**HEALTH EVIDENCE REVIEW COMMISSION (HERC)**

# COVERAGE GUIDANCE: PERCUTANEOUS INTERVENTIONS FOR CERVICAL SPINE PAIN

**As posted for public comment 5/7/2014 to 6/8/2014**

## HERC COVERAGE GUIDANCE

Therapeutic cervical spinal epidural injections are recommended for coverage for chronic cervical pain with radiculopathy (*weak recommendation*) only when all of the following criteria are met:

- documented herniated intervertebral disc with radicular pain in a corresponding dermatomal distribution.
- pain is intractable and conservative therapy has failed,
- fluoroscopic guidance or CT guidance is utilized,
- translaminar approach is utilized,
- no more than two injections without clinically meaningful improvement in pain and function, and
- maximum of three injections in six months.

Therapeutic cervical intraarticular facet joint injections and therapeutic cervical medial branch blocks are not recommended for coverage for facet joint pain (*strong recommendation*).

Facet joint radiofrequency neurotomy is recommended for coverage *(weak recommendation)* only when all the following criteria are met:

- at least 3 months of moderate to severe pain with functional impairment,
- pain is predominantly axial and not associated with radiculopathy,
- conservative therapy has failed, and
- complete or nearly complete pain relief (80% or greater) following fluoroscopically guided, low-volume local anesthetic blocks of the medial branch nerves, performed on two separate occasions using two commonly-used agents with different anticipated durations of action.

Note: Definitions for strength of recommendation are provided in Appendix A GRADE Element Description

## RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care

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- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCES

*Trusted Sources*

Hashimoto, R., Raich, A., Ecker, E., Henrikson, N., Wallace, L., Dettori, J., & Chou, R. (2011). *Spinal injections*. Olympia, WA: Washington Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/spinal_injections.html

Little, A., Pettinari, C., Vandegriff, S., Leof, A., Rahman, B., Zoller, E., Kriz, H., Gerrity, M., & King, V. (2013). *Spinal injections: Update to the March 2011 WA HTA report.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Hashimoto, R., Holmer, H.,Sherry, N., & Skelly, A. (2014). *Facet neurotomy.* Olympia, WA: Washington Health Technology Assessment Program. Retrieved from http://www.hca.wa.gov/hta/Pages/neurotomy.aspx

*Additional Sources*

Cohen, S.P., Bicket, M.C., Jamison, D., Wilkinson, I., & Rathmell, J.P. (2013). Epidural steroids: A comprehensive, evidence-based review. *Regional Anesthesia and Pain Medicine, 38*(3), 175-200. doi: 10.1097/AAP.0b013e31828ea086.

Lee, S.H., Kim, K.T., Kim, D.H., Lee, B.J., Son, E.S., & Kwack, Y.H. (2012). Clinical outcomes of cervical radiculopathy following epidural steroid injection: a prospective study with follow-up for more than 2 years. *Spine (Phila Pa 1976), 37*(12), 1041-1047. doi: 10.1097/BRS.0b013e31823b4d1f.

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

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## SUMMARY OF EVIDENCE

### Clinical Background

Chronic neck pain (defined as neck pain that persists more than three months) is common. Risk factors for spinal pain, including neck pain, include increasing age, spinal or disc degeneration, poor posture, anxiety, depression, and injuries. It can be attributed to a number of pathologic changes in the spine, including the following:

- Degenerative disc disease
- Herniated nucleus pulposus
- Spinal stenosis
- Facet joint syndrome
- Whiplash

Medical treatments available for chronic neck pain include non-invasive interventions such as physical therapy, pharmacologic therapy, psychological therapy, exercise, and spinal manipulation. For those patients with inadequate response to those treatments, spinal injections may be considered. Spinal injections involve the injection of an anti-inflammatory agent such as a steroid and/or an anesthetic agent into the spaces in and around the spinal nerves and joints. Types of spinal injection include epidural and facet joint injections and medial branch blocks. The latter two are generally used for pain believed to originate in the facet joint. It has been estimated that the point prevalences of facet joint pain are 10-15% in the low back and 45-55% in the neck. The primary symptom suggestive of facet joint pain is paraspinal tenderness at the affected facet joints, although other symptoms may be present as well, Diagnosis of facet joint pain cannot be accurately made by physical exam or imaging studies alone and diagnostic nerve blocks may be the most accurate assessment method. Epidural injections deliver medication into the epidural space of the spine to decrease inflammation of the nerve root. Two approaches are possible in the neck. The interlaminar or translaminar approach involves placement of the needle between the lamina of the vertebrae, delivering medication to both the right and left sides of the inflamed area. The transforaminal approach involves placement of the needle in the neural foramen, treating one side at a time.

Facet joint injections deliver the medications (anesthetic with or without a corticosteroid) into the facet joints and include several approaches. Medial branch blocks involve injection of the medication into the area of the medial branch of the posterior primary ramus. Prior to steroid injections, controlled diagnostic blocks of the joint or the nerves that supply the joint are often performed using local anesthetic. A positive block

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indicates that pain is eliminated and the affected nerve has been identified as the source of pain.

Once the facet joint is determined to be the source of pain as indicated by a positive diagnostic block, then prolonged pain relief may be achieved with destruction of the nerves to the affected joint in a procedure called facet neurotomy. Neurotomy does not cure the source of pain, but instead cuts off the pain signal from the brain by damaging the nerve. Different types of facet neurotomy are available, but the most common type employs radiofrequency needles to destroy the nerve tissue with heat generated by an electric current. During this procedure, the skin is anesthetized with a local anesthetic and the radiofrequency needles are advanced using guidance to confirm that the needles are properly positioned at the affected nerves. Then a radiofrequency current is applied to disrupt the ability of the nerves to transmit pain signals to the brain.

There are three types of radiofrequency (RF) neurotomy: standard, pulsed and cooled. Pulsed RF neurotomy delivers short bursts of radiofrequency current rather than the continuous flow utilized in non-pulsed RF neurotomy. Pulsed neurotomy allows the nerve tissue to cool between bursts, and is reported to reduce the destruction of neighboring tissue. Some other names used for this procedure include percutaneous radiofrequency denervation, nerve ablation, neurolysis, medial branch neurotomy, medial branch rhizotomy, and articular rhizolysis. Other types of facet neurotomy involve chemical ablation (application of ethyl alcohol, phenol, or sodium morrhuate; cryoablation (application of extreme cold); or laser ablation (application of laser beams) of the medial branch nerves to destroy the nerves and reduce or eliminate pain.

## Evidence Review

### Trusted Sources

These reports include studies of adults with sub-acute or chronic neck pain due to conditions including (but not limited to) degenerative disc disease, radiculopathy, disc herniation, spinal stenosis and facet joint pain. Evaluated treatments included epidural injections, intraarticular facet injections, medial branch blocks and facet neurotomy. Studies reporting on diagnostic injections, extraspinal injections (except as a comparator), chemonucleosis, intradiscal electrothermal therapy and coblation nucleoplasty were excluded. Comparators included any placebo injection (water, saline, local anaesthetic) or non-placebo controls. For efficacy, only randomized controlled trials (RCTs) were included.

A total of seven RCTs were identified that reported on efficacy. Studies were limited to the following populations:

- Chronic neck pain without disc herniation or radiculitis (one study)

- Chronic neck pain with disc herniation or radiculitis (one study)
- Chronic neck pain with resistant cervicobrachialgia (one study)
- Chronic neck pain of facet origin (two studies)
- Cervical post-surgery syndrome (one study)
- Cervical spinal stenosis (one study)

Most of the included studies evaluated one injection technique (interlaminar epidural, facet joint or medial branch block) and compared steroid plus local anaesthetic injection to local anaesthetic alone. However, the trial of patients with resistant cervicobrachialgia compared epidural steroid plus local anaesthetic injection to posterior neck muscle injection with the same substances. The one trial that evaluated facet joint injections compared steroid injection (without local anaesthetic) to local anaesthetic injection.

*Efficacy/Effectiveness*
For trials comparing cervical epidural steroid injections with:

- Placebo injections for neck pain with disc herniation and radiculitis, there is no benefit based on data from one lower-quality RCT (strength of evidence = very low).
- Placebo injections for neck pain without disc herniation and radiculitis, there is no benefit based on data from one lower-quality RCT (strength of evidence = very low).
- Intramuscular injections for neck pain with disc compression and radiculitis, there is evidence that epidural injections were superior based on data from one lower-quality RCT (strength of evidence = very low).
- Placebo injections for post-surgery syndrome, there is no benefit based on data from one fair quality RCT (strength of evidence = very low).
- Placebo injections for cervical spinal stenosis, there is no benefit based on data from one fair quality RCT (strength of evidence = very low).

For trials comparing cervical intraarticular facet joint steroid injections with:

- Placebo injections for confirmed facet joint pain, there is no benefit based on data from one lower-quality RCT (strength of evidence = very low).

For trials comparing cervical medial branch blocks with:

- Placebo injections for confirmed facet joint pain, there is no benefit based on data from one lower-quality RCT (strength of evidence = very low).

For trials comparing different approaches for administering cervical epidural steroids:

- There were no significant differences between anterolateral and posterolateral approaches in estimated change from baseline in pain score or disability index at two weeks or two months. There is no apparent difference in efficacy based on differing approaches for administering cervical epidural steroids (strength of evidence = very low).

For trials comparing RF neurotomy with:

- Sham neurotomy in patients with confirmed facet joint pain (based on 100% response to three medial branch blocks), significantly more patients in the RF neurotomy group had freedom from "accustomed pain" (risk difference, 50% (95% CI, 18% to 82%) (P = 0.0110) based on evidence from one small (N=24) RCT (strength of evidence = very low).

**Table 1. Efficacy/Effectiveness**

| Indication | Population characteristics | Comparator | Strength of Evidence | Conclusions |
|---|---|---|---|---|
| **Cervical Epidural Steroid Injections** | | | | |
| Neck pain with disc herniation and radiculitis | Cervical disc herniation or radiculitis, chronic neck pain > 6 months duration, no spinal stenosis unless accompanied by disc herniation, no prior cervical spine surgery, opioid use stable/ controlled | Placebo epidural injection (local anaesthetic) | Very low | No benefit in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one RCT. |
| Neck pain without disc herniation and radiculitis | Negative diagnosis of facet joint pain (by use of local anaesthetic blocks), absence of disc herniation/ radiculitis or spinal stenosis, chronic neck/arm pain > 6 months duration, opioid use stable/ controlled | Placebo epidural injection (local anaesthetic) | Very low | No benefit in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one RCT. |

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| Indication | Population characteristics | Comparator | Strength of Evidence | Conclusions |
|---|---|---|---|---|
| Neck pain with disc compression and radiculitis | Chronic resistant cervicobrachialgia, continued pre-study treatments (medications, PT).<br><br>Full text only available for purchase | Intramuscular injection (saline and local anaesthetic) | Very low | Epidural injections were superior to intramuscular injections in the posterior neck in terms of pain, analgesic use, and employment at one week and twelve months based on data from one RCT. |
| Post-surgery syndrome | Cervical post-surgery syndrome, surgery > 1 year previously with continued pain for at least 6 months after surgery, opioid use stable/ controlled | Placebo epidural injection (local anaesthetic) | Very low | No benefit in terms of pain or disability at 3, 6 and 12 months based on data from one RCT. |
| Cervical spinal stenosis | Cervical central spinal stenosis with or w/o foraminal stenosis, age > 30, chronic neck pain of at least 6 on a scale of 1-10, at least 6 months duration, failed to improve with conservative management (PT, chiro, exercise, drugs, bed rest), opioid use stable/ controlled | Placebo epidural injection (local anaesthetic) | Very low | No benefit in terms of pain or disability at 3, 6 and 12 months based on data from one RCT. |
| **Cervical Intraarticular Facet Joint Steroid Injections** | | | | |
| Confirmed facet joint pain | Neck pain lasting > 3 months due to MVA with documented positive response to medial branch block | Placebo facet injection (local anaesthetic) | Very low | No benefit in terms of the length of pain relief based on one RCT. No long-term data was reported. |
| **Cervical Medial Branch Blocks (local anaesthetic + steroid, ± Sarapin*)** | | | | |
| Confirmed facet joint | Non-specific neck pain > 6 months | Placebo injection | Very low | No benefit in terms of pain or function at both three |

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| Indication | Population characteristics | Comparator | Strength of Evidence | Conclusions |
|---|---|---|---|---|
| pain | duration, confirmed facet joint pain (response to local anaesthetic blocks), no radicular symptoms, failed conservative management (PT, chiro, exercise, drugs, bed rest), opioid use not heavy, continued previous interventions | (local anaesthetic ± Sarapin) | | and twelve months or on opioid use or employment at twelve months based on one RCT. |
| **Facet Neurotomy** | | | | |
| Confirmed facet joint pain | Failed conservative management (mean duration of pain 34 to 44 months), responded to 3 MBBs (100% pain relief) | Sham RF neurotomy | Very low | Significantly more patients in the RF neurotomy group had freedom from "accustomed pain" (risk difference, 50% (95% CI, 18% to 82%) (P = 0.01) |
| Cervicogenic headache | Cervicogenic HA of at least 2 years duration, rated at least 50 out of 100 on VAS, considerable pain at least 2 days/wk, no prior neck surgery | Injection of major occipital nerve | Low | No difference between groups in headache relief or a composite measure of success at 2 months |
| Facet joint pain | Patients with previously successful RF neurotomy | None – 3 case series | Very low | Patients are likely to experience a similar response to subsequent RF neurotomy procedures as they experienced during their first RF neurotomy procedure |

*Sarapin is a suspension of powdered sarracenia purpurea (pitcher plant). This study had a total of four patient groups, but outcomes were not reported by use of this product.

*Harms*

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- Major complications are rare following injections into the cervical spine and included a life-threatening generalized anaphylactic reaction, grand-mal seizure, dural puncture, subarachnoid puncture, and local hematoma. There were no cases of death or paralysis in the included studies, although there have been case reports of each in the published literature.
- Multiple publications have addressed the outbreak in fungal infections and deaths that resulted from the use of contaminated steroid preparations when delivering epidural steroid injections. As of December 27, 2012, there had been 620 cases of fungal meningitis, stroke presumed due to fungal meningitis, other central nervous system-related infection or septic arthritis attributed to the contamination, and 39 deaths.
- Other major complications were reported in case series of a mixture of lumbar and cervical spinal injection patients and included chest pain, tachycardia/hypertension, significant transient hypertensive episode, hematoma, dural puncture, and a severe vasovagal reaction.
- Minor complications are more common following lumbar or cervical spinal injections but are generally transient in nature, and include pain at the injection site, increased radicular pain/numbness/weakness, nerve root irritation, superficial infections, sympathetic blockade, facial flushing or rash, vasovagal reactions/fainting, headache, gastric complaints, dizziness, pruritus, irregular periods, and insomnia.
- With proper protective measures, total radiation exposure to the physician was within normal limits following a mean of 923 procedures (range, 100 to 1819) with an average length of radiation exposure of 9.8 seconds/procedure (range, 4.9 to 15.2) in all five case series identified.

**Table 2. Harms**

| Spinal Injections | Strength of Evidence | Conclusions |
|---|---|---|
| Major complications | High | Major complications are rare following injections into the cervical spine. There were no cases of death or paralysis in the included studies, although there have been case reports of each in the published literature.<br>In five RCTs, there were reports of subarachnoid puncture in 3/710 injections or patients and no reports of dural puncture or death. In four case series there were reports of life-threatening generalized anaphylactic reaction (1 case), grand-mal seizure (1 case), dural puncture (2 cases), and local hematoma (1 case) in 7240 injections or patients. |

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| Spinal Injections | Strength of Evidence | Conclusions |
|---|---|---|
| | | In three case reports of a mix of lumbar and cervical spinal injection patients, there was one case of each of the following major complications in 6935 injections: chest pain, tachycardia/hypertension, significant transient hypertensive episode, hematoma, dural puncture, and a severe vasovagal reaction. |
| Minor complications | High | Minor complications are more common but are generally transient in nature. They were rare as reported in 5 RCTs. One non-randomized study reported an overall minor complication rate of 1.64%. Complications included: pain at the injection site, increased usual pain, transient pain/weakness, nerve root irritation, transient global amnesia, superficial infections, sympathetic blockade, vasovagal reactions, facial flushing, headache, nausea. |
| Vascular puncture | Low | The mean incidence of intravascular puncture following fluoroscopically guided cervical spinal injections was 15.6% (range, 4.0–19.4%) as reported in two studies. These studies evaluated the incidence but not the consequences of intravascular injection.<br>The TruCath Spinal Injection System™ may decrease the incidence of vascular puncture. |
| Radiation exposure to the physician | Low | With proper protective measures, total radiation exposure was within normal limits following a mean of 923 procedures (range, 100 – 1819) with an average length of radiation exposure of 9.8 seconds/procedure (range, 4.9 – 15.2) in all five case series identified. |

For RF neurotomy, the only adverse event reported more frequently for RF neurotomy compared to sham was numbness in the area of the treated nerves. Other adverse events reported were psoriatic rash and pain associated with the procedure, neither of which differed significantly from the sham group. Overall strength of the evidence is low.

**Additional Sources**

Because of the weak evidence base for ESI, the subcommittee chose to consider additional evidence that was provided by the HERC-appointed expert for this topic. The expert provided a systematic review and a retrospective cohort study, both described below.

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Cohen 2013

This review included an extensive search of the literature, and all study types were included. However, details of the search, including number and type of studies, were not provided. Authors state that "recommendations were based on a conglomeration of factors including weighted evidence …, consensus guidelines when relevant, and perceived bias" (p. 175). No quality assessment of included studies was completed, and there was no explicit link between the evidence and recommendations. The review provides a summary of the literature and recommendations for use of epidural steroids in the spine.

Pertaining to injection approach:

There are two different approaches for delivering epidural steroids in the cervical region, interlaminar (IL), or translaminar, and transforaminal (TF). An interlaminar injection involves passage of the needle through the ligamentum flavum in the posterior midline of the spine. Advantages of this approach are purported to be a higher likelihood that the injected medication will reach adjacent spinal levels and the ability to treat bilateral pain. Disadvantages include the potential for dural puncture and the dorsal deposition of the medication, which is more distant from the site of pathology. The transforaminal approach involves placement of the needle within the neuroforamen. Theoretical advantages are that it is the most target specific, carries a lower risk of dural puncture and is associated with a greater incidence of ventral spread. However, they are associated with a higher risk of catastrophic neurological complications.

Pertaining to the efficacy of ESI in the cervical region:

For interlaminar injections, the authors cite three systematic reviews, one of which was supportive of the efficacy of ESI for a variety of conditions, while the other two reported that ESIs are probably effective in the short-term. One of these stated that definitive evidence was lacking, and that the evidence was stronger for herniated disc and non-osseous central stenosis. The other reported that evidence was lacking for long-term efficacy.

For transforaminal injections, the authors report a single RCT, but multiple nonrandomized studies reporting both short and long term efficacy. They also note multiple reports of potentially catastrophic complications. The authors recommend the following:

> "Overall, the literature suggests that although the TF approach may be more efficacious than the IL or caudal approaches, the difference in effect size is small. In the cervical, thoracic, and midlumbar to high lumbar regions, the increased risk for catastrophic neurological complications should preclude the use of TF ESI as a first-line treatment." (p. 181)

Lee 2012

Lee (2012) is a retrospective cohort study in which 98 patients who received cervical ESI for cervical radiculopathy without major neurologic deficit were followed for two years, then were analyzed based on whether they received spine surgery or not. Patients must have failed 4 weeks of conservative therapy and not have myelopathy or definite motor weakness. The injection was repeated up to 3 times at 1 to 2 week intervals, if pain relief was insufficient (less that 80% improved). Authors report that patients received an average of 1.8 ESI, and that at the 2-year follow up point, 80.6% of patients had not had surgery.

Analysis of clinical factors associated with proceeding to surgery found that having had a previous episode of cervical radiculopathy, pre-ESI pain score and post-ESI pain score were the only correlated factors. 15% of patients in the non-surgery group had a previous episode of cervical radiculopathy, compared to 42% in the surgery group ($p=0.02$). Prior to ESI, patients in the non-surgery group had a mean visual analogue scale (VAS) score for arm pain of 6.1, compared to 8.2 in the surgical group. Post ESI, the non-surgical group had a mean VAS pain score of 2.8 compared to 6.9 for the surgical group ($p<0.001$ for both). Factors for which there was no statistically significant difference between groups included gender, age, duration of symptoms, type of symptoms, compensation or number of ESI.

### Evidence Summary

There is no evidence of benefit of epidural steroid injections compared with placebo injections for neck pain in patients either with or without disc herniation and radiculitis, post-surgery syndrome or cervical spinal stenosis. On the other hand, epidural injections appear to be superior to intramuscular injections in patients with disc compression and radiculitis. Conclusions regarding the efficacy of ESI from other sources are mixed, but suggest if they are effective, it is likely only short-term. One study suggests that ESI may result in a decreased risk of cervical surgery. There is no evidence of benefit of cervical intraarticular facet joint steroid injections or medial branch blocks compared with placebo injections for confirmed facet joint pain. There is no apparent difference in efficacy based on differing approaches for administering cervical epidural steroids. There is limited evidence of benefit of RF neurotomy in patients with confirmed facet joint pain.

Major complications are rare following injections into the cervical spine but can include a life-threatening generalized anaphylactic reaction, grand-mal seizure, dural and subarachnoid puncture, paralysis and death. Expert opinion in one review notes multiple reports of potentially catastrophic complications using a transforaminal injection approach and recommends against their use, despite similar or better efficacy compared to intralaminar approaches. An outbreak in fungal infections and deaths that

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resulted from the use of contaminated steroid preparations when delivering epidural steroid injections occurred in 2012. Minor complications are more common but are generally transient in nature. No major complications of RF neurotomy have been reported.

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GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

| Indication/ Intervention | Balance between desirable and undesirable effects | Quality of evidence* | Resource allocation | Variability in values and preferences | Coverage Recommendation | Rationale |
|---|---|---|---|---|---|---|
| Epidural steroid injections | Balance may result in some net benefit | Effectiveness evidence: Very low<br><br>Harms evidence: High | Moderate | Moderate to high, given some may prefer interventional vs. pharmacologic vs. lifestyle or more conservative interventions | Recommended for coverage, only when all the following criteria are met: documented herniated intervertebral disc with radiculopathy in a corresponding distribution; pain is intractable and conservative therapy has failed, fluoroscopic guidance or CT guidance is utilized; translaminar (interlaminar) approach is utilized; no more than two injections without clinically meaningful improvement in pain and function; and maximum of three injections in six months. *(weak recommendation)* | Though quality of evidence from trusted sources is very low, there is evidence from additional sources, namely a retrospective single cohort study, of some benefit when the previously mentioned criteria are met. Additionally, other payer policies include a similar recommendation, namely Medicare and Washington State's payer policies. |
| Facet joint injections | No benefit | Effectiveness evidence: Very low<br><br>Harms | Moderate | Moderate to high, given some may prefer interventional | Not recommended for coverage *(strong recommendation)* | No net benefit; some harms |

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| Indication/ Intervention | Balance between desirable and undesirable effects | Quality of evidence* | Resource allocation | Variability in values and preferences | Coverage Recommendation | Rationale |
|---|---|---|---|---|---|---|
| | | evidence: High | | vs. pharmacologic vs. lifestyle or more conservative interventions | | |
| Therapeutic medial branch blocks | No benefit | Effectiveness evidence: Very low<br><br>Harms evidence: High | Moderate | Moderate to high, given some may prefer interventional vs. pharmacologic vs. lifestyle or more conservative interventions | Not recommended for coverage *(strong recommendation)* | No net benefit; not common practice; some harms |
| RF neurotomy | Some evidence of benefit, minimal harms | Effectiveness evidence: Very low<br><br>Harms evidence: High | Moderate | Moderate to high, given some may prefer interventional vs. pharmacologic vs. lifestyle or more conservative interventions | Recommended for coverage, only when all of the following criteria are met: at least 3 months of moderate to severe pain with functional impairment; pain is predominantly axial and not associated with radiculopathy; conservative therapy has failed; and at least 80% improvement from initial pain level following fluoroscopically-guided, low-volume local anesthetic blocks of the medial branch nerves, performed on two separate occasions. *(weak recommendation)* | Though quality of evidence from trusted sources is very low, the evidence shows there is some benefit when the previously mentioned criteria are met. Coverage with these criteria was recommended by appointed expert. |

*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee

Note: GRADE framework elements are described in Appendix A

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## POLICY LANDSCAPE

### Quality Measures

No pertinent quality measures were identified when searching the National Quality Measures Clearinghouse.

### Professional Society Guidelines

Guidelines reviewed in the WA HTA Spinal Injections report (Hashimoto, 2011) are included in Appendix D.

### Payer Coverage Policies

Coverage policies for selected payers are included here.

*Medicare*

Two local coverage determinations were identified in the Medicare Coverage Database.

- L30481 Epidural and Transforaminal Epidural Injections
- L33842 Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy

Medicare coverage guidance is detailed in Appendix E.

*Washington HTA Limitations of Coverage*

Therapeutic Epidural Injections in the lumbar or cervical-thoracic spine for chronic pain are a covered benefit when all of the following conditions are met:

- For treatment of radicular pain
- With fluoroscopic guidance or CT guidance
- After failure of conservative therapy
- No more than two without clinically meaningful improvement in pain and function, and
- Maximum of 3 in 6 months

## COMMITTEE DELIBERATIONS – VALUE-BASED BENEFITS SUBCOMMITTEE

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Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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## Appendix A. GRADE Element Descriptions

| Element | Description |
|---|---|
| Balance between desirable and undesirable effects | The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted |
| Quality of evidence | The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted |
| Resource allocation | The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted |
| Values and preferences | The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted |

**Strong recommendation**

***In Favor:*** The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

***Against:*** The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

**Weak recommendation**

***In Favor:*** The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

***Against:*** The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

**Quality or strength of evidence rating across studies for the treatment/outcome**[1]

***High*:** The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

***Moderate*:** The subcommittee is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

***Low*:** The subcommittee's confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

***Very low*:** The subcommittee has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

[1] Includes risk of bias, precision, directness, consistency and publication bias

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## Appendix B. Applicable Codes

| CODES | DESCRIPTION |
|---|---|
| **ICD-9 Diagnosis Codes** | |
| 720.9 | Unspecified inflammatory spondylopathy |
| 721 | Spondylosis , various |
| 722 | Degeneration/displacement intervertebral disc, various |
| 723 | Spinal stenosis, brachial neuritis or radiculitis, various |
| 724 | Spinal stenosis, various |
| 738.4 | Acquired spondylolisthesis |
| **ICD-10 Diagnosis Codes** | |
| M43.00-3 | Spondylolysis |
| M43.10-3 | Spondylolisthesis |
| M47.10-3 | Other spondylosis with myelopathy |
| M47.20-3 | Other spondylosis with radiculopathy |
| M47.811-3, M47.819 | Spondylosis without myelopathy or radiculopathy |
| M47.891-3 | Other spondylosis |
| M48.00-3 | Spinal stenosis |
| M50 | Cervical disc disorders |
| M54.10-3 | Radiculopathy |
| M54.2 | Cervicalgia |
| **ICD-9 Volume 3 (Procedure Codes)** | |
| 03.91 | Injection of anesthetic into spinal canal for analgesia |
| 03.92 | Injection of another agent into spinal canal |
| **CPT Codes** | |
| 62310 | Inject spine cervical/thoracic |
| 64479 | Inj foramen epidural c/t |
| 64480 | Inj foramen epidural add-on |
| 64490-64495 | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (flouro or CT), cervical, thoracic, lumbar or sacral; single, second or third level |
| 64633-64636 | Destruction by neurolytic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (flouro or CT), cervical, thoracic, lumbar or sacral; single, second or third level |
| 0213T–0218T | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical, thoracic, lumbar or sacral; single, second or third level |
| 77003 | Fluoroguide for spine injection |
| **HCPCS Level II Codes** | |
| None | |

Note: Inclusion on this list does not guarantee coverage

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## Appendix C. HERC Guidance Development Framework

*HERC Guidance Development Framework Principles*

This framework was developed to assist with the decision making process for the Oregon policy-making body, the HERC and its subcommittees. It is a general guide, and must be used in the context of clinical judgment. It is not possible to include all possible scenarios and factors that may influence a policy decision in a graphic format. While this framework provides a general structure, factors that may influence decisions that are not captured on the framework include but are not limited to the following:

- Estimate of the level of risk associated with the treatment, or any alternatives;
- Which alternatives the treatment should most appropriately be compared to;
- Whether there is a discrete and clear diagnosis;
- The definition of clinical significance for a particular treatment, and the expected margin of benefit compared to alternatives;
- The relative balance of benefit compared to harm;
- The degree of benefit compared to cost; e.g., if the benefit is small and the cost is large, the committee may make a decision different than the algorithm suggests;
- Specific indications and contraindications that may determine appropriateness;
- Expected values and preferences of patients.

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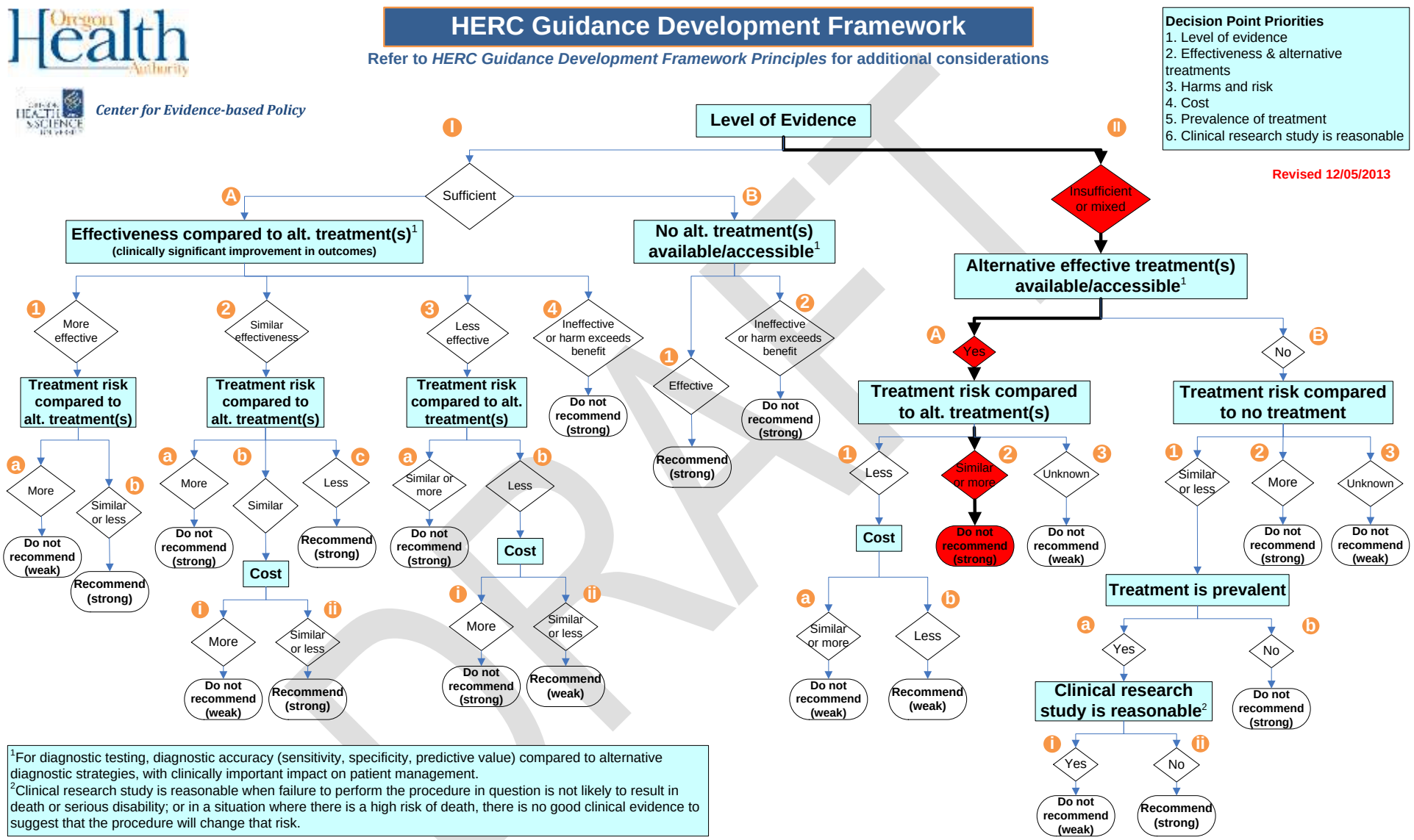
## Facet Joint Injections, Therapeutic Medial Branch Blocks




[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

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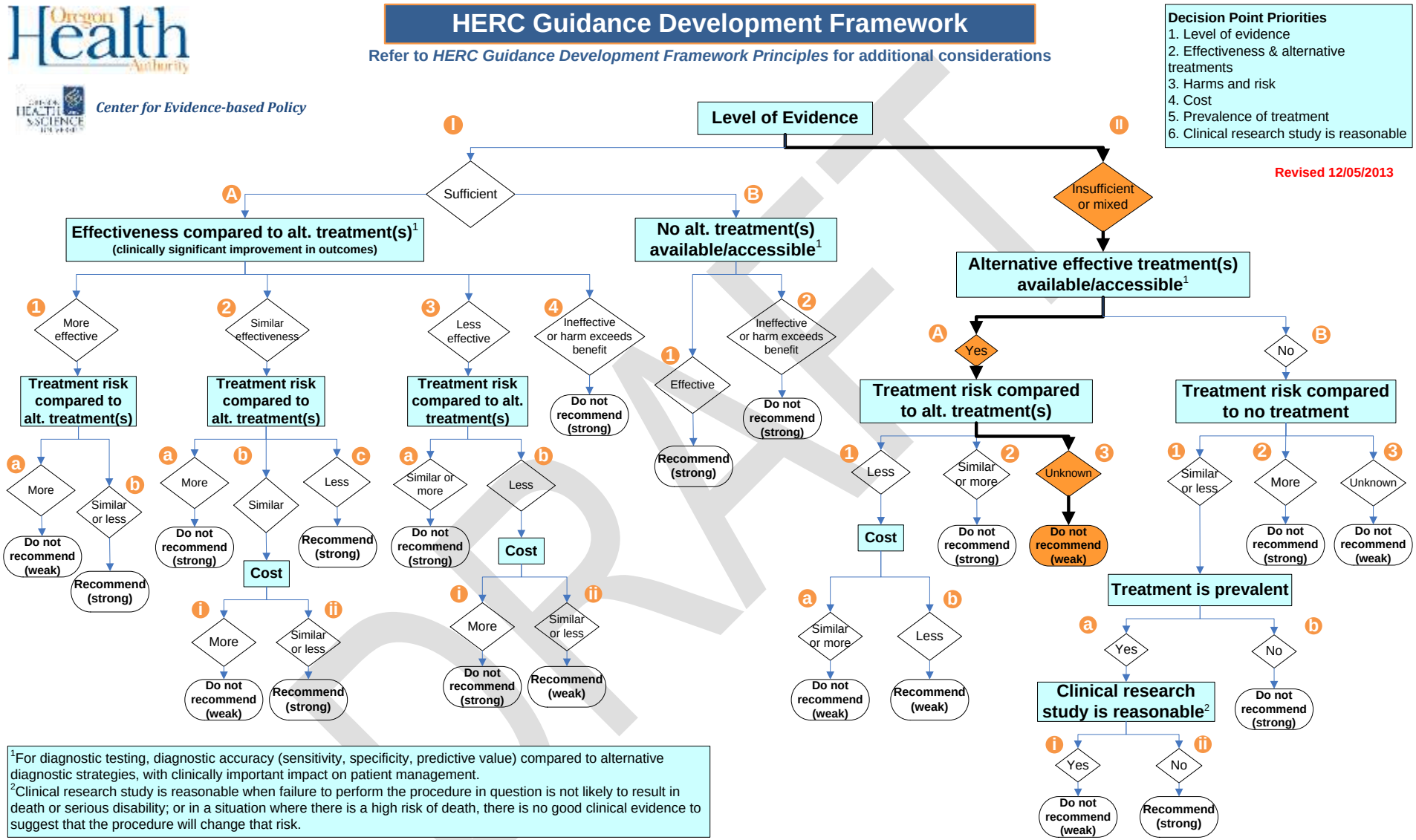
## Epidural Steroid Injections, RF Neurotomy

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## Appendix D. Guidelines Included in the WA HTA Spinal Injections Report

Hashimoto, R., Raich, A., Ecker, E., Henrikson, N., Wallace, L., Dettori, J., & Chou, R. (2011). *Spinal Injections*. Olympia, WA: Washington Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/documents/spinal_injection_draft_report.pdf

Fourteen guidelines were reported in this report. Of those, five pertain to cervical pain. One of those addressed chronic pain in general, was from 2008 and could not be retrieved, therefore was not assessed further. At the request of HERC staff, the quality of the other four guidelines was rated using an instrument adapted from the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration. A summary of the pertinent recommendations and the quality rating of each guideline is presented in the table below:

| Guideline | Recommendations | Quality |
|---|---|---|
| American Society of Interventional Pain Physicians. (2009) Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain (NGC:007428). [Updated in 2013]. http://asipp.org/Guidelines.htm | Cervical discography is indicated only when a treatment is available to test the diagnostic hypothesis of discogenic pain of the cervical spine in individuals who have been properly selected and screened to eliminate other sources of cervical pain.<br><br>There is good evidence for disc herniation and fair evidence for axial or discogenic pain, central spinal stenosis, and post cervical surgery syndrome. Cervical interlaminar epidural injections are indicated for these conditions with appropriate indications.<br><br>Diagnostic cervical facet joint nerve blocks are recommended in patients with somatic or non-radicular neck pain or headache and upper extremity pain, with duration of pain of at least 3 months, without preponderance of evidence of discogenic pain, disc herniation, or evidence of radiculitis.<br><br>There is fair evidence for conventional radiofrequency neurotomy and therapeutic facet joint nerve blocks with limited evidence for intraarticular injections. Consequently, the recommendation is that therapeutic facet joint nerve blocks or conventional radiofrequency neurotomy may be provided based on the response from controlled diagnostic blocks. | Poor |
| Institute for Clinical Systems Improvement. (2009). *Assessment and management of chronic pain* (NGC:007602). [Updated in 2013]. https://www.icsi.org/guidelines__more/ca | Examples of commonly used therapeutic procedures are as follows.<br><br>**Facet joint injection**<br>Facet joints are an important source of spinal pain in the cervical and lumbar regions. These joints can be reliably anesthetized by way of fluoroscopically guided joint injections. Generally, a depot cortico-steroid is administered concomitantly, which may provide short-term benefit for a subset of patients. However, clinical trials have failed to demonstrate any sustained therapeutic benefits following facet joint corticosteroid injections *(Nelemans, 2005 [Systematic Review])*. | Poor |

| Guideline | Recommendations | Quality |
|---|---|---|
| talog_guidelines_and_more/catalog_guidelines/catalog_neurological_guidelines/pain/ | **Percutaneous radiofrequency neurotomy**<br>Percutaneous radiofrequency (RF) neurotomy (sometimes erroneously referred to as facet rhyzotomy) is a treatment for neck or back pain generated by facet joints. Properly selected candidates for this procedure should experience complete or nearly complete relief of their pain following fluoroscopically guided, low-volume local anesthetic blocks of the medial branch nerves that innervate the pain-generating joint(s). To minimize false-positive results, an equivalent degree of relief of appropriate pharmacologic duration should be carefully documented on two separate occasions, using two different types of local anesthetic. The radiofrequency procedure is performed by placing an insulated needle electrode with an exposed tip adjacent to and in parallel with the medial branch nerves that supply the target joint(s). Radiofrequency current applied to the electrode then heats the adjacent tissues and coagulates the nerve supply to the joint. For the procedure to be effective, multiple lesions must be performed at each nerve location, using electrodes of sufficient diameter. The nerves do regenerate over time, so pain relief is not permanent, but the procedure can be repeated.<br><br>Radiofrequency neurotomy can provide pain relief for carefully selected patients, but this procedure should be performed only by an experienced pain medicine physician in the context of a longitudinal and comprehensive care plan. Proper patient selection and appropriate technique in positioning the radiofrequency electrodes are absolutely essential to the success of the procedure *(Bogduk, 2008 [Low Quality Evidence]; Nath, 2008 [Moderate Quality Evidence]; Hooten, 2005 [Guideline])*. Controversy in the literature regarding the efficacy of lumbar radiofrequency neurotomy has arisen from fundamentally flawed clinical trials that have used inappropriate patient selection criteria, and improper procedural technique.<br><br>**Epidural corticosteroid injections**<br>Epidural corticosteroid injections are one of the most commonly performed interventions for treatment of spinal pain with a radicular component. All epidural injections should be performed by an experienced physician, under fluoroscopic guidance, using contrast injection to detect vascular uptake and to demonstrate the injectate spread pattern. There are three approaches to the epidural space, including a transforaminal, intralaminar and a caudal technique. Limited evidence was found to support the efficacy of this procedure *(Riew, 2000 [High Quality Evidence]; Carette, 1997 [High Quality Evidence]; Dilke, 1973 [High Quality Evidence])*.<br><br>**Transforaminal epidural injection**<br>Transforaminal epidural injections can be used to determine the spinal level that is the source of radicular pain. The risks of cervical transforaminal epidural steroid injections have been well documented in case reports *(Beckman, 2006 [Low Quality Evidence]; Tiso, 2004* | |

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| Guideline | Recommendations | Quality |
|---|---|---|
| | *[Low Quality Evidence]; Furman, 2003 [Low Quality Evidence]*). Specifically, cervical transforaminal epidural steroid injections have been associated with spinal cord and brain injuries resulting in permanent neurological deficits and/or death. These adverse events have been caused by uptake of particulate corticosteroids into radicular or vertebral arteries, producing embolization, severe vasospasm, and either brain or spinal cord infarction. For cervical procedures, it is recommended that only non-particulate corticosteroids be utilized. These procedures should be performed only by an experienced pain medicine physician with access to and knowledge of the use of appropriate imaging equipment and patient monitoring facilities, and should be performed only in the context of a longitudinal care plan, as directed and coordinated by a pain medicine physician *(Bogduk, 2008 [Low Quality Evidence]; Tiso, 2004 [Low Quality Evidence])*. | |
| Work Loss Data Institute. (2008). *Neck and upper back (acute & chronic)* (NGC:006563). [Updated 2011]. Unable to retrieve full guideline (subscription only). http://www.guideline.gov/content.aspx?id=33185 | This guideline was not available without full subscription to the WLDI. Review of the summary on the NGC recommends consideration of ESI on the 4th visit, 3-4 weeks after onset of pain, only in those with neurologic findings, only for those "severe cases hoping to avoid surgery". | Unable to assess quality without access to full guideline |
| Work Loss Data Institute. (2008). *Pain (chronic)* (NGC:006564). [Updated 2011]. Unable to retrieve full guideline (subscription only) http://www.guideline.gov/content.aspx?id=33188 | This guideline was not available without full subscription to the WLDI. Review of the summary on the NGC did not specifically address neck pain, but states that epidural steroid injections and facet blocks are recommended. Additional information about indications is not provided in the NGC summary. | Unable to assess quality without access to full guideline |

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## Appendix E. CMS Local Coverage Decisions

### L30481 Epidural and Transforaminal Epidural Injections

*Original Effective Date:* For services performed on or after 04/15/2010
*Revision Effective Date:* For services performed on or after 02/01/2014
*Jurisdiction:* Includes Oregon

**Coverage Indications, Limitations, and/or Medical Necessity**
Epidural injections are used for acute and chronic pain, in addition to cancer pain management. Epidural injections are utilized both for diagnostic and therapeutic purposes.

A multi-disciplinary or collaborative comprehensive evaluation (e.g. orthopedics, neurologist, neurosurgeon, physiatrist, anesthesiologist, pain medicine specialist, and/or attending physician), is recommended prior to initiating a trial of these injections for relief of chronic recurrent pain.

Epidural steroid injections, both interlaminar/translaminar and transforaminal should be used only in the presence of radiculopathy.

**Indications for Diagnostic and Therapeutic Epidural Injections**
**Diagnostic** interlaminar/translaminar or caudal epidural steroid injections are seldom used. Although the medication injected can sometimes be confined to a limited area, bilateral effects and spread to adjacent levels often occur.

**Therapeutic** interlaminar/translaminar or caudal epidural injections and infusions of opioid, local anesthetic, or other medications may be used for the treatment of acute and chronic pain or cancer pain.

Epidural injections (interlaminar/translaminar or caudal) may be used for the following.

- Acute obstetric, post traumatic and postoperative pain
- Advanced cancer pain, primary or metastatic
- Acute/sub acute and chronic pain syndrome including cervical, thoracic and lumbar pain with radiculopathy and intervertebral disc disease (with neuritis or radiculitis) with or without myelopathy that has failed to respond to adequate conservative management.
- Nerve root injuries and neuropathic pain and post traumatic including post laminectomy syndrome (failed back syndrome).
- Spinal cord myelopathy
- Complex regional pain syndrome
- Epidural scarring from prior infection, hemorrhage and/or surgery

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- Multiple rib fractures
- Vertebral compression fractures
- Post herpetic neuralgia and herpes zoster
- Phantom limb pain

**Indications for Diagnostic and Therapeutic Transforaminal Epidural Injections**
Transforaminal epidural injection is a selective injection of the cervical, thoracic, lumbar or sacral nerve roots with proximal spread of contrast or local anesthetic through the neural foramen to the epidural space. With the aid of fluoroscopic or computed tomography (CT) imaging, the needle tip is placed within or adjacent to the lateral margin of the neural foramen and contrast material is injected to obtain a neurogram and visualize spread of the injected solution.

A small volume of local anesthetic is injected (less than or equal to 1.0 ml) in order to perform a diagnostic reproducible blockade of a specific nerve root. The diagnostic usefulness is lost if more than 1.0 ml of local anesthetic is injected (the block becomes unreliable since the spread of anesthetic to adjacent levels and structures likely occurs).

**Diagnostic** transforaminal epidural injections are appropriate for the following purposes.

- To differentiate the level of radicular nerve root pain.
- To differentiate radicular from non radicular pain
- To evaluate a discrepancy between imaging studies and clinical findings
- To identify the source of pain in the presence of multi-level nerve root compression
- To identify the level of pathology at a previous operative site

It might be necessary to perform injections at two different nerve root levels on the same date of service. When multiple levels of nerve root compression or stenosis is suspected to be responsible for the patient's symptoms, presence of the compression or stenosis on imaging studies should be documented in the medical record.

**Therapeutic** transforaminal epidural injections are appropriate for the following purposes:

Corticosteroid can be added as a therapeutic measure. Injections for therapeutic reasons can be of greater volume. The transforaminal injection can be performed for diagnostic, therapeutic or both purposes.

- Radicular pain resistant to more conservative measures or when surgery is contraindicated.
- Post-decompressive radiculitis or post surgical scarring

- Monoradicular pain, confirmed by diagnostic block in which a surgically correctible lesion cannot be identified
- Treatment of acute herpes zoster or post herpetic neuralgia

**General Indications and Limitations**

Epidural (interlaminar/translaminar or caudal) and transforaminal epidural corticosteroid injections should not exceed a series of three, per spinal region, within a six-month period when used as treatment for a pain disorder other than treatment for cancer pain. These may be performed at intervals of one week or greater. With each subsequent injection the medical record should clearly document the interval effects from the prior injection(s). Appropriate reasons for a repeat injection are: (a) significant improvement in the patient's symptoms from the prior injection, even if relapsed, or (b) carefully documented technical reasons that it is appropriate to repeat the procedure even if no prior improvement and (c) patients with persistent pain in whom the imaging findings suggest that the pathology should respond to corticosteroid injection. In the absence of a compelling technical reason, it is not appropriate to repeat a procedure a third time if there has been no improvement from the two preceding.

If corticosteroids are used, consideration should be given to the potential complications of repetitive corticosteroid administration.

Many of these procedures, such as those in the peri-operative period, may not require fluoroscopy.

For treatment of chronic pain, the standard of care is that these procedures be performed under fluoroscopic or CT guided imaging. Therefore injections for chronic pain performed without imaging guidance will be considered not medically necessary.

Fluoroscopic guidance **must** be utilized in the performance of single nerve root/transforaminal injections to ensure the precise placement of the needle and medications injected.

Anti-spasmodic drugs administered intrathecally (e.g., baclofen) to treat chronic intractable spasticity are addressed in the Infusion Pump NCD Pub. 100-3 Sec. 280.14. The CPT description of procedure codes 62310, 62311, 62318 and 62319 include anesthetic, antispasmodic, opioid, steroid, other solution; therefore the spasticity conditions are included in this LCD.

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## L33842 Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy

*Original Effective Date:* For services performed on or after 03/05/2014
*Revision Effective Date:* For services performed on or after 03/05/2014
*Jurisdiction:* Oregon

**Coverage Indications, Limitations, and/or Medical Necessity**

**Introduction:**
This policy does not address sacral conditions or injections or neurotomies. Sacral injections, identified on the claim by the ICD-9 code 724.6, are not subject to the requirements of this LCD.

Facet joints are paired diarthrodial articulations of the superior and inferior articular processes of adjacent vertebrae. The medial branches (MB) of the dorsal rami of the segmental nerves innervate facet joints and the MB nerves from the two adjacent dorsal rami innervate each joint. [Exceptions to this rule are the C2-3 facet joint, which is innervated by the third occipital nerve; and the L5-S1 facet joint, which is innervated by the L4 MB and the L5 dorsal ramus.]

Facet joint injection techniques are used in the diagnosis and/or treatment of chronic neck and back pain. However, the evidence of clinical efficacy and utility has not been well-established in the medical literature, which is replete with non-comparable and inadequately designed studies. Further, there is a singular dearth of long-term outcomes reports. This is particularly problematic given the steroid dosages administered. These drugs alone may develop the relief experienced by patients but are associated with serious adverse health events and could as well be administered orally. Hence, ongoing coverage requires outcomes reporting as described in this LCD to allow future analysis of clinical efficacy.

**Definitions**

- A zygapophyseal (aka facet) joint “level” refers to the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint.
- A “session” is defined as all injections/blocks/RF procedures performed on one day and includes medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RF ablations.
- A “region” is all injections performed in cervical/thoracic or all injections performed in lumbar (not sacral) spinal areas.
- "Diagnosis” of facet-mediated pain requires the establishment of pain relief following dual medial branch blocks (MBBs) performed at different sessions.

Neither physical exam nor imaging has adequate diagnostic power to confidently distinguish the facet joint as the pain source.

**Indications**

- Patient must have history of at least 3 months of moderate to severe pain with functional impairment and pain is inadequately responsive to conservative care such as NSAIDs, acetaminophen, physical therapy (as tolerated).
- Pain is predominantly axial and not associated with radiculopathy or neurogenic claudication.
- There is no non-facet pathology that could explain the source of the patient's pain, such as fracture, tumor, infection, or significant deformity.
- Clinical assessment implicates the facet joint as the putative source of pain.

**General Procedure Requirements:**

- Pre-procedural documentation must include a complete initial evaluation including history and an appropriately focused musculoskeletal and neurological physical examination. There should be a summary of pertinent diagnostic tests or procedures justifying the possible presence of facet joint pain.
- A procedure note must be legible and include sufficient detail to allow reconstruction of the procedure. Required elements of the note include a description of the techniques employed, nerves injected and sites(s) of injections, drugs and doses with volumes and concentrations as well as pre and post-procedural pain assessments. With RF neurotomy, electrode position, cannula size, lesion parameters, and electrical stimulation parameters and findings must be specified and documented.
- Facet joint interventions (diagnostic and/or therapeutic) must be performed under fluoroscopic or computed tomographic (CT) guidance. Facet joint interventions performed under ultrasound guidance will not be reimbursed.
- A hard (plain radiograph with conventional film or specialized paper) or digital copy image or images which adequately document the needle position and contrast medium flow (excluding RF ablations and those cases in which using contrast is contra-indicated, such as patients with documented contrast allergies), must be retained and submitted if requested.
- In order to maintain target specificity, total IA injection volume must not exceed 1.0 mL per cervical joint or 2 mL per lumbar joint, including contrast. Larger volumes may be used only when performing a purposeful facet cyst rupture in the lumbar spine.
- Total MBB anesthetic volume shall be limited to a maximum of 0.5 mL per MB nerve for diagnostic purposes and 2ml for therapeutic. For a third occipital nerve block, up to 1.0 mL is allowed for diagnostic and 2ml for therapeutic purposes.

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- In total, no more than 100 mg of triamcinolone or methylprednisolone or 15 mg of betamethasone or dexamethasone or equivalents shall be injected during any single injection session.
- Both diagnostic and therapeutic facet joint injections may be acceptably performed without steroids.

**Provider Qualifications**

Provider Qualifications' requirements must be met. Patient safety and quality of care mandate that healthcare professionals who perform Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy are appropriately experienced and/or trained to provide and manage the services. The CMS Manual System, Pub. 100-8, Program Integrity Manual, Chapter 13, Section 5.1 (http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf) underscores this point and states that "reasonable and necessary" services must be "ordered and/or furnished by qualified personnel." Services will be considered medically reasonable and necessary only if performed by appropriately experienced and/or formally trained providers.

The following training requirement applies only to those providers who have not provided these specific interventional pain management services on a regular basis (at least two times per month) during the ten years prior to the effective date of this LCD as may be established by claims billings. A basic requirement of payment is training and/or credentialing by a formal residency/fellowship program and/or other training program that accredited by a nationally-recognized body and whose core curriculum includes the performance and management of the procedures addressed in this policy. Recognized accrediting bodies include only those whose program accreditation gains the trainee eligibility to sit for a healthcare-related licensing exam or licensing itself, which in turn allows the licensee to perform these procedures. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics, the technical performance of the procedure(s) and utilization of the required associated imaging modalities, and the diagnosis and management of potential complications from the intervention.

The following credentialing requirement applies to all providers of the services addressed in this policy. If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting.

**Diagnostic Facet Joint Injections**

- Dual MBBs are necessary to diagnose facet pain due to the unacceptably high false positive rate of single MBB injections.

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- A second confirmatory MBB is allowed if documentation indicates the first MBB produced≥ 80% relief of primary (index) pain and duration of relief is consistent with the agent employed.
- Intraarticular facet block will not be reimbursed as a diagnostic test unless medial branch blocks cannot be performed due to specific documented anatomic restrictions.

**Therapeutic Injections**

- Medial Branch Blocks may provide temporary or long-lasting or permanent relief of facet-mediated pain. Injections may be repeated if the first MBB results in significant pain relief (> 50%) for at least 3 months.(See Limitations section for total number of injections that may be performed in one year.)
- Intraarticular injections may be covered for treatment of defined facet pain a) above or below a posterior spinal fusion when technical performance of MBBs is precluded, and/or b) when thermal RF neurotomy is precluded due to an implantable spinal cord stimulator or cardiac pacemaker or c) for rupture of symptomatic synovial cyst. Injections for these conditions and for axial pain with an arthritic joint may be repeated if the first intraarticular injection results in significant pain relief (> 50%) for at least 3 months. (See Limitations section for total number of injections that may be performed in one year.)
- Recurrent pain at the site of previously diagnosed facet pain (dual MBBs) may be treated without additional diagnostic blocks if > 50% pain relief from the previous blocks lasted at least 3 months.

**Thermal Medial Branch Radiofrequency Neurotomy (includes RF and microwave technologies):**

- Only when dual MBBs provide ≥ 80% relief of the primary or index pain and duration of relief is consistent with the agent employed may facet joint denervation with RF medial branch neurotomy be considered.
- Repeat denervation procedures involving the same joint will only be considered medically necessary if the patient experienced ≥ 50% improvement of pain and improvement in patient specific ADLs documented for at least 6 months.

**Limitations of Coverage:**

- A maximum of five (5) facet joint injection sessions inclusive of medial branch blocks, intraarticular injections, facet cyst rupture and RF ablations may be performed per year in the cervical/thoracic spine and five (5) in the lumbar spine.
- For each covered spinal region (cervical/thoracic or lumbar), no more than two (2) thermal RF sessions will be reimbursed in any calendar year, involving no more than four (4) joints per session, e.g., two (2) bilateral levels or four (4) unilateral levels.

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- Neither conscious sedation nor Monitored Anesthesia Care (MAC) is routinely necessary for intraarticular facet joint injections or medial branch blocks and are not routinely reimbursable. Individual consideration may be given for payment in rare unique circumstances if the medical necessity of sedation is unequivocal and clearly documented.
- Non-thermal RF modalities for facet joint denervation including chemical, low grade thermal energy (<80 degrees Celsius), as well as pulsed RF are not covered.
- Intraarticular and/or extraarticular facet joint prolotherapy is not covered.

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