MEDICAL POLICY STATEMENT
Arkansas PASSE

Policy Name & Number	Date Effective
Implantable Pain Pump-AR PASSE-MM-1502	08/01/2023
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. Comprehensive pain management care plans are most effective in managing chronic pain. These plans focus on the individual and incorporate conservative treatment with other modalities. These multidisciplinary treatments include promoting self-management and reducing the impact of pain on a person's daily life, even if the pain cannot be relieved completely. In conjunction with conservative therapy, additional pharmacological, nonsurgical, and surgical treatment options may be implemented. Interventional procedures for the management of refractory pain should only be performed by physicians qualified to deliver these treatments.

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, location and type of pain, life expectancy, and the availability of family and professional support. Studies on intrathecal therapy for chronic pain demonstrate increased cost-savings, quantifiable pain reduction at lower medication doses, reduced toxicity, increased survival, and reduced opioid diversion risk.

Intrathecal therapy should be reserved for cancer patients with a life expectancy of at least several months and be experiencing severe refractory pain or intolerable side effects from systemic treatments. Intrathecal therapy should be reserved for use in non-cancer chronic pain that is refractory to conventional and minimally invasive treatment. Prior to insertion of an implantable pain pump, trialing the infusion can assist in evaluating dosage for pain reduction, tolerability, and side effects.

The FDA has approved morphine and ziconotide as monotherapy for intrathecal infusion. Guidelines developed by the Polyanalgesic Consensus Conference help assist practitioners for safe and effective use in both malignant and non-cancer chronic pain. Implantable pain pumps are not without risk, which can be divided into separate categories: hardware malfunction, procedural-related complication, and medication-associated complication.

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 including both active and inactive conservative therapies.
    - **Active Conservative Therapies** - Actions or activities that strengthen muscle groups and target key spinal structures, including physical therapy, occupational

therapy, physician supervised home exercise program (HEP), and/or chiropractic care.
    - **HEP** - A six-week program requiring an exercise prescription and/or plan and a follow-up documented in the medical record after completion, or documentation of the inability to complete the 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 an inability to complete.
  - **Inactive Conservative Therapies** - Passive activities by the patient that aid in treating symptoms associated with pain, including rest, ice, heat, medical devices, TENS use, and/or pharmacotherapy (prescription or over the counter [e.g., non-steroidal anti-inflammatory drugs, acetaminophen]).
    - **Transcutaneous Electrical Nerve Stimulator (TENS)** - A device that utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins. Its 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.
- **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.
- **Refractory Pain** - Failure of multiple treatment therapies to reach adequate pain reduction and/or improvement in daily function **AND** psychiatric and psychosocial factors that could influence pain outcomes have been assessed and optimized.

D. Policy
  I. CareSource considers 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 malignant or 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.

II. CareSource considers a **preliminary trial** (1-2 days) for implantable pain pumps medically necessary for severe chronic intractable pain of **malignant origin** when **ALL** the following criteria are met:
   A. Life expectancy of at least 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 any of the following:
      1. Local infection;
      2. Sepsis;
      3. Coagulopathy.

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

IV. CareSource considers a **preliminary trial** 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. Oral or subcutaneous medication (including systemic opioids) treatment was ineffective or complicated by side effects;
   H. Failure of conservative therapy, as evidenced by **ALL** the following:
      1. Documentation in the medical record of at least 6 months of active conservative therapy (see definition above) within the past 12 months OR inability to complete active conservative therapy due to contraindication, increased pain, or intolerance;
      2. Documentation in the medical record of at least 6 months of inactive conservative therapy (see definition above) within the past 12 months;

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

VI. 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]).

VII. Exclusions
   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 Policies/Rules
NA

G. Review/Revision History

	DATE	ACTION
Date Issued	04/26/2023	New policy. Approved at Committee
Date Revised		
Date Effective	08/01/2023	
Date Archived		

H. References
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