Clinical Policy: Implantable Intrathecal or Epidural Pain Pump

Reference Number: CP.MP.173
Date of Last Revision: 01/24
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Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

An implantable, intrathecal drug delivery system consists of an implanted pump and catheter that delivers a drug directly into the spinal fluid. The device can be programmed for continuous or variable rates of infusion. Intrathecal drug delivery systems offer an invasive alternative for the long-term management of select patients with intractable pain.

Refer to CP.PHAR.149 Intrathecal Baclofen (Gablofen, Lioresal) for requests for Baclofen. Refer to the CP.MP.107 Durable Medical Equipment (DME) section on Pumps for criteria for other indications.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that **a *preliminary trial*** *of epidural or intrathecal administration of an opioid drug* is **medically necessary when all of the following criteria are met:**

A. Request is for either of the following indications:
   1. Chronic intractable pain of malignant origin when all of the following criteria is met:
      a. Inadequate response to, or intolerable side effects from, noninvasive methods of pain control such as systemic opioids;
      b. Life expectancy > three months;
      c. No evidence of epidural metastatic lesion(s) or tumor encroachment of the thecal sac by imaging;
   2. Chronic intractable pain of nonmalignant origin (e.g. failed back surgery syndrome, complex regional pain syndrome) when all the following criteria are met:
      a. Pathology for the pain has been identified;
      b. Life expectancy is > three months;
      c. Failure or inability to tolerate other conservative treatment methods, including but not limited to, systemic pharmacotherapy, physical therapy, behavioral health treatment for pain, and appropriate nonsurgical treatment;
      d. Compliance with previous attempts to treat the condition;
      e. A psychological evaluation confirms a mental health condition is not a major contributor to chronic pain symptoms;
      f. Active participation in psychotherapeutic interventions (e.g. cognitive behavioral therapy, relaxation training, biofeedback, coping skills training, stress management);
      g. Further surgical intervention or other treatment is not indicated or likely to be effective;
      h. Prior to the trial, systemic opioids have been weaned by at least 50%;
      i. Opioid induced hyperalgesia has been ruled out as a possible cause of the chronic pain symptoms.

B. None of the following contraindications:
   1. Known allergies to materials in the implant;
   2. Active alcohol or drug abuse, including but not limited to opioid addiction and intravenous drug abuse;
   3. Diagnosis of dementia or psychosis;
   4. Active systemic infection;
   5. Active infection at the site of implantation.

II. It is the policy of health plans affiliated with Centene Corporation that *implantation of a **permanent** epidural or intrathecal pain pump* to administer an opioid drug, alone or in combination with other non-opioid drugs, is **medically necessary when all of the following criteria are met:**

A. Request is for either of the following indications:
   1. Chronic intractable pain of malignant origin when the above criteria for the preliminary trial are met, and all of the following:
      a. The trial provided ≥ 50% reduction in pain with minimal side effects;*
      b. Body size is sufficient to support the weight and bulk of the device;
      c. No other implanted programmable devices for which the interaction between devices may inadvertently change the prescription;
      d. No known allergy or hypersensitivity to the drug being used;
   2. Severe chronic pain of non-malignant origin when the above criteria for the preliminary trial is met and all of the following:
      a. Preliminary trial provided ≥ 50% reduction in pain and increase in function with minimal side effects;
      b. There is a plan in place to continue to wean systemic opioids;
      c. No active coagulopathy;
      d. Body size is sufficient to support the weight and bulk of the device;
      e. No other implanted programmable devices for which the interaction between devices may inadvertently change the prescription;
      f. No known allergy or hypersensitivity to the drug being used;
      g. No evidence of increased intracranial pressure;
      h. No spinal anomalies that may complicate the implantation and fixation of a catheter for drug delivery;
      i. Continued active participation in any behavioral health or psychological treatment modalities.

B. None of the following contraindications:
   1. Known allergies to materials in the implant;
   2. Active alcohol or drug abuse, including but not limited to opioid addiction and intravenous drug abuse;
   3. Diagnosis of dementia or psychosis;
   4. Active systemic infection;
   5. Active infection at the site of implantation.

**Note*: The trial requirement for a percutaneous intrathecal or epidural drug delivery system for pain of malignant origin may be reviewed by a medical director on a case-by-

case basis for instances of advanced disease, when survival time is limited, or considered high risk for procedures.

Background

Chronic pain is often defined as pain that persists longer than six months. The American Society of Interventional Pain Physicians (ASIPP) defines chronic pain as, "a complex and multifactorial phenomenon with pain that persists six months after an injury and/or beyond the usual course of an acute disease or a reasonable time for a comparable injury to heal, that is associated with chronic pathologic processes that cause continuous or intermittent pain for months or years, that may continue in the presence or absence of demonstrable pathology and may not be amenable to routine pain control methods with healing never occurring."[5] Numerous health conditions can cause chronic pain, including, but not limited to, chronic cancer pain, failed back surgery syndrome, complex regional pain syndrome, diabetic neuropathy, and post-herpetic neuralgia.[2]

Opioid therapy for the treatment of chronic non-cancer pain is controversial, due to insufficient evidence of long-term efficacy and the risk of serious harm, including addiction and abuse, especially in the context of the ongoing opioid epidemic in the United States. For patients with chronic non-cancer pain, opioids should only be used when other potentially effective and safer therapies have not provided sufficient pain relief or experience intolerable side effects, and pain is adversely affecting a patient's function and/or quality of life. The potential benefits of opioid therapy should outweigh potential harms. Opioids should be combined with non-opioid pharmacotherapy and nonpharmacologic therapies as appropriate.[7]

Intrathecal therapy offers an invasive alternative for the long-term management of select patients with recalcitrant pain after all other methods have failed, including conservative and surgical treatment. Implantable intrathecal infusion systems, also referred to as intrathecal drug delivery (IDD) systems, provide targeted drug delivery to the central nervous system. They are most commonly used for cancer-related pain. Their use for management of pain of non-malignant origin is controversial and generally reserved for treatment of last resort. A number of medications are used, including opioids (e.g. morphine) or a combination of opioids along with a local anesthetic (e.g., ziconotide, clonidine.)

An implantable intrathecal drug delivery system (pain pump) consists of an implanted catheter and either a constant-flow or programmable pump. The implantation of a pump for intrathecal opioid infusion is preceded by an intrathecal or epidural trial infusion, with or without a catheter, to determine whether the patient exhibits an adequate response, consisting of a predefined improvement in pain (usually ≥ 50%) without intolerable adverse effects. If the trial is successful, the drug infusion system is implanted under general anesthesia. The catheter is introduced into the intrathecal space of the spine (generally at the lumbar level), tunneled subcutaneously, and typically positioned under fluoroscopic guidance so that the tip is located at the corresponding spinal level for processing the patient's pain. The catheter is connected to an infusion pump placed in a subcutaneous pocket in the abdomen.[2]

The literature evaluating intrathecal infusion systems for long-term management of chronic non-cancer pain is limited. Peer reviewed literature to date consists of observational studies,

uncontrolled retrospective studies, case studies and systematic reviews using variable methodologies and inclusion criteria. Some studies suggest that intrathecal opioids reduce pain long-term in a small proportion of individuals with chronic, non-cancer pain, however, large randomized controlled trials are lacking.

There are several contraindications to implantable drug delivery systems which can be divided into absolute and relative exclusions. Absolute contraindications include systemic infections, known allergies to materials in the implant, active intravenous drug abuse, psychosis or dementia, and infection at the implantation site. Relative contraindications include an atrophied patient (underweight BMI), ongoing anticoagulation that cannot be discontinued, active bleeding, high opioid tolerance, lack of social or family support, and lack of access to medical care. Intrathecal pump placement is an elective procedure; thus one must assess all potential absolute and relative contraindications before proceeding.[22]

A health technology assessment of Intrathecal Drug Delivery Systems for Noncancer Pain reported, "Compared with oral opioid analgesia alone or a program of analgesia plus rehabilitation, intrathecal drug delivery systems significantly reduced pain (27% additional improvement) and morphine consumption. Despite these reductions, intrathecal drug delivery systems were not superior in patient-reported well-being or quality of life. There is no evidence of superiority of intrathecal drug delivery systems over oral opioids in global pain improvement and global treatment satisfaction. Comparative evidence of harms was not found." [8]

American Society of Interventional Pain Physicians (ASIPP)
The evidence is limited for implantable intrathecal drug administration systems in managing patients with failed back surgery syndrome. [9]

American Society of Anesthesiologists/American Society of Regional Anesthesia and Pain Medicine
Studies with observational findings indicate that intrathecal opioid injections can provide effective pain relief for assessment periods ranging from 1 to 12 months for patients with neuropathic pain (Category B2 evidence). Consultants, ASA members, and ASRA members are equivocal with regard to whether intrathecal opioid injection or infusion should be used for neuropathic pain. However, they strongly agree that neuraxial opioid trials should be performed before considering permanent implantation of intrathecal drug delivery systems.[6]

North American Spine Society (NASS)
NASS has developed coverage recommendation on spinal intrathecal drug delivery systems for the treatment of chronic nonmalignant pain. Per NASS, the implantable infusion may benefit a small subgroup of patients with chronic nonmalignant pain and a clear spinal pathology, who have exhausted all other options to treat their symptoms. These patients should have a psychological evaluation to rule out drug and alcohol disorders and other psychological conditions.[9]

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted

CPT® Codes	Description
62320	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62321	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62323	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (i.e., fluoroscopy or CT)
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (i.e., fluoroscopy or CT)
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.

CPT® Codes	Description
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)

HCPCS Codes	Description
A4300	Implantable access catheter, (e.g., venous, arterial, epidural subarachnoid, or peritoneal, etc.) external access
A4301	Implantable access total catheter, port/reservoir (e.g., venous, arterial, epidural, subarachnoid, peritoneal, etc.)
E0782	Infusion pump, implantable, nonprogrammable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)
C1772	Infusion pump, programmable (implantable)
C1755	Catheter, intraspinal
J2274	Injection, morphine sulfate, preservative free for epidural or intrathecal use, 10 mg
S0093	Injection, morphine sulfate, 500 mg (loading dose for infusion pump)

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Specialist reviewed.	02/19	02/19
Added CPT codes: 62320, 62321, 62351, 62361	07/19	
Changed "no local infection at catheter site" in trial and permanent placement criteria to state "no active infection." References reviewed and updated.	01/20	01/20
References reviewed and updated. Added ICD-10 codes: G90.511, G90.512, and G90.513. Replaced "member" with "member/enrollee" in disclaimer.	12/20	01/21
Annual review. Reference reviewed, updated, and reformatted. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Updated "Refer to" note. In I. added "epidural or" intrathecal administration. In I.A.1. added Inadequate response "to or intolerable side effects from." II.A added when "the above criteria for" the preliminary trial is met "and the following: Body size is sufficient to support the weight and bulk of the device; No other implanted programmable devices for which the interaction between devices may inadvertently change the prescription; No known allergy or hypersensitivity to the drug being used." II.A. added "Note: The trial requirement for a percutaneous intrathecal or epidural drug delivery system for pain of malignant origin may be reviewed on a case-by-case basis for instances of advanced disease, when survival time is limited, or considered high risk for procedures." II.B added "when the above criteria for the preliminary trial is met and all of the following." Removed duplicate criteria from II.B "no active infection." Updated policy title from "Implantable Intrathecal Pain Pump" to "Implantable Intrathecal or Epidural Pain Pump."	01/22	01/22
Annual review. References reviewed and updated. ICD-10 code table removed. Minor rewording with no clinical significance. Reviewed by external specialist.	01/23	01/23
Annual review. Restructured and reformatted criteria section. In I.B. and II.B. added contraindications to include known allergies to materials in the implant; active alcohol or drug abuse, including but not limited to opioid addiction and intravenous drug abuse, diagnosis of dementia or psychosis; active systemic infection, active infection at the site of implantation. Background updated with no impact to criteria. References reviewed and updated.	01/24	

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid member/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare member/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.