Clinical Policy: Caudal or Interlaminar Epidural Steroid Injections / Trial of Implantable Intrathecal Pain Pump

Reference Number: WNC.CP.265 Coding Implications
Last Review Date: Revision Log

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description[1]

An implantable, intrathecal drug delivery system consists of an implanted pump and catheter that delivers a drug directly into the spinal fluid. The device can be programmed for continuous or variable rates of infusion. Intrathecal drug delivery systems offer an invasive alternative for the long-term management of select patients with intractable pain. *This policy covers the criteria for the trial of the pump; for permanent implantation, please contact the relevant vendor.*

Epidural steroid injections have been used for pain control in patients with radiculopathy, spinal stenosis, and nonspecific low back pain, despite inconsistent results as well as heterogeneous populations and interventions in randomized trials. Epidural injections are performed utilizing three approaches in the lumbar spine: caudal, interlaminar, and transforaminal. Generally, candidates for epidural steroid injection are individuals who have acute radicular symptoms or neurogenic claudication unresponsive to traditional analgesics and rest, with significant impairment in activities of daily living.

Note: For guidelines for transforaminal ESIs, reference *WNC.CP.266 Selective Nerve Root Blocks and Transforaminal Epidural Steroid Injections.*

Policy/Criteria[1]

I. It is the policy of WellCare of North Carolina® that **a preliminary trial of intrathecal administration of an opioid drug** is medically necessary for either of the following indications:

- **A.** Chronic intractable pain of malignant origin when **all** of the following criteria is met:
  1. Inadequate response to noninvasive methods of pain control such as systemic opioids;
  2. Life expectancy > 3 months;
  3. No evidence of epidural metastatic lesion(s) or tumor encroachment of the thecal sac by imaging;
  4. No active infection.
- **B.** Chronic intractable pain of nonmalignant origin (e.g., failed back surgery syndrome, complex regional pain syndrome) when **all** the following criteria are met:
  1. Pathology for the pain has been identified;
  2. Life expectancy is > 3 months;

3. Failure or inability to tolerate other conservative treatment methods, including but not limited to, systemic pharmacotherapy, physical therapy, behavioral health treatment for pain, and appropriate nonsurgical treatment;
4. Compliance with previous attempts to treat the condition;
5. No current drug and/or alcohol disorder, including but not limited to, opioid use disorder or addiction;
6. A psychological evaluation confirms a mental health condition is not a major contributor to chronic pain symptoms;
7. Active participation in psychotherapeutic interventions (e.g., cognitive behavioral therapy, relaxation training, biofeedback, coping skills training, stress management);
8. Further surgical intervention or other treatment is not indicated or likely to be effective;
9. No active infection;
10. Prior to the trial, systemic opioids have been weaned by at least 50%;
11. Opioid induced hyperalgesia has been ruled out as a possible cause of the chronic pain symptoms.

II. It is the policy of WellCare of North Carolina® that invasive pain management procedures performed by a physician are medically necessary *when the relevant criteria are met, only one procedure is performed per visit, with imaging guidance (except in rare instances, with documented justification), and the member is not currently being treated with full anticoagulation therapy. If on warfarin, international normalized ratio (INR) should be ≤ 1.4 prior to the procedure.* Discontinuing anti-platelet therapy is a clinical decision balancing risks and benefits of the procedure on therapy, versus the underlying medical condition if not treated appropriately.[23]

III. It is the policy of WellCare of North Carolina® that **caudal or interlaminar epidural steroid injections (ESIs)** are medically necessary for the following indications:

A. One caudal or interlaminar ESI for *acute pain management* (pain lasting < 3 months) when **all** of the following are met:
1. There is severe radicular pain that interferes substantially with activities of daily living (ADLs);
2. Severe pain persists after treatment with nonsteroidal anti-inflammatory drugs (NSAID) and/or opiates (both ≥ 3 days or contraindicated/not tolerated);
3. The member cannot tolerate chiropractic or physical therapy and the injection is intended as a bridge to therapy.

B. Initial ESI for *chronic pain,* **all** of the following*:*
1. Request is for one caudal or interlaminar ESI at one level in the cervical, thoracic or lumbar region;
2. Persistent radicular pain has been caused by spinal stenosis, disc herniation or degenerative changes in the vertebrae, as confirmed by physical exam and imaging;
3. Pain interferes with ADLs **and** has lasted for at least 3 months;
4. The member has failed to respond to conservative therapy including **all** of the following:

a. ≥ 6 weeks chiropractic, physical therapy or prescribed home exercise program;
b. NSAID ≥ 6 weeks or NSAID contraindicated or not tolerated;
c. ≥ 6 weeks activity modification;

C. Second caudal or interlaminar ESI for *chronic pain that did not improve from the first ESI*, **all** of the following:
1. Request is for an ESI at one level in the cervical, thoracic or lumbar region;
2. At least 2 weeks have passed since the first ESI;

D. Subsequent caudal or interlaminar ESI for *recurrence of chronic pain that had improved from the first or second ESI*, **all** of the following:
1. Initial injection(s) led to ≥ 50% relief and functional improvement for at least 2 months;
2. At least 2 months have passed since the last ESI;
3. Less than 4 injections have been administered within 12 months;
4. Less than 12 months have elapsed since the initial injection at the level requested;

IV. It is the policy of WellCare of North Carolina® that *a third or subsequent caudal or interlaminar ESI for chronic pain that **did not** improve from the first two ESIs* is considered **not medically necessary** because effectiveness has not been established.

V. It is the policy of WellCare of North Carolina® that *continuation of injections beyond 12 months or more than 4 therapeutic injections* is considered **not medically necessary** because effectiveness and safety have not been established. When more definitive therapies cannot be tolerated or provided, consideration will be made on a case by case basis.

VI. It is the policy of WellCare of North Carolina® that *caudal or interlaminar ESI for any other indication or location* is considered **not medically necessary** because effectiveness has not been established.

Background[1]

There is much debate on the efficacy and medical necessity of multiple interventions for managing spinal pain. Epidural glucocorticoid injections have been used for pain control in patients with radiculopathy, spinal stenosis, and nonspecific low back pain despite inconsistent results as well as heterogeneous populations and interventions in randomized controlled trials (RCT's). Epidural injections are performed utilizing three approaches in the lumbar spine: caudal, interlaminar, and transforaminal.[2] Generally, candidates for epidural steroid injection are individuals who have acute radicular symptoms or neurogenic claudication unresponsive to traditional analgesics and rest, with significant impairment in activities of daily living. Epidural steroid injections have been used in the treatment of spinal stenosis for many years, and no validated long-term outcomes have been reported to substantiate their use. However, significant improvement in pain scores, have been reported at three months after injection.

Zhai et al conducted a meta-analysis to assess the effects of various surgical and nonsurgical modalities, including epidural injections, used to treat lumbar disc herniation (LDH) or radiculitis. A systematic literature review identified RCTs that compared the effect of local

anesthetic with or without steroids. The outcomes included pain relief, functional improvement, opioid intake, and therapeutic procedural characteristics. The reviewers concluded the meta-analysis confirms that epidural injections of local anesthetic with or without steroids have beneficial but similar effects in the treatment of patients with chronic low back and lower extremity pain.[1]

Results of a two year follow-up of three randomized, double-blind, controlled trials, with a total of 360 patients with chronic persistent pain of disc herniation receiving either caudal, lumbar interlaminar or transforaminal epidural injections, showed similar efficacy of the three techniques with local anesthetic alone or local anesthetic with steroid.[2] Caudal and interlaminar trials used in the assessment showed some superiority of steroids over local anesthetic, at three and six month follow-up. Interlaminar with steroids were superior to transforaminal at 12-months.[2]

Opioid therapy for the treatment of chronic non-cancer pain is controversial, due to insufficient evidence of long-term efficacy and the risk of serious harm, including addiction and abuse, especially in the context of the ongoing opioid epidemic in the United States. For patients with chronic non-cancer pain, opioids should only be used when other potentially effective and safer therapies have not provided sufficient pain relief or experience intolerable side effects, and pain is adversely affecting a patient's function and/or quality of life. The potential benefits of opioid therapy should outweigh potential harms. Opioids should be combined with non-opioid pharmacotherapy and nonpharmacologic therapies as appropriate.[27]

Intrathecal therapy offers an invasive alternative for the long-term management of select patients with recalcitrant pain after all other methods have failed, including conservative and surgical treatment. Implantable intrathecal infusion systems, also referred to as intrathecal drug delivery (IDD) systems, provide targeted drug delivery to the central nervous system. They are most commonly used for cancer-related pain. Their use for management of pain of non-malignant origin is controversial and generally reserved for treatment of last resort. A number of medications are used, including opioids (e.g., morphine) or a combination of opioids along with a local anesthetic (e.g., ziconotide, clonidine).

An implantable intrathecal drug delivery system (pain pump) consist of an implanted catheter and either a constant-flow or programmable pump. The implantation of a pump for intrathecal opioid infusion is preceded by an intrathecal or epidural trial infusion, with or without a catheter, to determine whether the patient exhibits an adequate response, consisting of a predefined improvement in pain (usually ≥ 50%) without intolerable adverse effects. If the trial is successful, the drug infusion system is implanted under general anesthesia. The catheter is introduced into the intrathecal space of the spine (generally at the lumbar level), tunneled subcutaneously, and typically positioned under fluoroscopic guidance so that the tip is located at the corresponding spinal level for processing the patient’s pain. The catheter is connected to an infusion pump placed in a subcutaneous pocket in the abdomen.[28] Complications related to intrathecal therapy can be technical, biological, or medication related.[30]

The literature evaluating intrathecal infusion systems for long-term management of chronic noncancer pain is limited. Peer reviewed literature to date consists of observational studies, uncontrolled retrospective studies, case studies and systematic reviews using variable methodologies and inclusion criteria. Some studies suggest that intrathecal opioids reduce pain long-term in a small proportion of individuals with chronic, non-cancer pain, however, large randomized controlled trials are lacking.

A health technology assessment of Intrathecal Drug Delivery Systems for Noncancer Pain reported, "Compared with oral opioid analgesia alone or a program of analgesia plus rehabilitation, intrathecal drug delivery systems significantly reduced pain (27% additional improvement) and morphine consumption. Despite these reductions, intrathecal drug delivery systems were not superior in patient-reported well-being or quality of life. There is no evidence of superiority of intrathecal drug delivery systems over oral opioids in global pain improvement and global treatment satisfaction. Comparative evidence of harms was not found."[29]

American Society of Interventional Pain Physicians (ASIPP)
The evidence is limited for implantable intrathecal drug administration systems in managing patients with failed back surgery syndrome.[25]

American Society of Anesthesiologists/American Society of Regional Anesthesia and Pain Medicine
Studies with observational findings indicate that intrathecal opioid injections can provide effective pain relief for assessment periods ranging from one to twelve months for patients with neuropathic pain (Category B2 evidence). Consultants, ASA members, and ASRA members are equivocal with regard to whether intrathecal opioid injection or infusion should be used for neuropathic pain. However, they strongly agree that neuraxial opioid trials should be performed before considering permanent implantation of intrathecal drug delivery systems.[26]

North American Spine Society (NASS)
NASS has developed coverage recommendation on spinal intrathecal drug delivery systems for the treatment of chronic nonmalignant pain. Per NASS, the implantable infusion may benefit a small subgroup of patients with chronic nonmalignant pain and a clear spinal pathology, who have exhausted all other options to treat their symptoms. These patients should have a psychological evaluation to rule out drug and alcohol disorders and other psychological conditions.[25]

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage.

Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
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)

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original Approval date.	08/21	01/22
Merged criteria, background, ICD-10-CM codes, and references from retired policy WNC.CP.268 Implantable Intrathecal Pain Pump.	04/22	05/22
Annual review. Added "Note: regarding guidelines for transforaminal ESIs." Background updated with no impact on criteria. References reviewed and updated. Removed ICD-10 Diagnosis codes. NCHC verbiage removed from NC Guidance Verbiage.	05/23	05/23
Criteria I.B.4.B. Changed 3 TO 6 in "NSAID ≥ six weeks or NSAID contraindicated or not tolerated."	11/23	11/23
Annual Review. Deleted HCPCS code box.		

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North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a

condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:
   NCTracks Provider Claims and Billing Assistance Guide:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
   EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and

c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information
Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

a. Claim Type - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.
   Unlisted Procedure or Service
   CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.
   HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service
d. Modifiers - Providers shall follow applicable modifier guidelines.

e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to

recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.