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

Last Approval: 8/9/2023
Next Review Due By: August 2024

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 (Hayes 2022; Yang et al. 2020). An ESI involves the administration of medication, such as an anesthetic and/or 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 ESI (Chou 2021; Yang et al. 2021):

- **Translaminar, translumbar, or interlaminar** are the most common approaches 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.

ESIs 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 (Hayes 2022). Pain relief for several weeks following the diagnostic injection is indicative of inflammation within the area (Hayes 2022; Chou 2021). 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 (Hayes 2023; Kothari & Chuang 2023; Chou 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 (Chou 2021).

A **selective nerve root block (SNRB)** or **selective nerve root injection (SNRI)** is an injection of anesthetic alone for diagnostic purposes (Hayes 2022). The approach is similar to that of a transforaminal injection; however, the needle tip remains outside of the intervertebral foramen and is directed at the spinal nerve root rather than entering the epidural space (Hayes 2022). 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.

Regulatory Status

ESIs are considered a procedure and are not regulated by the Food and Drug Administration (FDA) (Hayes 2023). In 2014, the FDA issued a drug safety communication about ESIs, 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 (FDA 2014).” 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).

COVERAGE POLICY

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 ESI 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 that affects 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:
        i. Failure of conservative therapy (e.g., for the current episode of pain) that includes **ALL** of the following:
           1. Physical therapy 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 must have provided significant functional pain relief of at least 50% measured by a significant decrease in pain level, decrease in pain medication usage, and/or provided an increase in physical function that was 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)**: Maximum of 2 injections per region with injections 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 2 transforaminal injections may be performed per session** (i.e., single level bilaterally or two levels unilaterally).

- Caudal or interlaminar injection: no more than 1 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).

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

Diagnostic 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

ESIs **are considered not medically necessary** and may not be authorized for 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 ESIs) 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 non-diagnostic.
- 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
- Use of fluoroscopy 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.

SUMMARY OF MEDICAL EVIDENCE

Cervical ESI

Conger et al. (2020) completed a systematic review and meta-analysis of 8 studies with the objective of comparing fluoroscopy guided cervical transforaminal ESI to sham, placebo, or active treatments. The primary outcome measured for the meta-analysis was a pain reduction of ≥ 50% compared to baseline. Inclusion criteria included patients ≥ 18 years of age with cervical radicular pain due to disc herniation or degenerative spondylosis and outcomes reported at least 4 weeks after intervention. Studies that had a comparison group not meeting criteria (sham, placebo, or active treatment) were still included in the analysis as a single-group study and only the ESI data was extracted for analysis. Exclusion criteria included case reports, expert opinions, and unpublished data. Results were divided up into particulate and non-particulate based on the type of steroid the patient received for ESI. Results were reported based on "success rate" or the percentage of patients that had a pain reduction ≥ 50%. For particulate steroids, analysis showed success rates of 41% at 1-month and 48% at 3-months. The combined success rate (1-month and 3-months) was 43%. For non-particulate steroids, analysis showed success rates of 56% at 1-month and 68% at 3-months. The combined success rate was 64%. No serious adverse events were reported from the included studies. There were few minor side effects reported, including "cases of syncope and transient vertigo (n=3), transient dizziness, headache, or facial flushing (n=14), transient dizziness or nystagmus (n=3), increased pain in the arm or neck (n=3), and transient Horner syndrome (n=2)."

Thoracic ESI

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). A randomized controlled trial (RCT) completed by Manchikanti et al. (2014) 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 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.

Lumbar ESI

Yang et al. (2020) completed a meta-analysis of 6 RCTs with the goal of comparing the clinical effectiveness of ESI to conservation treatments for patients with lumbosacral radicular pain. Conservative treatments consisted of physical therapy, lifestyle modifications, exercise, and education. The meta-analysis included a total of 490 patients with 249 patients receiving ESI and 241 receiving conservative treatments. Inclusion criteria for RCTs included patient populations that were ≥ 18 years of age diagnosed with lumbar disc herniation or spinal stenosis that was confirmed using clinical or radiological evaluations. Exclusion criteria included review articles, abstracts, letters, case reports, absence of outcomes of interest (ODI, NRS, visual analog scale [VAS], and successful events). Post-injection follow-up pain scores (NRS and VAS) were reported in 5 of the RCTs. Follow-up periods were standardized to short-term (< 1 month), intermediate-term (1-3 months), and long-term (6 months-1 year). Short-term and intermediate-term follow-up periods were reported for pain scores by 3 RCTs with the pooled analysis showing ESI providing a significant reduction in pain compared to conservative treatments. Long-term follow-up periods were reported for pain scores by 2 RCTs (different from the short- and intermediate-term follow-up periods) with the pooled analysis showing that ESI was not more effective than conservative treatments. Functional improvement was determined using ODI and was reported in 4 RCTs. Short-term follow-up (1-3 months) was reported by 3 RCTs with pooled analysis showing equal effect between ESI and conservative treatments. Intermediate-term follow-up (3-6 months) showed no significant differences between ESI and conservative treatment. Successful events were dependent upon individual studies and

included the degree of overall improvement, reduction of ≥ 2 in leg pain scores, VAS reduction of > 20%, and patient satisfaction scores. Results for successful events were standardized based on criteria from each individual study. Pooled analysis showed that ESI had a significantly higher number of successful events when compared to conservative treatments.

SNRB

Fang et al. (2022) completed a systematic review and meta-analysis to compare the clinical efficacy of SNRBs using local anesthetic (LA) alone and a combination of steroids and LA (steroids+LA) for the treatment of degenerative disc disease. Inclusion criteria included studies with patient ages ≥ 18 years diagnosed with degenerative disc disease based on radiological evaluation (CT or MRI scans) and clinical manifestations of neck or waist pain along with nerve root pain. Exclusion criteria included a history of spinal surgery, nonspecific pains that were not definitively diagnosed as lumbar intervertebral or cervical disc herniation based on radiological exam, severe spinal canal stenosis, severe intervertebral disc degeneration, intravertebral disc disorders or herniations, and significant spinal instability. Outcomes measured were pain and functional measurement. Pain was reported using the NRS and VAS scales and both were considered equivalent and interchangeable for analysis. Follow-up ranged from 1 week to 2 years depending on the RCT. The follow-up selected for analysis were 3, 6, 12, 18, and 24 months due to the clinical significance of data at each of these time periods. A total of 22 RCTs reported follow-up at 3-months with all reporting NRS and ODI data. The mean deviation of NRS was 0.19 and the mean deviation of ODI was 0.98 with both showing steroids+LA as superior to LA alone. Nineteen RCTs reported NRS data and 13 reported ODI data at 6-months. The mean deviation of NRS was 0.11 with no significant difference between either group. However, the mean deviation of ODI was 1.13 with steroids+LA being superior. Nineteen RCTs reported NRS data and 15 reported ODI data at 12-months. The mean deviation of NRS was 0.11 with no significant difference between either group. The mean deviation of ODI was 0.94 with steroids+LA being superior. The same 9 RCTs reported NRS and ODI data at 18-months and 24-months. The mean deviation of NRS at 18-months was 0.10 and 24-months was 0.18 with no significant difference between either group. The mean deviation of ODI at 18-months was 0.73 and 24-months was 0.70 with no significant difference between either group.

National and Specialty Organizations

The **North American Spine Society (NASS)** (2020) published coverage policy recommendations on ESIs 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.

The **American Society of Interventional Pain Physicians (ASIPP)** evidence-based 2020 guidelines 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).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

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(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), cervical or thoracic, single level
64480	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), cervical or thoracic, each additional level (List separately in addition to code for primary procedure)
64483	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, single level
64484	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), 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.

APPROVAL HISTORY

08/09/2023	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References sections. Descriptions updated for codes 64479, 64480, 64483, and 64484. IRO Peer Review on July 13, 2023, by a practicing, board-certified physician with a specialty in Anesthesiology and Pain Management.
08/10/2022	Added clarification that caudal and interlaminar ESIs (62321 and 62323) are not appropriate to be requested or billed bilaterally.
04/13/2022	Coverage policy re-organized for additional clarity, added inclusion of thoracic region, added indications for SNRB. References and Summary of Evidence updated.
04/05/2021	Policy reviewed, no criteria changes. Coding updated (deleted CPT codes 0228T, 0229T, 0230T, 0231T; added CPT 64999).
04/23/2020	Policy reviewed, changed PT req. to min. of 4 weeks to be consistent with other guidelines and Molina pain management policies. IRO Peer Review by a practicing, board-certified physician with specialties in Pain Management and Physical Medicine and Rehabilitation.
06/19/2019	Policy reviewed, no changes to criteria.
03/08/2018	Policy reviewed, no changes to criteria.
07/2017	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.

REFERENCES

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11. Yang S, Kim W, Kong HH, et al. Epidural steroid injection versus conservative treatment for patients with lumbosacral radicular pain: A meta-analysis of randomized controlled trials. Medicine (Baltimore). 2020 Jul 24;99(30):e21283. doi: 10.1097/MD.0000000000021283. PMID: 32791709; PMCID: PMC7386972.

APPENDIX

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

Washington

For Medicaid reviews, consider and apply the following state-specific criteria: Health Technology Assessment (HTA) “Spinal Injections” Washington State Healthcare Authority, May 20, 2016.