Cigna Medical Coverage Policies – Musculoskeletal Implantable Intrathecal Drug Delivery System

Effective August 15, 2020

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 System

Definitions

- **An implantable intrathecal drug delivery system** (Pain pump or Baclofen pump) is 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 Guideline

- Please note this guideline does not apply to epidural injections administered for obstetrical or surgical epidural anesthesia.
- 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.

Indications

- The use of an implantable intrathecal or epidural drug delivery system is considered **medically necessary** for **ANY** of the following indications when the associated criteria are met:
  - Nonmalignant, 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®]) (i.e., intrathecal injection of Baclofen)
  - Cancer-related pain

Nonmalignant, Chronic Intractable Pain

- A trial with a percutaneous intrathecal or epidural drug delivery system for nonmalignant chronic intractable pain is considered **medically necessary** when **ALL** of the following criteria have been met:
  - There is a documented pathology (i.e., an objective basis for the pain complaint)

- Failure of at least six (6) months of noninvasive pain management, including active rehabilitative exercises and fixed schedule dosing of opioids or other analgesics unless contraindicated
- Further surgical intervention or other treatment is not indicated or likely to be effective
- Statement from a primary care physician, neurologist, physiatrist, psychiatrist, psychologist, or other licensed behavioral and/or medical health care provider attesting to the absence of untreated, underlying mental health conditions/issues (e.g., depression, drug, alcohol abuse) as a major contributor to chronic pain.
- Individual agrees to a 50% reduction in systemic opiates prior to undergoing an intrathecal opiate trial.

➢ A permanent implantable intrathecal or epidural drug delivery system for the above listed pain conditions is considered **medically necessary** if the individual has met the above criteria for a preliminary trial and has experienced > 50% reduction in pain and concomitant increase in function during an appropriate trial.

Severe, Refractory Spasticity/Chronic Intractable Dystonia

➢ 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 indications:

- There is failure, contraindication or intolerance to at least a six-week trial of oral antispasmodic drugs and physical therapy
- Individual has a baseline average Ashworth score of at least 3 (or a Modified Ashworth score of 2), and a Spasm Frequency score of at least 2.
  - An Ashworth score of 3 represents a considerable increase in muscle tone when testing resistance to passive movement about a joint with varying degrees of velocity.
  - A Modified Ashworth score of 2 represents a slight increase in muscle tone followed by minimal resistance of the range of motion.
  - A Spasm Frequency Score of 2 represents a patient's self-report of between 1 to 5 spasms per day.
- A permanent implantable infusion for the treatment of chronic intractable spasticity or chronic intractable dystonia is considered **medically necessary** when a preliminary trial of intrathecal antispasmodic drug administration, that meets the above medical necessity criteria, demonstrates a beneficial clinical response (e.g., demonstrates at least a 2-point reduction in the Ashworth or Spasm Frequency score for 4 hours following an intrathecal trial bolus of baclofen)

Cancer-Related Pain

- 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 noninvasive methods of pain control including systemic opioids.
- A permanent implantable intrathecal or epidural drug delivery system for the above listed pain conditions 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.
  - **Please Note:** 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 at high risk for procedures.

Non-Indications

- An intrathecal or epidural drug delivery system is considered **experimental, investigational or unproven** for **ANY** other indication, including cancer-related pain, spastic/dystonic, or other pain conditions that do not meet the above criteria.

Replacement

- Replacement of an implanted intrathecal or epidural drug infusion system is considered **medically necessary** when **BOTH** of the following criteria have been met:
  - The existing device is documented to be nearing end of battery life, will no longer be functional and cannot be repaired, or a built-in component provides notification of impending failure
  - There is no evidence to suggest the device has been abused or neglected.
- Replacement of an implantable/intrathecal infusion pump is considered **not medically necessary** when the existing infusion pump and/or components remain functional.

Procedure (CPT®) Codes

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) (eg, 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) (eg, 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) (eg, 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) (eg, 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 (ie, fluoroscopy or CT)
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, 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) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62326	Injection (s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance.
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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