Medicare
Coverage Issues Manual

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services

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CHANGE REQUEST 1814

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
60-14 - 60-14 (Cont.)	2 pp.	2 pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE: January 1, 2002*
IMPLEMENTATION DATE: January 1, 2002

Section 60-14, Infusion Pumps, revises the C-peptide requirement to be less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method. This change expands the value of the laboratory test to be considered in determining coverage of the insulin infusion pump for all diabetic patients. (Type II diabetics are no longer excluded.)

This section of the Coverage Issues Manual is a national coverage decision made under §1862(a)(1) of the Social Security Act (the Act). National coverage determinations (NCDs) are binding on all Medicare carriers, intermediaries, Peer Review Organizations, and other contractors. Under 42 CFR 422.256(b) an NCD that expands coverage is also binding on a Medicare+Choice Organization. In addition, an administrative law judge may not disregard, set aside, or otherwise review a national coverage decision issued under §1862(a)(1) of the Act. (42 CFR 405.732, 405.860.)

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

These instructions should be implemented within your current operating budget.

60-14 INFUSION PUMPS

THE FOLLOWING INDICATIONS FOR TREATMENT USING INFUSION PUMPS ARE COVERED UNDER MEDICARE:

A. External Infusion Pumps.--

1. Iron Poisoning (Effective for Services Performed On or After 9/26/84).--When used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload, only external infusion pumps are covered.

2. Thromboembolic Disease (Effective for Services Performed On or After 9/26/84).--When used in the administration of heparin for the treatment of thromboembolic disease and/or pulmonary embolism, only external infusion pumps used in an institutional setting are covered.

3. Chemotherapy for Liver Cancer (Effective for Services Performed On or After 1/29/85).--The external chemotherapy infusion pump is covered when used in the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the patient refuses surgical excision of the tumor.

4. Morphine for Intractable Cancer Pain (Effective for Services Performed On or After 4/22/85).--Morphine infusion via an external infusion pump is covered when used in the treatment of intractable pain caused by cancer (in either an inpatient or outpatient setting, including a hospice).

5. Continuous subcutaneous insulin infusion pumps (CSII) (Effective for Services Performed On or After 4/1/2000).--

An external infusion pump and related drugs/supplies are covered as medically necessary in the home setting in the following situation: Treatment of diabetes

In order to be covered, patients must meet criterion A or B:

(A) The patient has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e. at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen:

(1) Glycosylated hemoglobin level (HbAlc) > 7.0 percent
(2) History of recurring hypoglycemia
(3) Wide fluctuations in blood glucose before mealtime
(4) Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
(5) History of severe glycemic excursions

(B) The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

Diabetes needs to be documented by a fasting C-peptide level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method. (Effective for Services Performed on or after January 1, 2002.)

Continued coverage of the insulin pump would require that the patient has been seen and evaluated the treating physician at least every 3 months.

The pump must be ordered by and follow-up care of the patient must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII.

6. Other uses of external infusion pumps are covered if the contractor's medical staff verifies the appropriateness of the therapy and of the prescribed pump for the individual patient.

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

B. Implantable Infusion Pumps.--

1. 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 (1) the disease is unresectable or (2) where the patient refuses surgical excision of the tumor.

2. Anti-Spasmodic Drugs for Severe Spasticity.--An implantable infusion pump is covered when used 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:

o As indicated by at least a 6-week trial, the patient cannot be maintained on noninvasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side effects, and

o Prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.

3. Opioid Drugs for Treatment of Chronic Intractable Pain.--An implantable infusion pump is covered when used to administer opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients 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 criteria:

o The patient's history must indicate that he/she would not respond adequately to non-invasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain); and

o 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.

4. 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:

o The drug is reasonable and necessary for the treatment of the individual patient;