MEDICAID POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
07/26/2016	07/26/2017	07/26/2016

Policy Name	Policy Number
Implantable Pain Pumps	MM-0077

Policy Type		
☒ Medical	☐ Administrative	☐ Payment

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A. SUBJECT

Implantable Pain Pumps

B. BACKGROUND

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.

C. DEFINITIONS

- **Conservative therapy** is a multimodality plan of care. Start and end dates in the medical record substantiate duration of treatment. **Multimodality care plans include BOTH 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:
    - Information provided for an exercise prescription and/or plan documented in the medical record AND follow up documented in the medical record with member with information provided regarding completion of HEP, or inability to complete 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”)

- **Inactive conservative therapies** such as rest, ice, heat, medical devices, acupuncture, TENS unit, 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.

- A **TENS unit is a Transcutaneous Electrical Nerve Stimulator,** 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

Criteria

Drugs for treatment of chronic intractable pain

A prior authorization is required for each proposed preliminary trial injection and for each proposed placement of an Implantable Infusion Pain Pump for pain management.

I. CareSource considers a preliminary trial of spinal (epidural or intrathecal) administration of opioid drugs (e.g., morphine), ziconotide (Prialt), and/or clonidine as medically necessary for members with severe chronic intractable pain of malignant or non-malignant origin that is unresponsive to less invasive medical therapy and **ALL of the following criteria** are met:

A. The member's history must indicate that he or she has not responded adequately to injection and non-injection non-invasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain) and conservative therapy is documented in the contemporaneous medical record including **ONE of the following criteria**:

1. For cancer-related chronic pain, the request includes ALL of the following
   1.1 Life expectancy of greater than 3 months
   1.2 the patient has received conservative therapy lasting for six (6) months prior to the request with start and end dates in the medical record substantiating the duration of treatment, and basis for medically refractory pain, as defined by "Conservative therapy" in the Definitions section of this policy including **BOTH of the following**:
      a. Active therapies contain one of the following
         (1) Interventional pain therapies, dates, description, responses, side effects
      b. Passive conservative therapies contain one of the following
         (1) Prescription pain medications, including dates, quantities, responses, side effects
2. For patients with non-cancer chronic pain, the patient has received conservative therapy lasting for twelve (12) months prior to the request with start and end dates in the medical record substantiating the duration of treatment, and basis for medically refractory pain, as defined by "Conservative therapy" in the Definitions section of this policy including **BOTH of the following**
   2.1 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 of the following:**
      a. The patient has received ACTIVE conservative therapy lasting for six (6) MONTHS or more within the past twelve (12) months with start and end dates in the medical record substantiating the duration of treatment including **ONE of the following:**
         (1) physical therapy
         (2) occupational therapy

(3) a physician supervised home exercise program (HEP) as defined in CareSource policy
(4) chiropractic care

b. Or, the medical record documents at least **ONE of the following** exceptions to the conservative therapy requirement if, within the past 6 months the patient has conditions which may include:
(1) severe pain with significant functional loss at work or home
(2) severe pain unresponsive to outpatient medical management
(3) severe pain unresponsive to interventional pain procedures: include dates, descriptions, responses, side effects
(4) inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s)
(5) Prior successful implantable pain pump function for same specific condition with relief of at least 6 months' duration (start and end dates are documented in the medical record). 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

2.2 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 with start and end dates in the medical record substantiating the duration of treatment 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
g. prescription pain medications

II. A 1 to 2 day inpatient stay is considered medically necessary for a preliminary trial of spinal opioid drug administration.

III. CareSource considers an implantable infusion pump as medically necessary when used to administer opioid drugs (e.g., morphine), ziconotide (Prialt), and/or clonidine intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or non-malignant origin in members who meet **ONE of the following** criteria:
A. For cancer-related pain, a preliminary trial of spinal (epidural or intrathecal) opioid drug administration with a temporary intrathecal/epidural catheter has substantiated adequately acceptable pain relief with a 50 percent reduction in pain, and an acceptable degree of side effects (including effects on the activities of daily living), and acceptance by the member.
B. For chronic non-cancer pain (CNCP), a preliminary trial of spinal (epidural or intrathecal) opioid drug administration with a temporary intrathecal/epidural catheter has substantiated adequately acceptable pain relief with a 50 percent reduction in pain, and an acceptable degree of side effects (including effects on the activities of daily living), and acceptance by the member; and
1. a psychological evaluation has been obtained and indicates that the individual is a favorable candidate for permanent intrathecal pump implantation and
2. Patient is not an active abuser of chemicals or chemically dependent; psychological

assessment details the member's substance abuse history and medical records include a urine drug test toxicology results performed within the past 3 months prior to the date of the prior authorization request

NOTE: CareSource considers Implantable infusion pumps for intrathecal or epidural infusion of opioids, ziconotide, and clonidine as experimental and investigational as a treatment for gastroparesis and for all other indications because safety and efficacy for indications other than the listed above have limited data and/or above has not been established.

IV. CareSource considers implanted infusion pumps as medically necessary durable medical equipment (DME) when **ALL** of the following criteria are met:
   A. It is medically necessary that the drug be administered by an implanted infusion pump; and
   B. The infusion pump has been approved by the FDA for infusion of the particular drug that is to be administered. . Examples of FDA-approved implantable infusion pumps include Codman 3000, InfusAid Pump. MedStream Programmable Infusion System, Prometra Programmable Infusion Pump System, SynchroMed Infusion System, and SynchroMed II.
   C. Implantation of intrathecal pumps should be done by a physician and in a facility with experience and expertise in this procedure.
   D. Contraindications to implantable infusion pumps
   E. Implantable infusion pumps are considered not medically necessary for members with the following selected contraindications to implantable infusion pumps:
   F. Active infection that may increase the risk of the implantable infusion pump; or
   G. Body size of the member is insufficient to support the weight and bulk of the device; or
   H. Known allergy or hypersensitivity in the member to the drug being used (e.g., morphine, etc.); or
   I. Members with other implanted programmable devices where the crosstalk between devices may inadvertently change the prescription. For example, patients who have another implanted device, such as a cardiac pacemaker (due to lack of research in patients with other implanted devices).

<u>Experimental and investigational uses of implanted infusion pumps</u>
Implanted infusion pumps are considered experimental and investigational for all other indications, including any of the following:
Implantable pumps for *the infusion of baclofen for chronic neuropathic pain* (e.g., complex regional pain syndrome/reflex sympathetic dystrophy).
This policy does not address implantable baclofen pumps.

<u>Precautions</u>
FDA and 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. 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 principal receptor targets for oral or intravenous systemic analgesic therapy with opioids are the endogenous opioid receptors in the central nervous system.[1, 2] When cancer pain is refractory to oral or intravenous systemic analgesic therapy, or side effects become prohibitive, additional options include spinal analgesia and neurosurgical interventions.[3] Profound analgesia is achieved by the receptor–

ligand interaction of exogenous opioid-binding receptors in the periventricular and periaqueductal regions of the brain, including from an intrathecal source at spinal access, due to continuous CSF circulation. Intrathecal injections and infusions are transmitted directly inside of the blood-brain barrier (BBB), unlike epidural injections, which are outside of the BBB. Morphine injected into the cerebrospinal fluid (CSF) maintains a steady state concentration 3 orders of magnitude higher than plasma levels.[4] The relative potency intrathecal morphine is 10 times greater than epidural morphine, and 100 times greater than intravenous (IV) morphine on a milligram basis.[5, 6] 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.[7] A washout of morphine metabolites occurs in the 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.[8]

A randomized, controlled trial (RCT) of implantable pumps using opioids in cancer pain showed modest efficacy. Sixty of 71 IDDS patients (84.5%) achieved clinical success compared with 51 of 72 CMM patients (70.8%, P = .05). Investigators also found that IDDSs improved clinical success in pain control, reduced pain, significantly relieved common drug toxicities, and improved survival in patients with refractory cancer pain.[9]

No systematic review has identified an RCT of implantable pain pumps using opioids in CNCP[10]; yet despite such lack of evidence, the devices are commonly used for patients with CNCP.[11] In contrast, there is an RCT for ziconotide,[12] 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[13], but no RCT validates their safety and efficacy.. Recently a small RCT with only 10 study patients and 5 controls evaluated all subjects who already had implanted intrathecal pumps, where controls had pump dose reductions in morphine doses to evaluate whether pain intensity would increase. Seven patients withdrew due to worsening pain. Authors concluded that due to the small number of patients completing the study (n=8), further studies are warranted.[14]

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. Over 20 years of experience with carefully selected patients with chronic non-cancer pain. However, reductions in pain and improvements in function are less pronounced than for cancer pain.

V. Clinical evaluations and care of candidate patients for epidural injections should also address, at the discretion of the physician, according to prevailing standards of medical care:
   A. No acute spinal cord compression
   B. No local spinal or paraspinal malignancy
   C. No coagulopathy
   D. No current use of anticoagulants or antiplatelet therapy
   E. No local or systemic infection
      1. Selected body imaging evaluations to evaluate the area of pain, particularly for acute pain, or to evaluate escalations in chronic baseline pain. Appropriate imaging to rule out red flag conditions may be indicated if potential issues of trauma, osteomyelitis or anatomic locations of malignancy or other diagnoses are a concern.

CONDITIONS OF COVERAGE
HCPCS
CPT

AUTHORIZATION PERIOD

I. RELATED POLICIES/RULES

J. REVIEW/REVISION HISTORY

Date Issued: 07/26/2016
Date Reviewed: 07/26/2016
Date Revised:

K. REFERENCES

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