Last Approval: 8/10/2022 Next Review Due By: August 2023



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Epidural glucocorticoid injections, also known as epidural steroid injections (ESIs), have been used to treat radicular back and neck pain after other conservative and noninvasive treatments such as physical therapy and oral medications have failed. An epidural steroid injection (ESI) involves the administration of medication, most commonly an anesthetic and steroid, into the epidural space or adjacent areas of the spinal cord to treat inflammation resulting from conditions that affect the nerve roots. The procedure is performed under fluoroscopic guidance. There are three injection approaches for performing epidural steroid injection:

- Translaminar, translumbar or interlaminar is the most common approach for an epidural injection; needle placement is between the spinous processes of 2 vertebrae into the posterior epidural space.
- Caudal is a technique with a smaller incidence of spinal dural puncture; needle placement is through a small
 opening in the caudal canal just above the tailbone into the epidural space to treat the cauda equina and
 lumbar spinal nerves.
- Transforaminal is the most common technique for diagnostic purposes and for the neck region; needle
 placement is through the foramina, which are small bony openings between the vertebrae where the nerve
 root exits the spinal canal and enters the body.

Epidural steroid injections are performed for both diagnostic and therapeutic purposes. Diagnostic injections are performed to verify the source of pain within a particular region of the spinal column. Pain relief for several weeks following the diagnostic injection is indicative of inflammation within the area. Therapeutic injections are given to prolong pain relief and to reduce the inflammatory process over extended periods of time, which may allow patients to better participate in physical therapy or exercise programs (Chou, 2021; Robinson & Kothari, 2021). The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.

A selective nerve root block (SNRB) or selective nerve root injection (SNRI) is an injection of anesthetic alone used for diagnostic purposes. The approach is similar to that of a transforaminal injection; however, the needle tip remains outside of the intervertebral foramen directed at the spinal nerve root rather than entering the epidural space. Thus, when isolated nerve root irritation is suspected, SNRB is used as a diagnostic tool with positive response to the injection supporting nerve root irritation at a specific anatomical level. SNRB is commonly used in planning prior to surgical intervention (Bicket et al., 2018).

Food and Drug Administration (FDA). In 2014, the FDA issued a drug safety communication about epidural steroid injection, indicating that "injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death." The FDA required the addition of a warning to drug labels of injectable corticosteroids to describe the risks. The FDA advised in the announcement that patients should discuss the potential risks and benefits of epidural steroid injections, as well as alternatives, with their health care providers (FDA, 2014).

Last Approval: 8/10/2022 Next Review Due By: August 2023



COVERAGE POLICY

Epidural steroid injections (ESI) may be considered medically necessary for neck or back pain in adults who are age 18 years or older as part of a comprehensive pain management treatment program when ALL of the following criteria are met:

- 1. Indications are met for epidural steroid injection as indicated by **ONE** of the following:
 - a. For Initial (Diagnostic) injection(s) up to 2 injections, ALL of the following are met:
 - History, physical examination, and radiologic imaging supports **ONE** of the following:
 - i. Cervical, thoracic, or lumbar radicular pain, radiculopathy, or neurogenic claudication (lumbar)
 - ii. Post-surgical neck or back pain (e.g., post laminectomy syndrome) due to prior surgery (e.g., discectomy, laminectomy, or spinal fusion) and at least 6 months have elapsed since surgery
 - iii. Acute pain associated with herpes zoster
 - Pain is affecting activity of daily living functional ability (>4 on the NRS Pain Rating Scale*)
 - Member has tried and failed conservative therapy or conservative therapy is contraindicated, as demonstrated by ONE of the following:
 - Failure of conservative therapy (e.g., for the current episode of pain) that includes ALL of the following:
 - 1. Physical therapy (PT) for a minimum of 4 weeks (3-4x per week for a total of 12 sessions)
 - 2. Activity modification for a minimum of 6 weeks
 - 3. Drug therapy (e.g., NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, and/or opiates).
 - ii. Cervical, thoracic, or lumbar radicular pain with demonstrable correlation on physical exam and/or imaging that precludes the above requirement for therapy (e.g., acute proven disc herniation with radiculitis and disabling pain, worsening pain with physical therapy). There must be documentation submitted that explains why any of the above conservative therapy is contraindicated.
 - iii. Herpes zoster associated pain which has failed conservative measures and a waiting period is not appropriate.
 - b. For **Repeat (Therapeutic)** injection(s), the diagnostic or last therapeutic injection for the current episode of pain provided significant functional pain relief of at least 50% measured by a significant decrease in pain level, decrease in pain medications, and/or increase in physical function maintained for at least 6 weeks.
 - * The Numeric Rating Scale (NRS-11): Rating Pain Level
 - 0: No Pain
 - 1 3: Mild Pain (nagging, annoying, interfering little with ADLs)
 - 4 6: Moderate Pain (interferes significantly with ADLs)
 - 7 10: Severe Pain (disabling; unable to perform ADLs)
- 2. Frequency and location of injection(s) are appropriate, as indicated by ALL of the following:
 - a. Within acceptable limits for frequency of injections as indicated by ONE of the following:
 - Initial (Diagnostic) injection(s): 2 injections per region maximum with procedures at least 2 weeks apart.
 - Repeat injection(s): No more than 4 injections total per region (cervical/thoracic or lumbar) per rolling 12-month period, inclusive of any diagnostic injections. Note: cervical and thoracic regions are considered as one region for purposes of this limitation.
 - b. Number of injection(s) is appropriate, as indicated by ONE of the following:
 - Transforaminal injection(s): no more than two transforaminal injections may be performed per session** (i.e., single level bilaterally or two levels unilaterally).

MOLINA'
HEALTHCARE

Last Approval: 8/10/2022 Next Review Due By: August 2023

Caudal or interlaminar injection: no more than one caudal or interlaminar injection per session** and
not in conjunction with a transforaminal injection. (It is not reasonable and necessary to perform
caudal or interlaminar injections bilaterally.)

Diagnostic selective nerve root block (SNRB) may be considered medically necessary in the evaluation and diagnostic work-up of radicular pain when ONE of the following criteria are met:

- 1. When physical signs and symptoms differ from that found on imaging studies
- 2. When there is clinical evidence of multi-level nerve root pathology and the treatment plan requires isolating the pain source(s)
- 3. When the individual has had previous spinal surgery
- 4. For surgical planning

Limitations and Exclusions

Epidural Steroid Injections (ESIs) **are considered not medically necessary** and may not be authorized for the any of the following conditions:

- For non-radicular back pain.
- ESI used for treatment of non-radicular spinal pain or myofascial pain syndrome.
- Repeat ESI (after the initial one or two diagnostic ESI) performed more frequently than once every two to three
 months.
- A planned series of ESI without evaluation of response to each injection (e.g., series of three injections).
- No more than one SNRB at a single level is considered medically necessary, unless the first SNRB was nondiagnostic.
- SNRB performed at separate levels when multi-level nerve root pathology is suspected should not be performed within two weeks of a prior injection.
- No more than 6 SNRBs should be performed in a 12-month period of time, regardless of the number of levels involved.
- SNRBs are considered not medically necessary for any other indication because effectiveness has not been established.

The following are considered contraindications to the procedures:

- Known allergies to contrast agents, local anesthetics, or corticosteroids
- History of bleeding disorders or current use of medications that may increase the risk of bleeding should be evaluated for potential exclusion
- Active infection locally or systemically, spinal stenosis resulting in intraspinal obstruction, or previous fusion at the indicated spinal level
- No epidural space, an altered epidural space as a result of previous surgery, spinal compression, or congenital
 anatomic anomalies
- Other spinal pathology such as spinal tumors, cauda equina syndrome, spinal cord compression
- Co-morbidities that can be exacerbated by steroid use such as severe congestive heart failure, uncontrolled diabetes, and poorly controlled hypertension and other unstable medical conditions
- Fluoroscopy use in pregnant women

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

^{**} A session is defined as all injection procedures performed on one day.

Last Approval: 8/10/2022 Next Review Due By: August 2023



SUMMARY OF MEDICAL EVIDENCE

Cervical Epidural Steroid Injection

The published literature includes randomized controlled trials and systematic reviews examining the use of epidural steroid injections (ESIs) for cervical radiculopathy (CR) in adult patients. The studies included patients with CR for whom conservative therapies had failed (e.g., rest, analgesics, anti-inflammatory medications, PT, and exercise). Clinical symptoms were often correlated with MRI or other radiographic findings. There are no randomized controlled trials evaluating the use of ESIs in the pediatric population. The duration of CR symptoms varied, with some patients having acute symptoms (e.g., 15 days duration) and others reporting a longstanding condition (≥ 1 year). Most studies included patients with CR symptoms that had not responded to ≥ 6 months of conservative treatment. Most studies evaluated a combined ESI and anesthetic injection and follow-up times varied considerably among studies, ranging from 3 weeks to 68 months, with most studies including ≤ 12 months follow-up. In studies that compared ESI (steroid plus anesthetic) with epidural injection of anesthetic only, no beneficial effects of the steroids were detected on any outcome measures. Some suggested superior pain relief from administration of steroids plus anesthetic by catheter compared with injection, but only in patients who reported pain for > 6 months. ESIs did not improve disability or reduce the need for surgery in most of the studies. The overall body of evidence regarding epidural steroid injection (ESI) for cervical radiculopathy (CR) does not show beneficial effect of ESIs on pain or disability associated with CR compared with epidural injection with anesthetic only. Despite the lack of evidence regarding ESIs for CR, the procedure has become standard in the pain management community.

Thoracic Epidural Steroid Injection

Disc related pathology, spinal stenosis, and post spinal surgery syndrome are much less common in the thoracic region than in the cervical or lumbar regions, thus the body of evidence studying thoracic ESI is much smaller than that for cervical or lumbar ESI (ASIPP, 2021). One randomized controlled trial (RCT) involving 110 patients suggests that ESI for the treatment of thoracic radicular pain results in clinically significant reductions in pain from baseline and has similar outcomes as treatment with anesthetic injection alone. Group I was treated with injections with local anesthetic while Group II received injections with local anesthetic with steroids. Repeat thoracic ESIs were provided based on positive response to prior epidural injections only when increased levels of pain were reported by the subjects. Outcomes were assessed at 3, 6, 12, 18, and 24 months using the Numeric Rating Scale (NRS), Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake. A successful outcome was considered as greater than 3 weeks of significant improvement (greater than 50% decrease in NRS score and ODI score measured at baseline) following the first two injections. Significant improvement was seen in 71% in Group I and 80% in Group II at the end of two years with all participants, or 80% and 86% respectively when only successful patients were included. A major limitation of this study is the lack of placebo group (Manchikanti et al., 2014).

Lumbar Epidural Steroid Injection

The published literature includes randomized controlled trials and systematic reviews examining ESIs for lumbar radiculopathy (LR) in adults. The studies included patients with low back pain and sciatica for whom conservative treatment had failed (i.e., rest, analgesics and anti-inflammatory medications, physical therapy, and exercise). Clinical symptoms were often correlated with magnetic resonance imaging (MRI) or computerized tomography (CT) scan results. There are no randomized controlled trials evaluating the use of ESIs in the pediatric population. ESIs were performed via the interlaminar, transforaminal, or caudal route. The outcome measures varied, but most pain assessments used the (visual analog scale [VAS] score) and the degree of disability (Oswestry Disability Index [ODI] score). Several studies also assessed the need for subsequent surgery. Follow-up times varied considerably among studies, ranging from 3 weeks to 2 years or more. The majority of the studies reported pain relief following epidural anesthetic with or without steroids. The overall body of evidence regarding epidural steroid injection (ESI) for lumbar radiculopathy (CR) shows that while epidural steroid injections (ESIs) are associated with some pain relief; most studies suggest that the effects are attributable to the anesthetic rather than the steroids. Despite the lack of evidence regarding ESIs for LR, the procedure has become standard in the pain management community.

MOLINA' HEALTHCARE

Last Approval: 8/10/2022 Next Review Due By: August 2023

A 2015 Agency for Healthcare Research and Quality (AHRQ) technology assessment reviewed 79 randomized controlled trials evaluating efficacy of epidural injections for treatment of lumbosacral radiculopathy, spinal stenosis, non-radicular back pain, or chronic post-surgical back pain. The report concluded that ESIs for radiculopathy were associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits were small and not sustained, and there was no effect on long-term risk of surgery. Evidence did not suggest that effectiveness varies based on injection technique, corticosteroid, dose, or comparator. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain (Chou et al., 2015).

Diagnostic Selective Nerve Root Blocks (SNRB)

There is limited evidence to suggest SNRBs may be of use in surgical planning for use in isolation and identification of a nerve root causing radiculopathy. A 2022 controlled trial by Sasso et al. examined surgical outcomes at 1 year post cervical or lumbar decompression surgery in 101 patients who initially underwent diagnostic SNRB and magnetic resonance imaging (MRI). Of the 101 patients, 90% had a positive and 10% had a negative SNRB. Of those patients with positive SNRB, 91% had good outcomes at 1 year, whereas 60% of the patients with a negative SNRB had good outcomes. Of patients with a positive MRI result, 87% had good surgical outcomes, whereas a similar percentage of patients with a negative MRI (85%) had good outcomes. When findings between SNRB and MRI differed (n=20), surgery at a level consistent with the SNRB was more strongly associated with a good surgical outcome (Sasso et al., 2005).

Yeom et al. (2008) conducted a single-blinded prospective controlled study to evaluate the accuracy of diagnostic lumbar SNRBs and analyze potential causes of false results. A total of 105 block anesthetics were performed under fluoroscopic guidance in 47 consecutive patients with pure radiculopathy from a single confirmed level. 47 blocks were performed at the symptomatic level and 58 were performed at the adjacent asymptomatic "control" level. The definition of a positive block was considered 70% pain relieve determined by receiver-operator characteristic (ROC) analysis. The diagnostic lumbar SNRB had a sensitivity of 57%, a specificity of 86%, an accuracy of 73%, a positive predictive value of 77%, and a negative predictive value of 71%. Identified causes of false negatives were attributed to the following causes identifiable on spot radiographs: insufficient infiltration, insufficient passage of the injectate, and intraepineural injections. False positives resulted from overflow of the injectate from asymptomatic levels into either the epidural space or symptomatic level. The authors concluded that accuracy of SNRB is moderate. In order to improve accuracy, great care should be taken to avoid inadequate blocks and overflow while closely interpreting spot radiographs.

National and Specialty Organizations

A practice guideline published by the American Society of Anesthesiologists Task force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine indicates that caudal, interlaminar, and transforaminal epidural injections are generally good for managing disc herniation or radiculitis for; fair for axial or discogenic pain without disc herniation, radiculitis or facet joint pain with caudal, and interlaminar epidural injections, and limited for transforaminal epidural injections; fair for spinal stenosis with caudal, interlaminar, and transforaminal epidural injections; and fair for post-surgery syndrome with caudal epidural injections and limited with transforaminal epidural injections (Benzon et al., 2010).

The **North American Spine Society (NASS)** (2020) published coverage policy recommendations on epidural steroid injections and selective spinal nerve blocks based on high-level evidence and professional consensus. The guidelines note that there is ample high-quality evidence to support ESIs for radicular pain caused by disc herniation. They also note that although there is a smaller body of evidence to support ESIs for radicular pain caused by conditions other than disc herniation, evidence is sufficient to support a trial of ESI for this type of pain in some cases Suggested frequency is no more than 6 ESIs per 12-month period, no more than 2 transforaminal ESIs at a single setting, and no more than 1 caudal or intralaminar ESI per session. The recommendation is made that injections be performed "independently based on the patient's symptoms and response to prior injections and approach," and further state that there is no basis for a "series of 3" ESIs planned in advance. ESIs are not indicated for non-radicular pain.



Last Approval: 8/10/2022 Next Review Due By: August 2023

The American Society of Interventional Pain Physicians (ASIPP) evidence-based guideline on Epidural Interventions in the Management of Chronic Spinal Pain states the following:

- Strong evidence supports fluoroscopically guided epidural injections with or without steroids for caudal epidural injections, lumbar interlaminar and transforaminal injections, and cervical interlaminar epidural injections for cases of disc herniation.
- There is fair to moderate evidence to support the use of thoracic epidural injections for treatment of thoracic disc herniation.
- Some evidence supports lumbar and cervical interlaminar and lumbar transforaminal epidural injections for treatment in the presence of spinal stenosis or axial discogenic pain without facet joint pain, however the body of evidence is smaller and of lower quality than in the case of disc herniation.

Detailed frequency and location guidelines are provided in the guideline including a limit of 2 diagnostic procedures per region at least 2 weeks apart (preferably 4-6 weeks depending upon the steroid used) and a limit of 4 injections per region per year, where cervical and thoracic regions are considered as one region (Manchikanti et al., 2021).

For a list of the peer-reviewed and evidence-based literature used in the development and update of this policy, please see the *References* section.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT	Description
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 (e.g., 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 (e.g., fluoroscopy or CT)
64479	Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, single level
64480	Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, each additional level (List separately in addition to code for primary procedure)
64483	Injection, anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, single level
64484	Injection, anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, each additional level (List separately in addition to code for primary procedure)
64999	Unlisted procedure, nervous system

*It is not medically reasonable and necessary to perform caudal ESIs or interlaminar ESIs bilaterally, therefore CPT 62321 and 62323 are not bilateral procedures.

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

Last Approval: 8/10/2022

Next Review Due By: August 2023



APPROVAL HISTORY

Added clarification that caudal and interlaminar ESIs (62321 and 62323) are not appropriate to be requested or billed bilaterally.

Coverage policy re-organized for additional clarity, added inclusion of thoracic region, added indications for SNRB. References

and Summary of Evidence updated.

4/05/2021 Policy reviewed, no criteria changes. Coding updated (deleted CPT codes 0228T, 0229T, 0230T, 0231T; added CPT 64999).

4/23/2020 Policy reviewed, changed PT req. to min. of 4 weeks to be consistent with other guidelines and Molina pain management policies.

Policy reviewed, no changes to criteria.

Policy reviewed no changes to criteria.

3/08/2018 Policy reviewed, no changes to criteria.
Policy reviewed, no changes to criteria.
Reduced PT requirement from 20 session

Reduced PT requirement from 20 sessions to 10-12 sessions over 8 weeks, changed improvement scales to significant functional pain relief of 50% measured by a decrease in pain medication and increase in functional ability, changed therapeutic frequency criteria from 3 injections in 6 months to 2 injections allowed in 12 months, removed loss of bladder control as an indication, removed cervical ESIs higher than the C6-7 level from exclusions, and removed the requirement for a comprehensive psychosocial assessment. Coding tables updated. Changes based on 2017 ODG Guidelines per AMR review.

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Molina Clinical Policy Epidural Steroid Injections (ESI) for Back and I

Epidural Steroid Injections (ESI) for Back and Neck Pain: Policy No. 032

Last Approval: 8/10/2022

Next Review Due By: August 2023



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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.