MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
Implantable Pain Pump-OH MCD-MM-0077	09/01/2022-02/28/2023
Policy Type	
MEDICAL	

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 a multifaceted condition with many etiologies that can severely impact an individual's quality of life, with an estimated prevalence as high as 40% in adults in the United States. Comprehensive pain management care plans are most effective in managing a patient's chronic pain. These plans focus on a person-centered approach and incorporate conservative treatment with other modalities. These multidisciplinary treatments include promoting self-management and aim to reduce the impact of pain on a patient's daily life, even if the pain cannot be relieved completely. In addition to conservative therapy, additional treatment options may include nonpharmacologic or pharmacologic treatments, nonsurgical interventions and surgical interventions. Interventional procedures for the management of pain unresponsive to conservative therapy should be provided only by physicians qualified to deliver these health services.

Implantable pain pumps may be a treatment option for individuals experiencing severe chronic pain that is refractory to medical management. Most commonly used in individuals with cancer-related pain, these devices deliver prescription medication through subcutaneous infusion with an intrathecal catheter. Their use should be evaluated for appropriateness by a specialist based on the patient's medical status, care goals, cost, and the availability of family and professional support. When patients with chronic pain are treated with intrathecal therapy, recent studies indicate success in pain reduction with improved outcomes in analgesic therapy, reduced toxicity, and increased survival.

While 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, adverse events have occurred 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 to 6 months or longer). Patients should be carefully monitored during the preliminary trial period. The Food and Drug Administration (FDA) and Institute for Safe Medication Practice (ISMP) have reported problems with intrathecal pumps. Due to device design, accidents have occurred where an injected drug refill intended for the reservoir was accidentally injected into the intrathecal catheter access port, causing an overdose. The relative potency of intrathecal morphine is 10 times greater than epidural morphine, and 100 times greater than intravenous (IV) morphine on a milligram basis.

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.

C. Definitions

- **Chronic Pain** - Pain that persists beyond normal healing time, lasting or recurring for more than three months.
- **Conservative Therapy** - A multimodality plan of care. Multimodality care plans include both active and inactive conservative therapies.
  - **Active Conservative Therapies** - Include physical therapy, occupational therapy, a physician supervised home exercise program (HEP), and/or chiropractic care.
  - **Inactive Conservative Therapies** - Include rest, ice, heat, medical devices, acupuncture, TENS units, and/or prescription medications.
- **Implantable Pain Pump** - A medical device implanted under the skin that delivers medication intrathecally using a pump and catheter. Medication can be added to the refillable pump for a continuous or variable rate (e.g., bolus) of infusion.
- **Terminal Condition** - An incurable condition caused by disease, illness, or injury from which there is no reasonable medical probability of recovery and which can be expected to cause death.
- **Transcutaneous Electrical Nerve Stimulator (TENS Unit)** - 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. **Medical necessity review is NOT required** when the implantable pain pump and 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;
   C. To an individual who has cancer or another condition associated with the individual's cancer or history of cancer.

II. **Medical necessity is required for all other circumstances**. CareSource considers all implantable pain pumps, including trial administration, permanent placement and single shot intrathecal injections, and removal or revision of the implanted device medically necessary for the treatment of severe chronic intractable pain of **non-malignant origin** when **ALL** the following clinical criteria in this policy 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 FDA-approved for pain management;
   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 other treatments have failed to alleviate the pain.

III. CareSource considers a **preliminary trial** (1-2 days) for implantable pain pumps medically necessary for severe chronic intractable pain of **non-malignant origin** when **ALL** the following criteria are met:
   A. Pain has persisted for at least six months;
   B. A 1- to 2-day observation stay is required for a preliminary trial of spinal opioid drug administration;
   C. Pain pathology has been identified;
   D. 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 3 months;
   E. Psychological evaluation has been performed and confirms pain is not due to mental health causes;
   F. Surgical intervention is not indicated;
   G. Proven unresponsive to less invasive medical therapy for at least six months as documented in the patient's medical record, including **ALL** 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 **ONE** of the following**:**
         a. The patient has received ACTIVE conservative therapy lasting for at least 6 months within the past 12 months including **at least ONE** 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 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
         b. The medical record documents **at least ONE** of the following exceptions to the conservative therapy requirement, if within the past 6 months:
            01. Severe pain with significant functional loss at work or home;
            02. Severe pain unresponsive to outpatient medical management;

03. Severe pain unresponsive to interventional pain procedures: include dates, descriptions, responses, side effects;
04. Inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s); or
05. Prior successful implantable pain pump function for the same specific condition with relief of at least 6 months duration. Device interrogation reports with interpretation reports in the medical records must be acquired within a minimum 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;

3. 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 6 months or more within the past 12 months that includes **at least ONE** of the following**:**
   a. Rest;
   b. Ice;
   c. Heat;
   d. Medical devices;
   e. Acupuncture;
   f. TENS unit use as defined in CareSource policy;
      01. 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 (prescription or over the counter) (e.g., 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** the criteria above (III. A. B. C. D. E. F. and G.) 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. Prior intolerance to implanted devices.
   D. Spinal column structure that stops cerebrospinal fluid from flowing freely or will not allow for intrathecal medicine delivery.
   E. Known allergy or hypersensitivity to the drug selected for pump use.
   F. Known or suspected allergy to a component of the implantable pain pump.
   G. Presence of other implanted programmable devices that may result in miscommunication between the devices impacting pump function (e.g., 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/or 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	Added criteria requirements in sections D. Policy I.–VI.
	07/08/2020	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.
	08/26/2020	PA is now required for removal/revision of the implanted device.
	05/26/2021	Annual Update: Removed PA language; added *Terminal Condition* definition.
	05/11/2022	Annual Review: updated background, references, contraindications, re-organized criteria, defined chronic pain
Date Effective	09/01/2022	
Date Archived	02/28/2023	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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Independent medical review – 05/2019