

CIGNA MEDICAL COVERAGE POLICIES - MUSCULOSKELETAL CMM-210: Implantable Intrathecal Drug Delivery Systems

Effective Date: August 04, 2026



EviCore
By EVERNORTH

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.

These guidelines include procedures EviCore does not review for Cigna. Please refer to the [Cigna CPT code list](#) for the current list of high-tech imaging procedures that EviCore reviews for Cigna.

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Table of Contents

Guideline	Page
Definitions	3
General Guidelines	6
Indications	8
Non-Indications	13
Codes (CMM-210)	15
References (CMM-210)	18

Definitions

Guideline	Page
Definitions.....	4

Definitions

CMM.PN.DF.210

v1.0.2026

- Ashworth Scale (AS)** a tool used to 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
- 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.

Modified Ashworth Scale (MAS)

a tool used to 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 range of motion (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 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

General Guidelines

Guideline	Page
General Guidelines.....	7

CMM-210: Implantable Intrathecal Drug Delivery Systems

General Guidelines

CMM.PN.GG.210

v1.0.2026

Application of Guideline

- The guideline criteria are only applicable to the use of an implantable intrathecal or epidural drug delivery system for the treatment of 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 with documentation that the individual is unresponsive to, cannot tolerate, or has a contraindication to oral antispasmodic drugs (i.e., baclofen [Lioresal®])
 - cancer-related pain
- The guideline criteria are not applicable 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

- The guideline criteria are not applicable to an intrathecal or epidural drug delivery system used with the following injectates: Spinraza, chemotherapy, neurolytic substances, antibiotics, antivirals, biologics (e.g., platelet-rich plasma, stem cells, amniotic fluid, etc.), or any other injectates that are considered **not in scope** of management.

Health Equity Considerations

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Indications

Guideline	Page
Non-Malignant, Chronic Intractable Pain.....	9
Severe, Refractory Spasticity/Chronic Intractable Dystonia.....	10
Cancer-Related Pain.....	11
Replacement.....	12

CMM-210: Implantable Intrathecal Drug Delivery Systems

Non-Malignant, Chronic Intractable Pain

CMM.PN.IN.210

v1.0.2026

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 provider-directed non-invasive pain management that includes BOTH of the following (unless there is a documented contraindication):
 - active rehabilitative exercise for at least six (6) months
 - a fixed schedule dosing of opioids or other analgesics for at least six (6) months
- 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., a face-to-face or virtual assessment [with or without psychological questionnaires and/or psychological testing]) reveals no evidence of an inadequately controlled mental and/or behavioral health conditions/issues (e.g., substance-use disorders, depression, 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

Permanent implantation of an 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 have been met for a trial of intrathecal or epidural opioid administration.
- The trial resulted in BOTH of the following:
 - documented pain relief of >50% for eight (8) hours
 - documented concomitant increase in function

Severe, Refractory Spasticity/Chronic Intractable Dystonia

CMM.PN.IN.210

v1.0.2026

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 to, cannot tolerate, or has a contraindication to a trial of BOTH of the following:
 - oral antispasmodic drugs (i.e., baclofen [Lioresal®]) for at least six (6) weeks
 - physical therapy for at least six (6) weeks
- Individual has BOTH of the following (as defined in **Definitions**):
 - a baseline average Ashworth Score of at least three (3) or a Modified Ashworth Score of two (2)
 - a Penn Spasm Frequency Score of at least two (2)

Permanent

Permanent implantation of an 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 have been met for a trial of intrathecal antispasmodic drug administration.
- The trial resulted in a beneficial clinical response as evidenced by 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 baclofen
 - at least a 2-point reduction in the Penn Spasm Frequency Score for four (4) hours following an intrathecal trial bolus of baclofen

Cancer-Related Pain

CMM.PN.IN.210

v1.0.2026

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

Permanent implantation of an intrathecal or epidural drug delivery system for cancer-related pain is considered **medically necessary** when the above criteria have been met for a trial and the trial resulted in documented pain relief of at least 50%.

- **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

CMM.PN.IN.210

v1.0.2026

Replacement of an implanted intrathecal or epidural drug delivery 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

Guideline	Page
Non-Indications.....	14

CMM-210: Implantable Intrathecal Drug Delivery Systems

Non-Indications

CMM.PN.NI.210

v1.0.2026

Not Medically Necessary

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

Codes (CMM-210)

Guideline	Page
Codes (CMM-210).....	16

CMM-210: Implantable Intrathecal Drug Delivery Systems

Codes (CMM-210)

CMM.PN.PC.210

v1.0.2026

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

Code	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 (i.e., 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.

Code	Code Description/Definition
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

References (CMM-210)

Guideline	Page
References (CMM-210).....	19

CMM-210: Implantable Intrathecal Drug Delivery Systems

References (CMM-210)

CMM.PN.RF.210

v1.0.2026

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