be considered for an implanted pump, for continuous infusion.

Note: This policy was developed by the Health Care Financing Administration (HCFA), and does not reflect the sole opinion of the intermediary, or the intermediary medical director.

Sources of Information

Medicare Coverage Issue Manual, Section 60-14

Texas Medicare Part A Newsletter No.5-96

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N/A

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