MEDICAL POLICY STATEMENT
INDIANA MEDICAID

Policy Name		Policy Number	Date Effective
Implantable Pain Pump		MM-0705	01/01/2021-12/31/2021
Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

Medical Policy Statement prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

Table of Contents

A. Subject 2
B. Background 2
C. Definitions 5
D. Policy 6
E. Conditions of Coverage 8
F. Related Polices/Rules 8
G. Review/Revision History 8
H. References 9

A. Subject

Implantable Pain Pump

B. Background

Chronic pain is defined by the International Association for the Study of Pain as: “pain that persists beyond normal tissue healing time, which is assumed to be three months”.

Drug delivery through continuous infusion is an important option for pain associated with cancer and for cancer treatment patients that are refractory to and/or intolerant of systemic pharmacotherapy. When pain relief cannot be achieved with conventional or more conservative therapies, continuous infusion should be evaluated for appropriateness through a specialist based on the patient’s medical status, care goals, cost and the availability of family and professional support. When treated with intrathecal therapy, recent studies indicate success in pain reduction with improved outcomes in analgesic therapy, reduced toxicity and increased survival.

Implantable pain pumps are medical devices which are inserted subcutaneously to deliver drugs for infusion through intrathecal catheters. Implantable pain pumps allow drug delivery directly to specific sites and can be programmed for continuous or variable rates of infusion. Implantable intrathecal drug delivery systems (IDDSs) have been used to manage refractory cancer pain and reduce pain in both non-malignant chronic pain and refractory malignant pain, but adverse events are common and more studies are needed to confirm efficacy and safety. Intrathecal therapy should be reserved for severe intractable pain and be effective on a long term basis (4-6 months or longer). Observation care should be considered during the preliminary trial administration period.

Clinical evaluations and patient care for intrathecal drug delivery into the intrathecal space should also address (at the discretion of the physician and according to prevailing standards of medical care) no acute spinal cord compression, local spinal or paraspinal malignancy, coagulopathy, use of anticoagulants or antiplatelet therapy or local or systemic infection. Selected body imaging evaluations to evaluate the area of pain, particularly for acute pain, or to evaluate escalations in chronic baseline pain should be considered.

The Food and Drug Administration (FDA) and Institute for Safe Medication Practice (ISMP) has reported problems with intrathecal pumps. Some models of this device have two ports; one port refills the reservoir and the second one is used for removing CSF or myelography and leads directly into the intrathecal catheter. Documented accidents occurred when an injected drug refill intended for the reservoir was accidentally injected into the intrathecal catheter access port. The patient received a massive overdose. The ISMP points out that a manufacturer’s template map is mistakenly used to try to locate the reservoir, the medication could be injected directly into the catheter, and then into the intrathecal space.

The relative potency intrathecal morphine is 10 times greater than epidural morphine, and 100 times greater than intravenous (IV) morphine on a milligram basis. High-dose oral or parenteral morphine is complicated by high plasma concentrations of the principal metabolite, non-analgesic morphine-3-glucuronide (M3G), that exceed those of the parent drug by 10-fold after IV dosing and by 20-fold after oral dosing. A washout of morphine metabolites occurs in the cerebrospinal fluid (CSF) following conversion from systemic to IV morphine, thereby clearing central nervous system (CNS) concentrations of neuro-excitatory metabolite substrates that may cause hyperalgesia, myoclonus, or seizures.

No systematic review has identified a Randomized Controlled Trial (RCT) of implantable pain pumps using opioids in chronic non-cancer pain (CNCP); yet despite such lack of evidence, the devices are commonly used for patients with CNCP. In contrast, there is an RCT for ziconotide, and an FDA drug registry of RCTs available for implantable pain pumps using ziconotide for CNCP. Case reports, open label series and anecdotes are numerous for opioid pumps in CNCP, but no RCT validates their safety and efficacy.

Chronic intrathecal opioids infused via implantable pumps provide satisfactory pain relief for patients who suffer from intractable cancer pain. Outcomes show patients are less dependent on hospital services, thereby improving the quality of their lives. However, reductions in pain and improvements in function are less pronounced in those with pain of a non-malignant origin.

Professional Society Recommendations:
The following professional society's recommendations are derived from the latest guidelines and scientific based literature available.

American College of Physicians (ACP) & American Pain Society (APS) (October 2007)
Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society.

- Clinicians should conduct a focused history and physical examination to help place patients with low back pain into 1 of 3 broad categories: nonspecific low back pain, back pain potentially associated with radiculopathy or spinal stenosis, or back pain potentially associated with another specific spinal cause. The history should include assessment of psychosocial risk factors, which predict risk for chronic disabling back pain;
- Clinicians should not routinely obtain imaging or other diagnostic tests in patients with nonspecific low back pain;
- Clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination;
- Clinicians should evaluate patients with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis with magnetic resonance imaging (preferred) or computed tomography only if they are potential candidates for surgery or epidural steroid injection;

- Clinicians should provide patients with evidence-based information on low back pain with regard to their expected course, advise patients to remain active, and provide information about effective self-care options;
- For patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks,
- and relative lack of long-term efficacy and safety data before initiating therapy. For most patients, first-line medication options are acetaminophen or nonsteroidal anti-inflammatory drugs; and
- For patients who do not improve with self-care options, clinicians should consider the addition of nonpharmacological therapy with proven benefits—for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation.

American College of Physicians (ACP) (April 2017)

The ACP's recommendations for Noninvasive Treatments for Acute, Subacute and Chronic Low Back Pain: A Clinical Practice Guideline are as follows:

- Clinicians and patients should select nonpharmacological treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). If pharmacologic treatment is desired, clinicians and patients should select nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants (moderate-quality evidence);
- Clinicians and patients should initially select nonpharmacological treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction, tai chi, yoga, motor control exercise, progressive relation, electromyography biofeedback, low –level laser therapy, operant therapy, cognitive behavioral therapy or spinal manipulation; and
- In patients with chronic low back pain who have had an inadequate response to nonpharmacological therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients.

American Society of Anesthesiologists (ASA) (2010)

The ASA Task Force on Pain Management issued general practice guidelines for chronic pain management in 2010 as follows:

- Epidural steroid injections with or without local anesthetics may be used as part of a multimodal treatment regimen to provide pain relief in selected patients with radicular pain or radiculopathy; and
- Transforaminal epidural injections should be performed with appropriate image guidance to confirm correct needle position and spread of contrast before injecting a therapeutic substance.

American Society of Clinical Oncology (ASCO) (2016)

The ASCO issued new guidelines on chronic pain management in adult cancer survivors in 2016 as follows:

- Clinicians should screen for pain at each encounter with a patient. Recurrent disease, second malignancy or late onset treatment effects should be evaluated, treated and monitored;
- Clinicians may prescribe non-pharmacologic interventions such as physical medicine and rehabilitation, integrative therapies (e.g., acupuncture and massage), interventional therapies, and psychological approaches (e.g., guided imagery, hypnosis, and meditation);
- Systemic non-opioid analgesics (NSAIDS, acetaminophen) and adjuvant analgesics (selected antidepressants and anticonvulsants), may be prescribed to relieve chronic pain and/or improve physical function;
- Clinicians should assess the risk of adverse effects of opioids used in pain management and incorporate universal precautions to minimize abuse, addiction and adverse consequences; and
- Clinicians may follow specific state regulations that allow access to medical cannabis or cannabinoids for patients with chronic pain after considering the potential benefits and risks of the available formulations.

C. Definitions

- **Implantable Pain Pump** - Implantable pain pumps are medical devices which are inserted subcutaneously to deliver drugs for infusion through intrathecal catheters. Implantable pain pumps allow drug delivery directly to specific sites and can be programmed for continuous or variable rates of infusion.
- **Conservative Therapy** - is a multimodality plan of care. Multimodality care plans include ALL of the following:
  - **Active Conservative Therapies** - such as physical therapy, occupational therapy, a physician supervised home exercise program (HEP) or chiropractic care.
    - **Home Exercise Program (HEP)** - includes two components that are both required to meet CareSource policy for completion of conservative therapy:
      - An exercise prescription and/or plan documented in the medical record.
      - A follow up documented in the medical record regarding completion of a HEP (after suitable six (6) week period), or inability to complete a HEP due to a stated physical reason i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete”).
  - **Passive Conservative Therapies** - such as rest, ice, heat, medical devices, , TENS unit and prescription medications.
    - If a TENS unit is part of the care plan, the frequency of use, and duration of use with dates must be documented in the medical record. General statements in the medical record such as “Patient has a TENS unit” do not document use, and will not suffice to meet this policy criterion.
- **Transcutaneous Electrical Nerve Stimulator (TENS Unit)** - is a durable medical equipment device dispensed by prescription. It use, frequency, duration, and start dates must be documented in the medical record to be considered part of conservative therapy during the period of prior authorization request.

D. Policy

I. Prior authorization is required for all implantable pain pumps, including trial administration, permanent placement and single shot intrathecal injections for the treatment of severe chronic intractable pain of malignant or non-malignant origin. Prior authorization is also required for the removal or revision of the implanted device. Implantable pain pumps are conisered medically necessary when ALL of the following are met:
   A. Attempts to ameliorate physical and behavioral abnormalities which may cause an exaggerated reaction to pain have failed.
   B. The medication must require administration through the intrathecal route and be effective on a long term basis.
   C. The infusion pump has been approved by the FDA for infusion of the particular drug that is to be administered.
   D. The type and dosage of the medication must reasonably be expected to alleviate or reduce the pain.
   E. Implantation is performed by a physician, and in a facility with experience and expertise in this procedure.
   F. An evaluation by an orthopedic surgeon, neurologist, neurosurgeon, oncologist, pain management physician or other specialist familiar with the underlying disease is required to validate that other treatments have failed to alleviate the pain.

II. Prior authorizations are not required for the following services:
   A. Electronic analysis/studies post implantation; and
   B. Refilling of implanted device.

III. CareSource considers a preliminary trial for implantable pain pumps medically necessary for severe chronic intractable pain of malignant origin when the following criteria are met:
   A. Life expectancy of at least three (3) months.
   B. Proven unresponsive to less invasive medical therapy as documented in the patient's medical record and available upon request, including:
      1. Oral or subcutaneous medication (including systemic opioids) treatment was ineffective or complicated by side effects.
   C. There is no evidence of tumor encroachment on the thecal sac or epidural metastatic lesions.
   D. There are no contraindications evident, including:
      1. Local infection;
      2. Sepsis; and
      3. Coagulopathy.

IV. CareSource considers a permanently placed implantable pain pump medically necessary for severe chronic intractable pain of malignant origin when the patient has met ALL of the criteria above (III. A. B. C. and D.) and has achieved at least a 50% reduction in pain documented in the medical record.

V. CareSource considers a preliminary trial for implantable pain pumps medically necessary for severe chronic intractable pain of non-malignant origin when the following criteria are met:
   A. A one (1) to two (2) day observation stay is required for a preliminary trial of spinal opioid drug administration.
   B. Pain pathology has been identified.
   C. There is no evidence of current drug and/or alcohol abuse, including:
      1. No opioid disorder or addiction
      2. Documentation in the medical record indicating at least one negative drug test result performed within the last three (3) months.
   D. Psychological evaluation has been performed and confirms pain is not due to mental health causes.
   E. Surgical intervention is not indicated.
   F. Proven unresponsive for at least six (6) months to less invasive medical therapy as documented in the patient's medical record, including ALL of the following:
      1. Oral or subcutaneous medication (including systemic opioids) treatment was ineffective or complicated by side effects.
      2. ACTIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record that includes at least ONE (1) of the following**:**
         a. The patient has received ACTIVE conservative therapy lasting for six (6) months or more within the past twelve (12) months including ONE (1) of the following:
            01. Physical therapy;
            02. Occupational therapy;
            03. A physician supervised home exercise program (HEP) as defined in this policy; or
            04. Chiropractic care.
            OR
      3. The medical record documents at least ONE (1) of the following exceptions to the conservative therapy requirement, if within the past 6 months:
         a. Severe pain with significant functional loss at work or home;
         b. Severe pain unresponsive to outpatient medical management;
         c. Severe pain unresponsive to interventional pain procedures: include dates, descriptions, responses, side effects;
         d. Inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s); or
         e. Prior successful implantable pain pump function for the same specific condition with relief of at least 6 months' duration.
            01. Device interrogation reports with interpretation reports in the medical records must be acquired within a minimum 3 months of a prior authorization request and must be submitted with each prior authorization request, and justify replacement of any component of an implantable pain pump.
      4. PASSIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record lasting for six (6) months or more within the past twelve (12) months that includes at least ONE (1) of the following**:**
         a. Rest;

b. Ice;
c. Heat;
d. Medical devices;
e. TENS unit use as defined in CareSource policy; or

f. Pain medications (RX or OTC) such as: non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen. Opioid narcotics are not required for consideration.

VI. CareSource considers a permanently placed implantable pain pump medically necessary for severe chronic intractable pain of non-malignant origin when the patient has met ALL of the criteria above (V. A. B. C. D. E. and F.) and has achieved at least a 50% reduction in pain documented in the medical record.

VII. Implantable infusion pumps are not medically necessary for members with the following contraindications:
A. Active infection
B. Insufficient body size to support the bulk and weight of the device
C. Known allergy or hypersensitivity to the drug selected for pump use
D. Presence of other implanted programmable devices that may result in miscommunication between the devices impacting pump function.
1. For example, patients who have another implanted device, such as a cardiac pacemaker (due to lack of research in patients with other implanted devices).

VIII. Exclusions: Intrathecal or Epidural Infusion of Opioids, Ziconotide and Clonidine
A. Treatment for gastroparesis; and
B. All other indications.

E. Conditions of Coverage

F. Related Polices/Rules

Implantable Pain Pump PY-1068

G. Review/Revision History

	DATE	ACTION
Date Issued	05/01/2019	
Date Revised	06/10/2020 08/26/2020	Annual Update: Addition of PA non-requirement criteria in section II. A. B. and C. revision of 1-2 day *inpatient* stay to *observation* stay. PA is now required for removal/revision of the implanted device.
Date Effective	01/01/2021	
Date Archived	12/31/2021	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy

H. References

1. Intrathecal Opioids for Chronic Noncancer Pain. (2014, March 27). Retrieved March 19, 2019, from www.hayesinc.com
2. Portenoy, R. K. (2017, December 20). Cancer Pain Management: Interventional therapies. Retrieved March 24, 2019, from www.uptodate.com
3. Smith, T. J., & Staats, P. S. (2002). Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: Impact on pain, drug-related toxicity and survival. Retrieved March 23, 2019 from www.pubmed.ncbi.nlm.nih.gov
4. Smith, T. J., & Staats, P. J. (2005). An implantable drug delivery system (IDDS) for refractory cancer pain provides sustained pain control, less drug-related toxicity, and possibly better survival compared with comprehensive medical management (CMM). Retrieved on March 23, 2019 from www.ncbi.nlm.nih.gov
5. D. Paul, K. M. Standifer, C. E. Inturrisi, and G. W. Pasternak, "Pharmacological characterization of morphine-6 beta-glucuronide, a very potent morphine metabolite," (1989, Nov).Retrieved on June 5, 2020 from from www.ncbi.nlm.nih.gov
6. J. Sawe, "High-dose morphine and methadone in cancer patients. Clinical pharmacokinetic considerations of oral treatment". Retrieved on June 5, 2020 from from www.ncbi.nlm.nih.gov
7. M. T. Smith, A. W. Wright, B. E. Williams, G. Stuart, and T. Cramond, (1999, Jan). "Cerebrospinal fluid and plasma concentrations of morphine, morphine-3-glucuronide, and morphine-6-glucuronide in patients before and after initiation of intracerebroventricular morphine for cancer pain management ". Retrieved on June 5, 2020 from from www.ncbi.nlm.nih.gov
8. J. A. Turner, J. M. Sears, and J. D. Loeser, (2001, Feb). "Programmable intrathecal opioid delivery systems for chronic noncancer pain: a systematic review of effectiveness and complications," Retrieved on June 5, 2020 from from www.ncbi.nlm.nih.gov
9. R. N. Harden, C. E. Argoff, and D. A. Williams, 2014, Nov), "Intrathecal opioids for chronic pain: a call for evidence," Retrieved on June 5, 2020 from from www.ncbi.nlm.nih.gov
10. R. L. Rauck, M. S. Wallace, M. S. Leong, M. MineHart, L. R. Webster, S. G. Charapata*, et al.*, (2006) "A Randomized, Double-Blind, Placebo-Controlled Study of Intrathecal Ziconotide in Adults with Severe Chronic Pain," Retrieved on June 5, 2020 from from www.ncbi.nlm.nih.gov
11. G. Bennett, M. Serafini, K. Burchiel, E. Buchser, A. Classen, T. Deer*, et al.*, (2000) "Evidence-Based Review of the Literature on Intrathecal Delivery of Pain Medication," *Journal of Pain and Symptom Management,* vol. 20, pp. S12-S36, 2000 2000. Retrieved on June 5, 2020 from from www.ncbi.nlm.nih.gov

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review: 5/2019