If you wish to save the PDF, please ensure that you change the file extension to .PDF (from .ashx).

Local Coverage Determination (LCD): Implantable Infusion Pump for Treatment of Chronic Intractable Pain (L33529)

Contractor Information

Contractor Name	Contract Number	Contract Type
Noridian Healthcare Solutions, LLC opens in new window	01182	MAC - Part B

Back to Top

LCD Information

Document Information

LCD ID
L33529

LCD Title
Implantable Infusion Pump for Treatment of Chronic Intractable Pain

Jurisdiction
California - Southern

Original Effective Date
For services performed on or after 09/16/2013

Revision Effective Date
For services performed on or after 11/01/2013

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Title XVIII of the Social Security Act, §1862(a)(7) and 42 Code of Federal Regulations (CFR), §411.15 et seq., exclude routine physical examinations.

Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

CMS Manual System, Publication 100-03, *Medicare National Coverage Determinations Manual,* Chapter 1, §280.14(2)(C), allows coverage for an implantable infusion pump for opioid drugs for the treatment of chronic intractable pain.

CMS Manual System, Publication 100-02, *Medicare Benefit Policy Manual,* Chapter 15, §§50 and 50.1, defines a Drug or Biological.

CMS Manual System, Publication 100-02, *Medicare Benefit Policy Manual,* Chapter 15, §§50.4.1 and 5.4.2, addresses coverage for off-label uses of FDA-approved medications.

CMS Manual System, Publication 100-02, *Medicare Benefit Policy Manual,* Chapter 15, §50.4.3, sets for reasonable and necessary drug services.

CMS Manual System, Publication 100-02, *Medicare Benefit Policy Manual,* Chapter 15, §50.4.7, addresses the denial of Medicare payment for compounded drugs produced in violation of Federal Food, Drug, and Cosmetic Act.

CMS Manual System, Publication 100-04, *Medicare Claims Processing Manual,* Transmittal 54, Change Request 3022, this transmittal states that the payment limit for infusion drugs furnished through an item of implanted durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP. It also indicates that the above services must be identified using the "KD" modifier.

CMS Manual System, Publication 100-04, *Medicare Claims Processing Manual,* Transmittal 75, Change Request 3105, makes corrections to CR 3022 on the Medicare Drug Pricing Amounts Under Part B. This transmittal states that the payment limit for infusion drugs furnished through a covered item of durable medical equipment on or after January 1, 2004, will be 95 percent of the AWP reflected in the published compendia as of October 1, 2003, regardless of whether or not the durable medical equipment is implanted. It also indicates that the above services must be identified using the "KD" modifier. (See Documentation Requirements section for more information regarding the "KD" modifier).

CMS Manual System, Publication 100-08, *Program Integrity Manual,* Chapter 3, §3.4.1.3; Diagnosis Code Requirement.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

An implanted infusion pump for chronic pain is covered by Medicare when used to administer opioid drugs, singly or in combination with other opioid or non-opioid drugs, 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 three (3) months, and who have proven unresponsive to less invasive medical therapy. In order to be considered medically reasonable and necessary, all of the following criteria must be met:

1. The administration of the medication must require the intrathecal or epidural route and be effective on a long-term basis.
2. Oral or subcutaneous medication treatment should be ineffective or complicated by unacceptable side effects.
3. The patient's medical condition must require the use of an infusion pump for pain relief.
4. The type and dosage of the medication must reasonably be expected to alleviate or reduce the pain.

In addition, an evaluation by an orthopedic surgeon, neurologist, neurosurgeon, oncologist or other specialist familiar with the underlying disease is required to validate that other treatments have failed to alleviate the pain. Documentation that the patient is unresponsive to less invasive medical therapy should be kept in the patient's medical record and made available upon Medical Review request.

If the above criteria have been met, a preliminary trial of intraspinal opioid or non-opioid drug administration can be undertaken with a temporary intrathecal/epidural catheter to substantiate acceptable pain relief, degree of side effects including effects on the activities of daily living, and patient acceptance.

Any drug(s) used to fill the implantable pump must be appropriate for the treatment of the individual patient. Drugs compounded for the special needs of a patient may be covered. Drugs filling the pump are often obtained singly or mixed with other drugs from compounding pharmacies. Unless the medications are administered in the exact concentrations available from national pharmaceutical companies, the medications will be considered as compounded. FDA approved drugs used for indications other than what is accepted on the official label may be covered under Medicare if the contractor determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice. The following are examples of medications that are approved for off-label intrathecal use. **This list of drugs is not an all inclusive list.** Additional medications may be added to the off-label coverage list upon the submission of appropriate documentation.

- Clonidine (Duraclon) (J0735-KD)
- Bupivicaine (J3490-KD)
- Sufentanil (J3490-KD)
- Methadone (J1230-KD)

Contraindications to coverage: Implantation of an infusion pump is contraindicated under the following circumstances:

- The patient has a known allergy or hypersensitivity to the drug being used (e.g., morphine, Duraclon, etc.).
- Patients who have an infection.
- Patients whose body size is insufficient to support the weight and bulk of the device.

Back to Top

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x Not Applicable

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999 Not Applicable

CPT/HCPCS Codes
Group 1 Paragraph: CPT Codes

Group 1 Codes:

62318	INJECTION(S), INCLUDING INDWELLING CATHETER PLACEMENT, CONTINUOUS INFUSION OR INTERMITTENT BOLUS, OF DIAGNOSTIC OR THERAPEUTIC SUBSTANCE(S) (INCLUDING ANESTHETIC, ANTISPASMODIC, OPIOID, STEROID, OTHER SOLUTION), NOT INCLUDING NEUROLYTIC SUBSTANCES, INCLUDES CONTRAST FOR LOCALIZATION WHEN PERFORMED, EPIDURAL OR SUBARACHNOID; CERVICAL OR THORACIC
62319	INJECTION(S), INCLUDING INDWELLING CATHETER PLACEMENT, CONTINUOUS INFUSION OR INTERMITTENT BOLUS, OF DIAGNOSTIC OR THERAPEUTIC SUBSTANCE(S) (INCLUDING ANESTHETIC, ANTISPASMODIC, OPIOID, STEROID, OTHER SOLUTION), NOT INCLUDING NEUROLYTIC SUBSTANCES, INCLUDES CONTRAST FOR LOCALIZATION WHEN PERFORMED, EPIDURAL OR SUBARACHNOID; LUMBAR OR SACRAL (CAUDAL)
62350	IMPLANTATION, REVISION OR REPOSITIONING OF TUNNELED INTRATHECAL OR EPIDURAL CATHETER, FOR LONG-TERM MEDICATION ADMINISTRATION VIA AN EXTERNAL PUMP OR IMPLANTABLE RESERVOIR/INFUSION PUMP; WITHOUT LAMINECTOMY
62351	

	IMPLANTATION, REVISION OR REPOSITIONING OF TUNNELED INTRATHECAL OR EPIDURAL CATHETER, FOR LONG-TERM MEDICATION ADMINISTRATION VIA AN EXTERNAL PUMP OR IMPLANTABLE RESERVOIR/INFUSION PUMP; WITH LAMINECTOMY
62355	REMOVAL OF PREVIOUSLY IMPLANTED INTRATHECAL OR EPIDURAL CATHETER
62360	IMPLANTATION OR REPLACEMENT OF DEVICE FOR INTRATHECAL OR EPIDURAL DRUG INFUSION; SUBCUTANEOUS RESERVOIR
62361	IMPLANTATION OR REPLACEMENT OF DEVICE FOR INTRATHECAL OR EPIDURAL DRUG INFUSION; NONPROGRAMMABLE PUMP
62362	IMPLANTATION OR REPLACEMENT OF DEVICE FOR INTRATHECAL OR EPIDURAL DRUG INFUSION; PROGRAMMABLE PUMP, INCLUDING PREPARATION OF PUMP, WITH OR WITHOUT PROGRAMMING
62365	REMOVAL OF SUBCUTANEOUS RESERVOIR OR PUMP, PREVIOUSLY IMPLANTED FOR INTRATHECAL OR EPIDURAL INFUSION
62367	ELECTRONIC ANALYSIS OF PROGRAMMABLE, IMPLANTED PUMP FOR INTRATHECAL OR EPIDURAL DRUG INFUSION (INCLUDES EVALUATION OF RESERVOIR STATUS, ALARM STATUS, DRUG PRESCRIPTION STATUS); WITHOUT REPROGRAMMING OR REFILL
62368	ELECTRONIC ANALYSIS OF PROGRAMMABLE, IMPLANTED PUMP FOR INTRATHECAL OR EPIDURAL DRUG INFUSION (INCLUDES EVALUATION OF RESERVOIR STATUS, ALARM STATUS, DRUG PRESCRIPTION STATUS); WITH REPROGRAMMING
62369	ELECTRONIC ANALYSIS OF PROGRAMMABLE, IMPLANTED PUMP FOR INTRATHECAL OR EPIDURAL DRUG INFUSION (INCLUDES EVALUATION OF RESERVOIR STATUS, ALARM STATUS, DRUG PRESCRIPTION STATUS); WITH REPROGRAMMING AND REFILL
62370	ELECTRONIC ANALYSIS OF PROGRAMMABLE, IMPLANTED PUMP FOR INTRATHECAL OR EPIDURAL DRUG INFUSION (INCLUDES EVALUATION OF RESERVOIR STATUS, ALARM STATUS, DRUG PRESCRIPTION STATUS); WITH REPROGRAMMING AND REFILL (REQUIRING SKILL OF A PHYSICIAN OR OTHER QUALIFIED HEALTH CARE PROFESSIONAL)
95990	REFILLING AND MAINTENANCE OF IMPLANTABLE PUMP OR RESERVOIR FOR DRUG DELIVERY, SPINAL (INTRATHECAL, EPIDURAL) OR BRAIN (INTRAVENTRICULAR), INCLUDES ELECTRONIC ANALYSIS OF PUMP, WHEN PERFORMED;
95991	REFILLING AND MAINTENANCE OF IMPLANTABLE PUMP OR RESERVOIR FOR DRUG DELIVERY, SPINAL (INTRATHECAL, EPIDURAL) OR BRAIN (INTRAVENTRICULAR), INCLUDES ELECTRONIC ANALYSIS OF PUMP, WHEN PERFORMED; REQUIRING SKILL OF A PHYSICIAN OR OTHER QUALIFIED HEALTH CARE PROFESSIONAL

Group 2 Paragraph: HCPCS Codes

See Supplemental Instructions Article regarding coding guidelines for submitting claims for drugs.

Group 2 Codes:
J3490 UNCLASSIFIED DRUGS

ICD-9 Codes that Support Medical Necessity
Group 1 Paragraph: There is a wide variety of possible ICD-9-CM codes that contain indications associated with severe pain. The potential ICD-9-CM codes are too numerous to list, including nearly all types of end stage malignancy. Report the most appropriate ICD-9-CM code that supports the specific cause of the severe, intractable, chronic pain. Non-specific ICD-9-CM codes such as lumbago, low back pain, disc disease, myositis or myalgia will require additional documentation to show that conservative therapy was unsuccessful and to verify the need for the service.

Group 1 Codes:
XX000 Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity
Paragraph: Any ICD-9 code that does not represent the specific cause of the severe, intractable, chronic pain.

N/A
Back to Top

General Information

Associated Information
Supportive documentation evidencing the condition and treatment is expected to be documented in the medical record and be available upon request.

The patient's medical record documentation must support the reasonable and necessary requirements as outlined under the indications and limitations of coverage.

The patient's history must indicate that he/she would not respond adequately to noninvasive methods of pain control, such as:

- Systemic opioids
- Combination of oral analgesics (including opioids) plus other drugs known to relieve pain such as muscle relaxants, clonidine, antidepressants, anti-seizure medication or others known to mediate pain.
- Attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain.

Change Requests (CR) 3022 and 3105, instruct providers to use the "KD" modifier when billing for infused drugs through an implantable infusion pump. The "KD" modifier identifies the drugs billed as being infused. Please refer to the above CRs for further information regarding the use of the "KD" modifier.

All of the procedure codes that are related to the refilling and the management of the pump must be billed and documented on the same claim form, including the drugs that are being administered through the pump. The drugs are not to be billed on a separate claim form.

At the time of the pump refill and/or the pump interrogation and/or the pump reprogramming, documentation should include at a minimum:

- the pump status before and after the refill,
- the patient's response to the current medication dose and rate,
- the reasons for any change in dose or the types of medications,
- any necessary reassessment of the patient's overall condition and treatment goals (this may be reported as an E&M service),
- proof that all applicable "incident to" requirements are met, and
- proof that any medication billed to Medicare represents a cost to the physician or group accepting Medicare payment.

A preliminary trial of the intraspinal (intrathecal/epidural) opioid drug or non-opioid administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequate acceptable pain relief and the degree of side effects (including the effects on the activities of daily living) and the patient's acceptance of the therapy must be documented in the patient's record.

Legible physician's medical documentation must be maintained in the patient's medical record and meet the criteria contained in this policy. The subsequent determination that the medical record is lacking the justification for the services and/or the documentation of the services are illegible will result in a denial of not reasonable and necessary.

A periodic reassessment of the patient should be performed according to the needs of the patient and the applicable medical standards.

The frequency for interrogating/reprogramming the pump (62367 and 62368) should be supported by the patient's symptoms. The frequency for refill must take into account the size of the pump.

Sources of Information and Basis for Decision

Dougherty P, Staats PS. Intrathecal Drug Therapy for Chronic Pain: From Basic Science to Clinical Practice. *Anesthesiology.* Dec 1999;91(6):1891-918.

Chang HM. Chronic Pain, Cancer Pain Management. *Med. Clinics of North America.* May 1999;83(3):712-36.

Fanciullo GJ, Rose RJ, Lunt PG, Whalen PK, Ross E. The state of implantable pain therapies in the United States: a nationwide survey of academic teaching programs. *Anesth Analg.* Jun 1999;88(6):1311-6.

Gilmer-Hill HS, Boggan JE, Smith KA, Frey CF, Wagner FC, Eein LS. Intrathecal morphine delivered via subcutaneous pump for intractable pain in pancreatic cancer. *Surg Neurol.* Jan 1999:51(1):6-11.

Angel IF, Gould HJ, Carey ME. Intrathecal morphine pump as a treatment option in chronic pain of nonmalignant origin. *Surg Neurol.* Jan 1998;49(1):92-8.

Back to Top

Revision History Information

Please note: The Revision History information included in this LCD prior to 1/24/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 1/24/2013 will display as a row in the Revision History section of the LCD and numbering will begin with "R2".

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
11/01/2013	R1	This LCD was revised to reflect the corporate name change from Noridian Administrative Services, LLC to Noridian Healthcare Solutions, LLC that was effective on 05/01/2013.	• Other (Corporate name change)

Back to Top

Associated Documents

Attachments Submitting Claims for Compounded opens in new window (PDF - 47 KB)

Related Local Coverage Documents N/A

Related National Coverage Documents N/A

Public Version(s) Updated on 11/01/2013 with effective dates 11/01/2013 - N/A Updated on 06/07/2013 with effective dates 09/16/2013 - N/A Back to Top

Keywords

N/A Read the **LCD Disclaimer opens in new window** Back to Top