Cigna Medical Coverage Policies – Musculoskeletal Implantable Intrathecal Drug Delivery Systems

Effective August 1, 2024

Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

CMM-210: Implantable Intrathecal Drug Delivery Systems

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Definitions

- **Ashworth Scale (AS):** a tool classify the degree of spasticity and muscle tone. The following represents the clinical description of spasticity in the muscle being evaluated:
  - **0**: No increase in tone
  - **1**: Slight increase in tone giving a catch when the limb is moved in flexion or extension
  - **2**: More marked increase in muscle tone, but limb easily flexed
  - **3**: Considerable increase in tone, passive movement difficult
  - **4**: Limb rigid in flexion or extension
- **Modified Ashworth Scale (MAS):** a tool classify the degree of spasticity and muscle tone. The following represents the clinical description of spasticity in the muscle being evaluated:
  - **0**: No increase in tone
  - **1**: Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is(are) moved in flexion or extension
  - **1+**: Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
  - **2**: More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
  - **3**: Considerable increase in tone, passive movement difficult
  - **4**: Limb rigid in flexion or extension
- **Penn Spasm Frequency Score (PSFS):** a measure that assesses an individual's perception of spasticity frequency. The following represents the spasm frequency scoring:
  - **0**: No spasm
  - **1**: Mild spasms induced by stimulation
  - **2**: Infrequent full spasms less than once per hour
  - **3**: Spasms occurring more than once per hour
  - **4**: Spasms occurring more than 10 times per hour
- **Implantable Intrathecal Drug Delivery System** (pain pump or baclofen pump)**:** a device used for the continuous infusion of a drug directly into the cerebrospinal fluid via a catheter placed in the intrathecal or epidural space. A pump is placed in the subcutaneous tissue of the abdomen and connected to the catheter. The pump reservoir holds the medication(s), and the pump is programmed to give a set dose of medication over time. For most individuals, it should be used as part of a program to facilitate restoration of function and return to activity, and not just for pain reduction. An intrathecal drug delivery trial can be accomplished by either a single intrathecal bolus injection or an intrathecal catheter infusion.

General Guidelines

Application of Guideline

- This guideline only applies to the use of an implantable intrathecal or epidural drug delivery system for **ANY** of the following conditions:
  - Non-malignant, chronic intractable pain (e.g., failed back surgery syndrome with low back pain and/or radicular pain, post-herpetic neuralgia, complex regional pain syndrome)
  - Severe, refractory spasticity or chronic intractable dystonia in individuals who are unresponsive to or cannot tolerate oral anti-spasticity agents (i.e., baclofen [Lioresal®])
  - Cancer-related pain
- This guideline does not apply to an implantable intrathecal or epidural drug delivery system for obstetrical or surgical epidural anesthesia use.
- The determination of medical necessity for the performance of an implantable intrathecal or epidural drug delivery system is always made on a case-by-case basis.

Injectates

- This guideline does not apply to an implantable intrathecal or epidural drug delivery system for the following: Spinraza, chemotherapy, neurolytic substances, antispasmodics, antibiotics, antivirals, biologics (e.g., platelet rich plasma, stem cells, amniotic fluid, etc.), or any other injectates that are not in scope of management.

Indications

Non-Malignant, Chronic Intractable Pain

Trial

- A trial with a percutaneous intrathecal or epidural drug delivery system for non-malignant chronic intractable pain is considered **medically necessary** when **ALL** of the following criteria have been met:
  - There is documented pathology of non-malignant, chronic intractable pain (e.g., failed back surgery syndrome with low back pain and/or radicular pain, post-herpetic neuralgia, complex regional pain syndrome)
  - There has been a failure of at least six (6) months of non-invasive pain management that includes **BOTH** of the following (unless there is a documented contraindication):
    - Active rehabilitative exercises
    - A fixed schedule dosing of opioids or other analgesics
  - Further surgical intervention or other treatment is not indicated or likely to be effective

- An attestation from a primary care physician, neurologist, physiatrist, psychiatrist, psychologist, or other licensed behavioral and/or medical health care provider (i.e., face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of inadequately controlled mental and/or behavioral health conditions/issues (e.g., substance use disorders, depression, or psychosis) as a major contributor to chronic pain
- Individual agrees to a 50% reduction in systemic opioids prior to undergoing an intrathecal opioid trial

Permanent

- A permanent implantable intrathecal or epidural drug delivery system for non-malignant chronic intractable pain is considered **medically necessary** when **BOTH** of the following criteria have been met:
  - The above criteria for a trial of intrathecal or epidural opioid administration has been met
  - During an appropriate trial there is documentation of **BOTH** of the following:
    - There has been >50% reduction in pain for eight (8) hours
    - There has been a concomitant increase in function

Severe, Refractory Spasticity/Chronic Intractable Dystonia

Trial

- A trial with a percutaneous intrathecal drug delivery system for severe, refractory spasticity or chronic intractable dystonia is considered **medically necessary** for **EITHER** of the following clinical scenarios:
  - There is documentation that the individual is unresponsive, cannot tolerate, or has a contraindication to at least a six (6) week trial of **BOTH** of the following:
    - Oral antispasmodic drugs (i.e., baclofen [Lioresal®])
    - Physical therapy
  - Individual has **BOTH** of the following (as defined in **Definitions**):
    - A baseline average Ashworth score of at least 3 (or a Modified Ashworth score of 2)
    - A Spasm Frequency score of at least 2

Permanent

- A permanent implantable intrathecal or epidural drug delivery system for the treatment of severe, refractory spasticity or chronic intractable dystonia is considered **medically necessary** when **ALL** of the following criteria have been met:
  - The above criteria for a trial of intrathecal antispasmodic drug administration has been met
  - The trial resulted in a beneficial clinical response including, but not limited to, **EITHER** of the following:
    - At least a 2-point reduction in the Ashworth Score or Modified Ashworth Score for four (4) hours following an intrathecal trial bolus of Bbclofen
    - At least a 2-point reduction in the Spasm Frequency Score for four (4) hours following an intrathecal trial bolus of baclofen

Cancer-Related Pain

Trial

- A trial with a percutaneous intrathecal or epidural drug delivery system for cancer-related pain is considered **medically necessary** when there is failure, intolerance or contraindication to non-invasive methods of pain control including systemic opioids.

Permanent

- A permanent implantable intrathecal or epidural drug delivery system for cancer-related pain is considered **medically necessary** if the individual has met the above criteria for a preliminary trial and has experienced at least a 50% reduction in pain during an appropriate trial.
  - **Criteria exception:** A trial with a percutaneous intrathecal or epidural drug delivery system for cancer-related pain is not required in the presence of advanced disease, when survival time is limited, and when the individual is considered high-risk for procedures.

Replacement

- Replacement of an implanted intrathecal or epidural drug infusion system is considered **medically necessary** for **ANY** of the following:
  - The existing device is documented to be nearing end of battery life
  - The existing device will no longer be functional and cannot be repaired
  - A built-in device component provides notification of impending failure

Non-Indications

Not Medically Necessary

- An implantable intrathecal or epidural drug delivery system (trial, permanent, or replacement) placed without meeting the criteria listed in the **Definitions**, the **General Guidelines**, and the **Indications** sections is considered **not medically necessary**.
- An intrathecal or epidural drug delivery system is considered **not medically necessary** for **ANY** other indication
- Replacement of an implantable intrathecal infusion pump when the existing infusion pump and/or components remain functional is considered **not medically necessary**.

Procedure (CPT®) Codes (CMM-210)

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

CPT®	Code Description/Definition
62320	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance.
62321	Injection(s), of diagnostic or therapeutic substance(s) (e.g,. anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance.
62323	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (i.e., fluoroscopy or CT)
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance.
62325	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (i.e., fluoroscopy or CT)
62326	Injection (s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance.
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (i.e., fluoroscopy or CT)
62350	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy
62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
62361	Implantation or replacement of device for intrathecal or epidural drug infusion; nonprogrammable pump
62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump with or without programming

This list may not be all-inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

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