MEDICAL POLICY STATEMENT
OHIO MEDICAID

Policy Name		Policy Number	Date Effective
Implantable Pain Pump		MM-0077	10/01/2021-08/31/2022
Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

Medical Policy Statement prepared by CareSource and its affiliates 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 CareSource and its affiliates 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.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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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) (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 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.
- **Terminal Condition** - means an irreversible, incurable, and untreatable condition that is caused by disease, illness, or injury and will likely result in death. A terminal condition is one in which there can be no recovery, although there may be periods of remission.
- **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.
  - **Inactive Conservative Therapies** - such as rest, ice, heat, medical devices, acupuncture, TENS unit and prescription medications.
- **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. CareSource considers all implantable pain pumps, including trial administration, permanent placement, single shot intrathecal injections and removal and revision of the implanted device medically necessary when all of the clinical criteria in this policy are met. Medical necessity review is NOT required when the drug is prescribed under one of the following circumstances:

A. To an individual who is a hospice patient in a hospice care program;

B. To an individual who has been diagnosed with a terminal condition but is not a hospice patient in a hospice care program; and
C. To an individual who has cancer or another condition associated with the individual's cancer or history of cancer.

II. CareSource considers implantable pain pumps, including trial administration, permanent placement and single shot intrathecal injections for the treatment of severe chronic intractable pain of non-malignant origin 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.

III. 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), including the following two requirements:

(1) An exercise prescription and/or plan documented in the medical record;
(2) A follow up documented in the medical record regarding completion of an 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").

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 six (6) months duration.
      01. Device interrogation reports with interpretation reports in the medical records must be acquired within a minimum three (3) months of a medical necessity review and must be submitted with each medical necessity review and justify replacement of any component of an implantable pain pump.
4. INACTIVE 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. Acupuncture;
   f. TENS unit use as defined in CareSource policy; or
      01. 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" does not document use, and will not suffice to meet this policy criterion.
   g. Pain medications (RX or OTC) such as: non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen. Opioid narcotics are not required for consideration.

IV. 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 (III. A. B. C. D. E. and F.) and has achieved at least a 50% reduction in pain documented in the medical record.

V. Implantable infusion pumps are not medically necessary for members with any of 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; or
   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).

VI. Exclusions:
   A. An intrathecal or epidural drug infusion of Opioids, Ziconotide and Clonidine is considered investigational for all other indications outside of this policy.

E. Conditions of Coverage

NA

F. Related Polices/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	07/26/2016	
Date Revised	04/17/2019 07/08/2020 08/26/2020 05/26/2021	Added criteria requirements in sections D. Policy I. – VI. Annual Update: Addition of PA non-requirement criteria in sections D. I. and II; revision of 1-2 day *inpatient* stay to *observation* stay; removal of coverage for pain of a malignant origin. PA is now required for removal/revision of the implanted device. Annual Update: Removed PA language; added *Terminal Condition* definition.
Date Effective	10/01/2021	
Date Archived	08/31/2022	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

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12. Ohio Revised Code. ORC 1751.691 (2017, April 6) Prior authorization requirments or other utlilzation review measures as conditions of providing coverage of an opioid analgesic. Retrieved on May 17, 2021 from codes.ohio.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