

Health Technology Clinical Committee

Findings and Coverage Decision

Topic: Spinal Injections Meeting Date: March 18th, 2011 Final Adoption: June 17th, 2011

Number and Coverage Topic

20110318B - Spinal Injections

HTCC Coverage Determination

Therapeutic Medial Branch Nerve Block injections, Intradiscal injections and Facet injections are **not a covered benefit**

Therapeutic Lumbar Epidural Injections; Cervical-thoracic Epidural Injections and Sacroiliac Joint Injections are a **covered benefit** for the treatment of chronic pain

HTCC Reimbursement Determination

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.
- Therapeutic Sacroiliac Joint Injections for chronic pain is a covered benefit when all of the following conditions are met:
 - With Fluoroscopic guidance or CT guidance
 - After failure of conservative therapy, and
 - No more than one without clinically meaningful improvement in pain and function, subject to agency review

❖ Non-Covered Indicators

 Therapeutic Medial Branch Nerve Block injections; Intradiscal injections and Facet injections are not a covered benefit.

Agency Contact Information

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
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Health Technology Background

The Spinal Injections topic was selected and published in December 2009 to undergo an evidence review process. The evidence based technology assessment report indicates that an estimated 75% of the population has had an episode of back pain at some point in their life. While most acute back pain resolves within a few months, surveys report that approximately 5% of the population has chronic back pain, a percentage which implicates significant social and economic impacts. The risk of spinal pain increases with age as a result of disc disease and spinal degeneration. Those affected can have disabling symptoms that can dramatically affect their quality of life and ability to perform a variety of activities. Chronic spinal pain can be attributed to a number of pathologies, including (but not limited to) degenerative disc disease (DDD), herniated nucleus pulposus (HNP) (or herniated/slipped disc), spinal stenosis, radiculopathy, failed back surgery syndrome (FBSS), facet joint syndrome, and whiplash.

Treatment for chronic back pain typically begins with the identification of the underlying cause of pain and follows with conventional medical management (CMM), which varies with the diagnosis. CMM may include conservative/ non-invasive interventions such as physical therapy and rehabilitation, pharmaceutical pain management, psychological therapy and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulation, electrical stimulation, injections outside the spine, implanted devices, acupuncture/acupressure, and modified work.

Patients who don't respond to non-invasive treatment are typically referred for more invasive and non-surgical therapies such as spinal injections in an attempt to provide pain relief. Spinal injections involve the injection of an anti-inflammatory agent such as a steroid and/or an anesthetic into the spine or space around the spinal nerves and joints. One of the theoretical advantages of spinal injections is that they deliver the treatment medication directly to the site involved in the source of pain. Types of spinal injection include epidural, facet joint, intradiscal, and sacroiliac joint injections. Spinal injections can be used for diagnostic and therapeutic purposes.

In November 2010, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed Spinal Injections report is 299 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on March 18th, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at http://www.hta.hca.wa.gov under the committee section.



Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The committee concludes that the best available evidence on Spinal Injections has been collected and summarized. The evidence is presented below:

- The evidence based technology assessment report estimates 75% of the population has an episode of back pain at some point in their life. While most acute back pain resolves within a few months, surveys report that approximately 5% of the population has chronic back pain, with significant social and economic impacts. Those affected can have disabling symptoms that can dramatically affect their quality of life and ability to perform a variety of activities. The source and pathology of chronic spinal pain is not well understood but has been attributed degenerative disc disease (DDD), herniated nucleus pulposus (HNP) (or herniated/slipped disc), spinal stenosis, radiculopathy, failed back surgery syndrome (FBSS), facet joint syndrome, among other causes.
- The evidence based technology assessment report indicates treatment for chronic back pain typically begins with the identification (or ruling out) of underlying cause of pain and beginning conventional medical management (CMM). CMM may include conservative/ non-invasive interventions such as physical therapy and rehabilitation, pharmaceutical pain management, psychological therapy and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulation, electrical stimulation, injections outside the spine, implanted devices, acupuncture/acupressure, and modified work.
- The evidence based technology assessment report indicates that a small percentage of non-responsive patients may proceed to invasive therapies, including spinal injections. Spinal injections are not curative but are intended to provide pain relief and functional improvement for up to several months. Spinal injections involve the injection of an anti-inflammatory agent such as a steroid and/or an anesthetic into the spine or space around the spinal nerves and joints. One of the theoretical advantages of spinal injections is that they deliver medication directly to the site thought to be the source of pain. Types of spinal injection include epidural, facet joint, intradiscal, and sacroiliac joint injections. Spinal injections can be used for diagnostic and therapeutic purposes. According to one study examining Medicare claims of lumbosacral injections, the number of epidural steroidal injections increased 271% and the number of facet injections increased 231% from 1994 to 2001. A similar study found that lumbar facet joint injections/diagnostic blocks increased 161% from 2002 to 2006.
- Despite dramatic growth in procedures, evidence about the impact of spinal injections on important patient oriented outcomes related to impact on pain, physical function, opioid use; return to work; quality of life; patient satisfaction; avoidance of more invasive surgery; expected duration of impact; need for repeat procedures; frequency and type of harms; as well as clinical impacts of multilevel or procedure differences and any evidence about differential effect based on different patient, social or provider characteristics; different injection types; and impact of cost is needed.
- The evidence based technology assessment report indicates that the Spinal injection evidence base is extensive: initial search resulted in over 2,700 potential citations; and based on evaluation against inclusion criteria, 1 Systematic review; 22 RCTs, 24 Observational Studies and two economic studies were included.
 - Evidence was identified on five injection types: epidural (lumbar and cervical); facet joint; sacroiliac; intradiscal injections and medial branch blocks.
 - Key strengths of the overall body of evidence are a large evidence base including randomized clinical trials.



Limitations in the overall body of evidence: despite well validated measures to evaluate treatment outcomes, evidence is limited by the variety of different measures or non-validated measures used; most studies were limited by a focus on one outcome - impact on short term pain; studies not including a placebo arm are limited when measuring subjective improvement in pain; many studies were limited by short duration (3 month or less) for treatment of a chronic condition; there remains uncertainty over clinically meaningful improvement for pain and function; and the variety of injection methods and types.

2. Is the technology safe?

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- Major Complications: the evidence based technology assessment report indicated that major reported complications of spinal injection include dural puncture; subarachnoid puncture and angina pectoris, though rates are rare.
 - There were no cases of death or paralysis related to the procedure in the included studies, though death unrelated to the procedure was reported in 10 of 1146 patients in the RCTs, and there have been case reports of death and paralysis in the published literature.
 - For dural or subarachnoid punctures, or other life threatening complications, the reported rates ranged from 3 in 710 injections to 5 in 7240 (cervical) and 1 in 1556 injections to 1 in 10,416 injections for lumbar.
 - Vascular Puncture: the evidence based technology assessment report indicated the mean incidence of intravascular puncture following fluoroscopically guided lumbar spinal injections was 10.18% (range, 1.9–22%) as reported in five case series designed to assess its incidence.
- Minor Complications: the evidence based technology assessment report indicated that minor complications are more common but are generally transient in nature. The overall minor complication rate ranged from 0.06% to 16.3% of injections or patients in 19 RCTs and 14 case series, and complications included: pain at the injection site, increased radicular pain/numbness/weakness, nerve root irritation, superficial infections, sympathetic blockade, facial flushing, vasovagal reactions/fainting, headache, gastric complaints, dizziness, pruritis, irregular periods, and insomnia.
- Radiation Exposure to the Physician: the evidence based technology assessment report indicated the 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 we identified.
 - The evidence based technology assessment report reported that approximately 50% of four million interventional medical procedures per year are performed under fluoroscopic guidance. Fluoroscopy for spinal injections is routinely used to ensure correct needle placement, accurate delivery of the injectate, and avoidance of complications. Incorrect needle placement during spinal injections without the use of fluoroscopy has been reported by various studies in 12.5% to 38.3% of patients. A C-arm fluoroscope allows the X-ray tube to be moved around the prone patient and an image intensifier enhances the image, making it easier to interpret. Although studies have shown that radiation exposure to physicians using fluoroscopy for spinal injections is within safety limits, other methods, including ultrasound and CT, are being investigated as non-radioactive or lower radioactive methods of needle guidance.



3. <u>Is the technology effective?</u>

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

- Discussion focused on the following categories of injections: lumbar epidural; cervical/thoracic epidural; facet joint injection; sacroiliac joint injection; medial branch block; and intradiscal injection. Further differentiation was not focused on as the evidence based technology report indicated low to very low overall strength of evidence of different impact. The low level of evidence reported no consistent differential impact based on the approach to administering the injection; the diagnosis, pre-injection pain intensity; type of steroid, gender, age or other patient characteristics.
- Epidural Steroid Injections for lumbar or low back pain with sciatica or radiculopathy was highly studied and reported on; however, the overall strength of evidence is low based on the individual trial limitations and the inconsistency in results. Low back pain with sciatica or radiculopathy the evidence is mixed about the impact of spinal injection on pain (and in some studies function); with some studies showing a inferior results compared to placebo or other interventions and some studies showing a positive result.
 - When compared to placebo for caudal or interlaminar: *In the short-term* (≤ 3 months) there was mixed evidence based on data from twenty RCTs, seventeen of which were included in the Chou/APS SR (seven were considered to be higher-quality trials). Seven of seventeen studies included in the SR reported no benefit or inferior results while another seven reported positive results and three reported unclear results. Three LoE IIb RCTs published after the SR were added here, two reported on pain (both negative) and three on function (two negative and one positive) at three months. *In the long-term* (> 3 months) there was mixed evidence based on data from twelve RCTs, nine of which were included in the Chou/APS SR. Seven of nine studies included in the SR reported no benefit or inferior results while positive results were reported by one study and another reported mixed results. Regarding the more recent RCTs included here, two reported on pain (both negative at twelve months, although one was positive at six months) and three on function (mixed results, one positive, one mixed, and one negative). (SoE = Low)
 - O When compared to placebo for transforaminal: mixed evidence based on data from four RCTs, two of which were included in the Chou/APS SR and considered to be higher-quality and two of which were more recent LoE IIb studies. In terms of pain relief, the data suggest a benefit at two weeks (one study), mixed results at one month (two studies- one positive and one negative), and no benefit by 3 months. No benefit in function was reported at three months by two studies. Long-term data were mixed as reported by two higher-quality RCTs, both of which were reported in the Chou/APS SR, with one study reported positive results while the other showed no benefit. When compared to intramuscular injections, transforaminal steroid injections were superior to intramuscular injections in terms of pain relief at one month based on data from one LoE IIb RCT. (SoE = Low)
- Epidural Steroid Injections for lumbar or low back pain without sciatica or radiculopathy was also studied and reported on, and the overall strength of evidence is low to moderate based on the individual trial limitations and indication studied. The evidence indicates no benefit of spinal injections compared either to placebo, physical therapy, trigger point injection, discectomy or dry needling.
 - Low back pain (without sciatica or radiculopathy) compared to placebo showed no benefit based on data from three RCTs, one of which was included in the Chou/APS SR Version Officially Adopted on 6-17-2011



and considered to be a lower-quality trial. The two more recent RCTs rated IIb also reported no benefit in pain, function, or opioid use at three months or in employment at twelve months. (SoE = Moderate)

- Spinal Stenosis compared to placebo: In the short-term (24 hours 3 months), there was no benefit based on data from four RCTs, three of which was included in the Chou/APS SR; one was considered to be a higher-quality trial. Three of four studies reported no benefit; one study reported improved walking distance at one week. In a recent RCT, LoE IIb there was no benefit in pain, function, or opioid use at three months. (SoE = moderate). In the long-term (13 30 months), there was no benefit based on data from two RCTs as reported in the Chou/APS SR. (SoE = Low)
- Failed back surgery syndrome compared to placebo: no benefit based on data from three RCTs, two of which were included in the Chou/APS SR and considered to be lower-quality trials. In the one recent LoE IIb RCT, there was no benefit in pain, function, or opioid use at three months. (SoE = Moderate)
- Spinal Stenosis compared to physical therapy or control: no benefit in terms of pain, function, or quality of life at three and six months based on data from one LoE IIb RCT. (SoE = Very Low)
- Epidural Steroid Injections for cervical pain reported overall strength of evidence of very low based on small number of trials, trial limitation and inconsistent results. The evidence indicates mixed benefit of epidural cervical spinal injections.
 - For neck pain with disc herniation and radiculitis (comparator = placebo): 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 LoE IIb RCT. (SoE = Very Low)
 - Neck pain <u>without</u> disc herniation and radiculitis (comparator = placebo): 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 LoE IIb RCT. (SoE = Very Low)
 - Neck pain with disc compression and radiculitis (comparator = intramuscular injection): 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 LoE IIb RCT. (SoE = Very Low)
- Facet Joint Steroid Injections overall had low strength of evidence of no benefit based on four RCTs.
 - Confirmed or presumed lumbar facet joint pain compared to placebo: no benefit in the first three months based on data from two RCTs included in the Chou/APS SR, one of which was considered to be lower-quality. Although one of the studies reported a statistically meaningful benefit at six months in patient improvement following steroid injection, the rationale for this late response is not clear. (SoE = Low)
 - Non-radicular back pain and facet joint osteoarthritis compared to hyaluronic acid: no benefit in the injection of steroids versus hyaluronic acid into the facet joint at six months based on data from one higher-quality RCT included in the Chou/APS SR. (SoE = Low)
 - Confirmed cervical facet joint pain compared to placebo: no benefit in terms of the length of pain relief based on data from one LoE IIb RCT. No long-term data was reported. (SoE = Very Low)
- Sacroiliac Joint Steroid Injections had low overall strength of evidence of benefit based on one RCT.
 - For sacroiliac Joint Pain, compared to placebo: sacroiliac joint injections were superior to placebo injections based on data from one higher-quality RCT included in the Chou/APS SR. (SoE = Low)



- Intradiscal Injections overall had moderate strength of evidence of no benefit based on seven RCTs.
 - For discogenic back pain, steroid injection compared to placebo: no benefit based on data from three RCTs included in the Chou/APS SR, one of which was higher-quality. (SoE = Moderate)
 - For sciatica compared to chemotherapy: no benefit based on data from three RCTs included in the Chou/APS SR, one of which was higher-quality. (SoE = Moderate)
 - For low back pain without radiculopathy using neurolytic agent compared to placebo: intradiscal injections with methylene blue were superior to placebo injections in terms of pain, function, patient satisfaction, and analgesic use in the long-term (6-24 months) based on data from one LoE IIa RCT. (SoE = Low)
- Medial Branch Blocks overall had low to very low strength of evidence of no benefit based on four RCTs.
 - For confirmed lumbar facet joint pain compared to placebo: no benefit in terms of pain or function at both three and twelve months or on opioid use at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
 - For presumed lumbar facet joint pain compared to Sarapin: no benefit in injections with Sarapin with or without steroid based on data from one higher-quality and one lowerquality RCT included in the Chou/APS SR. (SoE = Low)
- For confirmed cervical facet joint pain compared to placebo: no benefit in terms of pain or function at both three and twelve months or on opioid use or employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)

4. **Special Populations?**

- Approach of the Epidural Steroid Injection: the evidence based technology assessment report indicated no consistent evidence from a systematic review of six RCTs and two additional RCTs published since the systematic review that one approach is more efficacious in administering lumbar epidural steroid. The results of one lower quality RCT suggest that interlaminar injections may not be as efficacious as transforaminal in patients with axial only pain from spinal stenosis. However, more study is needed to verify these findings.
- Diagnosis: the evidence based technology assessment report indicated no consistent evidence that epidural steroid injections have differential efficacy or effectiveness among various diagnoses of the lumbar or cervical spine.
- Pre-injection pain intensity or duration, type of steroid, sex, age, or MRI findings: the evidence based technology assessment report indicated no consistent evidence that pre-injection pain intensity or duration, type of steroid used as injectate, sex, age or pre-injection MRI findings are associated with outcome in patients receiving epidural steroid injections of the lumbar or cervical spine.

5. Is the technology cost-effective?

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

The evidence based technology assessment report reported no evidence that epidural steroid injections are cost effective based on data from two economic analyses. One moderately well conducted cost utility analysis (QHES 78/100) suggested that one epidural steroid injection is a more cost effective patient management strategy than up to three injections and that cost effectiveness ratios for epidural steroid injections are too high to be considered cost effective by

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UK conventions. Further, the budget impact of epidural spinal injections is likely large because of high use. Poor economic data (QHES 49/100) from a second trial (Karppinen) suggested that over one year epidural steroid injections do not show cost or outcome advantages compared to saline injections, and that contained herniations may be more responsive to steroid injection than bulges or extrusions.

- The evidence based technology assessment report reported no economic data were available for facet injections, medial branch blocks, sacroiliac joint injections, or intradiscal injections or for any type of cervical injection.
 - Washington state agency utilization and cost information indicated costs for Spinal Injections of \$55M for the past four years with a rising trend.

6. Medicare Decision and Expert Treatment Guidelines

Committee reviewed and discussed the Medicare Decision and expert guidelines as identified and reported in the technology assessment report.

- The Centers for Medicare and Medicaid Services have no published National coverage determinations (NCD) for any spinal injections.
- Guidelines a search of the core sources and relevant specialty groups identified fourteen guidelines.
 - American Pain Society (APS), 2009: For patients with nonradicular low back pain, the APS is unable to assess the benefit of epidural steroid injection, facet joint steroid injection, medial branch block, or sacroiliac joint injection based on insufficient or poor evidence. Corticosteroid facet joint injection is not recommended based on moderate evidence. Intradiscal steroid injection is not recommended for treatment of nonradicular low back pain based on good evidence. For patients with radicular low back pain, the APS found moderate evidence for short-term (through three months) benefit from epidural steroid injections based on fair evidence. A recommendation for epidural steroid injection for patients with symptomatic spinal stenosis is not offered based on insufficient or poor evidence.
 - American Society of Interventional Pain Physicians, 2009: The recommendation for caudal epidural steroid injection in managing lumbar spinal pain with disc herniation and radiculitis or discogenic pain without disc herniation or radiculitis is 1A or 1B, indicating a strong recommendation where the benefits outweigh the risks of treatment. In addition, the recommendation for caudal epidural steroid injection for patients with post-lumbar laminectomy syndrome and spinal stenosis is 1B or 1C, also indicating a strong recommendation. The recommendation for use of cervical interlaminar epidural injection for disc herniation and radiculitis to achieve short-term relief is 1C. For patients seeking long-term relief, the recommendation is 2B (weak recommendation), indicating benefits are balanced with risks and burdens of treatment. In patients with spinal stenosis and discogenic pain without disc herniation and radiculitis the recommendation is 2C (very weak, with uncertainty in estimates of benefits, risk, and burden of treatment). The recommendation for lumbar transforaminal epidural injections is 1C. Intraarticular facet joint injections are not recommended. Cervical, thoracic, and lumbar facet joint nerve blocks are recommended to provide both short-term and long-term relief in the treatment of chronic facet joint pain (recommendation 1B or 1C).
 - Institute for Clinical Systems Improvement (ICSI), 2009: Epidural steroid injections and facet joint injections are classified as level I (standard, first-line) therapeutic procedures, and are recommended as part of a comprehensive treatment plan that includes pharmacologic, rehabilitative, and psychological interventions. Evidence is limited when such procedures are used alone.



- American College of Occupational and Environmental Medicine (ACOEM), 2008: Epidural glucocorticosteroid injection is recommended as a treatment option for subacute radicular pain syndromes, and as an option for second-line treatment of acute flare-ups of spinal stenosis associated with true radicular or radiculomyelopathic symptoms based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). Epidural glucocorticosteroid injection is not recommended to treat chronic neck pain or for dorsal spine symptoms that predominate over leg pain based on evidence that harms and cost exceed benefits to the patient (Evidence Rating C: limited evidence). The ACOEM makes no recommendation regarding the use of facet joint injection for flare-ups of neuropathic pain or chronic low back pain (Evidence Rating I: insufficient evidence). Facet joint injection is not recommended for any radicular pain syndrome, chronic non-specific axial pain, and repeat injections are not recommended for patients who failed to achieve lasting functional improvements after a prior injection for neuropathic or chronic low back pain based on evidence that treatment is ineffective or that costs or harms outweigh benefits to the patient (Evidence Rating B: moderate evidence).
- Institute for Clinical Systems Improvement (ICSI), 2008: ICSI recommends epidural steroid injection only after conservative treatment has failed and to avoid surgical intervention. ICSI finds limited evidence for the efficacy of epidural steroid injection, but indicates it may allow patients to progress with conservative treatments. Epidural steroid injection should be performed under fluoroscopy with contrast in order to prevent treatment failure.
- Work Loss Data Institute, Low back lumbar & thoracic (acute & chronic), 2008: Epidural steroid injection and sacroiliac joint injections are recommended as part of a comprehensive treatment plan for low back pain. Specifically, epidural steroid injection is recommended to avoid surgery for severe cases with radiculopathy, but does not offer long-term functional benefit. "Series of three" epidural steroid injections, facet joint injection (multiple series, thoracic, and medical branch blocks), and intradiscal steroid injection were considered but are not recommended.
- Work Loss Data, Neck and upper back (acute & chronic), 2008: Epidural steroid injection is recommended as part of a comprehensive treatment plan for radicular pain. Specifically, epidural steroid injection is recommended to avoid surgery in severe cases with neurologic findings. Facet joint injection was considered but is not recommended.
- Work Loss Data, Pain (chronic), 2008: Epidural steroid injection is recommended as part of a comprehensive treatment plan. Facet blocks are classified as under study by the Institute and are not currently recommended.
- American Academy of Neurology, 2007: The American Academy of Neurology indicates the use of epidural steroid injections may result in a small magnitude of improvement in radicular lumbosacral pain when evaluated 2-6 weeks post-injection, but the recommendation is classified as a level C (possibly effective) due the small number of relevant studies, highly select patient population, and variation in comparison treatments in the evidence base. Epidural steroid injections are not recommended for radicular lumbosacral pain due to a lack of evidence for improvement of function, need for surgery or long-term pain relief beyond 3 months. This recommendation is classified as level B (probably ineffective based on Class I-III evidence). There was insufficient evidence to make a recommendation regarding the use of epidural steroid injections to treat cervical radicular pain.
- American College of Occupational and Environmental Medicine, 2007: The use of epidural glucocorticosteroid injection is recommended as a second-line treatment of acute spinal stenosis flare-ups, and as a treatment option for acute or subacute radicular



pain syndromes lasting at least 3 weeks after treatment with NSAIDs and when pain is not trending towards spontaneous resolution. Both treatments are recommended based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). The use of facet joint injections is not recommended for acute, subacute, chronic low back pain, and radicular pain syndrome based on evidence that the treatment is ineffective or that harms and cost exceed benefits to the patient (Evidence Rating B: moderate evidence). Sacroiliac joint corticosteroid injection is recommended as an option for patients with specified known cause of sacroilitis (Evidence Rating C: limited evidence). The use of epidural glucocorticosteroid injection is not recommended for acute, subacute, or chronic low back pain in the absence of radicular signs and symptoms (Evidence Rating C: limited evidence).

- American College of Physicians and the American Pain Society, 2007: Epidural steroid injection is an option for patients with prolapsed lumbar disc with persistent radicular symptoms who have not responded to noninvasive therapy. No specific recommendation is given for this or any other injection therapy of interest.
- North American Spine Society (NASS), 2007: The NASS recommends nonfluoroscopically-guided interlaminar epidural steroid injection as a treatment option for short-term symptom relief in patients with neurogenic claudication or radiculopathy. A single radiographically-guided transforaminal injection may also provide short-term symptom relief for patients with radiculopathy (Grade B: fair evidence). A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections may provide long-term symptom relief in patients with radiculopathy or neurogenic intermittent claudication, but evidence supporting this recommendation is of poor quality.
- <u>EuroCOST: European evidence-based guideline COST B13 Working Group on Guidelines for Chronic Low Back Pain, 2006:</u> Epidural steroid injection, facet joint injection, and facet nerve blocks are not recommended based on a lack of evidence or conflicting evidence. Intradiscal injections are not recommended for the treatment chronic nonspecific low back pain based on evidence they are not effective (level B: moderate evidence).
- American Association of Neurological Surgeons; Congress of Neurological Surgeons, 2005: Lumbar epidural injections and facet injections are recommended as treatment options for temporary, symptomatic relief in some patients with chronic low back pain, but epidural injections are not recommended for long-term relief of pain, based on Class III evidence (unclear clinical certainty). Facet injections are not recommended as long-term treatment for low back pain based on Class I evidence (high clinical certainty).

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information.

- The committee concluded that the current evidence on Spinal Injections demonstrates that there is sufficient evidence to cover with conditions the use of therapeutic Epidural injections in the lumbar or cervical-thoracic spine for chronic pain.
- The committee concluded that the current evidence on Spinal Injections demonstrates that there is sufficient evidence to cover with conditions therapeutic Sacroiliac joint injections for chronic pain.



• The committee concluded that the current evidence on Spinal Injections demonstrates that there is insufficient evidence to cover the other therapeutic spinal injections: Facet joint injections; medial branch block injections; and Intradiscal injections.

The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover with conditions lumbar epidural injections. Based on these findings, the committee voted to cover with conditions cervical-thoracic epidural injections. Based on these findings, the committee voted to not cover medial branch blocks. Based on these findings, the committee voted to not cover facet injections. Based on these findings, the committee voted to not cover facet injections. Based on these findings, the committee voted to cover with conditions Sacroiliac joint injections.

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, therapeutic Epidural Injections in the lumbar or cervical-thoracic spine is 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
- Maximum of 3 in 6 months

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, therapeutic Sacroiliac Joint Injections for chronic pain is a covered benefit when all of the following conditions are met:

- With Fluoroscopic guidance or CT guidance
- After failure of conservative therapy
- No more than one without clinically meaningful improvement in pain and function, under agency review

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.