HERC Coverage Guidance

Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain with radiculopathy (weak recommendation).

Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain without radiculopathy (e.g., spinal stenosis, non-radiculillary pain) (strong recommendation).

Corticosteroid injections (including facet joint, medial branch, and sacroiliac joint) are not recommended for coverage for the treatment of low back pain (strong recommendation).

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

RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as they seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of the Affordable Care Act and health system transformation, reaching these goals may require a focus on population-based health interventions from a variety of sectors as well as individually focused clinical care. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that happen outside of the typical clinical setting.

The HERC selects topics for its reports to guide public and private payers based on the following principles:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

Our reports are based on a review of the relevant research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.
Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. For some conditions, the HERC has reviewed evidence and identified effective interventions, but has not made coverage recommendations, as many of these policies are implemented in settings beyond traditional healthcare delivery systems.
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 several 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. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by the Commission based on the assessments rendered by Chou and colleagues in the AHRQ review. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the Commission.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Estimate of Effect for Outcome/ Confidence in Estimate</th>
<th>Resource Allocation</th>
<th>Values and Preferences</th>
<th>Other Considerations</th>
</tr>
</thead>
</table>
| **Long-term function**                | No difference compared to controls SMD -0.23, 95% CI -0.55 to 0.10  
  ●●○○ (Low confidence, based on 8 RCTs, N=950) | Covering the intervention effectively requires coverage of diagnostic imaging (MRI or CT) to identify potential candidates who would not otherwise require imaging. | Patients with low back pain would highly value having effective treatments to improve their symptoms, and would likely prefer interventions that are less invasive, less time-consuming, less risky and less demanding on the patient. Given the variety of available | There is moderate confidence that ESIs result in immediate-term improvements in pain, although this does not reach predefined thresholds of a minimum clinically important difference. There are a number of other evidence- |
| (Critical outcome)                    |                                                       |                     |                        |                      |
| **Long-term risk of surgery**         | No difference compared to controls RR 0.97, 95% CI 0.75 to 1.25  
  ●●○○ (Moderate confidence, based on 14 RCTs, N=1208) |                     |                        |                      |
| (Critical outcome)                    |                                                       |                     |                        |                      |
| **Short-term function**               | No difference compared to controls Standardized mean difference (SMD) -0.03, 95% CI -0.20 to 0.15  
  ●●○○ (Moderate confidence, based on 11 RCTs, N=1226) |                     |                        |                      |
<p>| (Important outcome)                   |                                                       |                     |                        |                      |</p>
<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Change in utilization of other therapies&lt;br&gt;(Important outcome)</td>
<td>Reduced short-term risk of surgery&lt;br&gt;RR 0.62, 95% CI 0.41 to 0.92&lt;br&gt;●●○○ (Low confidence, based on 8 RCTs, N=845)</td>
<td>based guidance. Given a lack of proven benefit, they are unlikely to be cost-effective.</td>
<td>interventions for low back pain, patient preferences are likely to be highly variable.</td>
<td>based treatments for back pain. A review of selected studies using image-correlation, imaging guidance, and a transforaminal approach (consistent with current local standard of care) also demonstrated mixed results, with the majority favoring no effect.</td>
</tr>
<tr>
<td>Adverse events&lt;br&gt;(Important outcome)</td>
<td>Few harms or serious adverse events compared to controls&lt;br&gt;●●○ (Moderate confidence, based on 29 RCTs, N=2792)</td>
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**Balance of benefits and harms:** We have moderate confidence that ESIs for low back pain with radiculopathy produce no improvement in function in either the short or long term. The immediate-term benefit in pain did not reach predefined thresholds of a minimum clinically important difference. Despite anecdotal and noncomparative evidence, we find no clinically significant benefits from this intervention. Harms appear to be rare. The balance of benefits and harms appears to be neutral.

**Rationale:** We have low to moderate confidence that epidural corticosteroid injections for low back pain with radiculopathy do not affect functional outcomes compared to controls and that ESIs do not decrease rates of future surgery. There are immediate-term benefits in pain, however, they do not reach a threshold for a clinically important benefit. Epidural corticosteroid injections are more costly than evidence-based conservative management, and multiple other interventions are available. Therefore, we make a weak recommendation for noncoverage of these procedures.

**Recommendation:** Epidural corticosteroid injections are not recommended for coverage for back pain with radiculopathy (weak recommendation).
Coverage question: Should epidural corticosteroid injections be recommended for the treatment of low back pain with spinal stenosis?

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Long-term function</strong></td>
<td>No difference compared to controls</td>
<td></td>
</tr>
<tr>
<td><em>(Critical outcome)</em></td>
<td>Weighted mean difference (WMD) 2.78, 95% CI -1.24 to 6.79</td>
<td>●●○○ <em>(Low confidence, based on 2 RCTs, N=160)</em></td>
</tr>
<tr>
<td><strong>Long-term risk of surgery</strong></td>
<td>No difference compared to minimally invasive lumbar decompression</td>
<td></td>
</tr>
<tr>
<td><em>(Critical outcome)</em></td>
<td>RR 0.76, 95% CI 0.38 to 1.54</td>
<td>●●○○ <em>(Low confidence, based on 1 RCT, N=30)</em></td>
</tr>
<tr>
<td><strong>Short-term function</strong></td>
<td>No difference compared to controls</td>
<td></td>
</tr>
<tr>
<td><em>(Important outcome)</em></td>
<td>SMD -0.03, 95% CI -0.31 to 0.26</td>
<td>●●●○ <em>(Moderate confidence, based on 5 RCTs, N=615)</em></td>
</tr>
<tr>
<td><strong>Change in utilization of other therapies</strong></td>
<td>Insufficient data</td>
<td></td>
</tr>
<tr>
<td><em>(Important outcome)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adverse events</strong></td>
<td>Few harms or serious adverse events compared to controls</td>
<td>●●○○ <em>(Low confidence, based on 8 RCTs, N=821)</em></td>
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<tr>
<td><em>(Important outcome)</em></td>
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Balance of benefits and harms: We have low to moderate confidence that there is no functional benefit from these interventions and that they do not decrease rates of future surgery.

Rationale: Based on the lack of benefit, multiple alternative interventions, and the cost of the interventions, we recommend noncoverage of these procedures.

Recommendation: Epidural corticosteroid injections are not recommended for coverage for low back pain with spinal stenosis *(strong recommendation).*
Coverage question: Should epidural corticosteroid injections be recommended for the treatment of non-radicular low back pain?

<table>
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<tr>
<td><strong>Long-term function</strong>&lt;br&gt;(Critical outcome)</td>
<td>No difference compared to controls</td>
<td>●●○○ (Low confidence, based on 2 RCTs, N=240)</td>
</tr>
<tr>
<td><strong>Long-term risk of surgery</strong>&lt;br&gt;(Critical outcome)</td>
<td>Insufficient data</td>
<td></td>
</tr>
<tr>
<td><strong>Short-term function</strong>&lt;br&gt;(Important outcome)</td>
<td>No difference compared to controls</td>
<td>●●○○ (Low confidence, based on 2 RCTs, N=240)</td>
</tr>
<tr>
<td><strong>Change in utilization of other therapies</strong>&lt;br&gt;(Important outcome)</td>
<td>No difference in opioid use at 2 years compared to controls</td>
<td>●●○○ (Low confidence, based on 2 RCTs, N=240)</td>
</tr>
<tr>
<td><strong>Adverse events</strong>&lt;br&gt;(Important outcome)</td>
<td>Few harms or serious adverse events compared to controls</td>
<td>●●○○ (Low confidence, based on 2 RCTs, N=240)</td>
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</table>

**Balance of benefits and harms:** We have low confidence that epidural corticosteroid injections for nonradicular low back pain do not affect functional outcomes or use of opioids compared to controls. We have insufficient evidence to determine whether they affect rates of surgery.

**Rationale:** Based on evidence of no benefit, the availability of effective alternative treatments, and the cost of this intervention compared to evidence-based conservative management, we recommend noncoverage for these procedures.

**Recommendation:** Epidural corticosteroid injections are not recommended for coverage for non-radicular low back pain (**strong recommendation**).
**Coverage question:** Should facet joint corticosteroid injections (including medial branch injections) be recommended for the treatment of low back pain?

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Long-term function (Critical outcome)</td>
<td>No difference compared to controls</td>
<td>●●○○ (<em>Low confidence, based on 2 RCTs, N=204</em>)</td>
</tr>
<tr>
<td>Long-term risk of surgery (Critical outcome)</td>
<td>Insufficient data</td>
<td></td>
</tr>
<tr>
<td>Short-term function (Important outcome)</td>
<td>No difference compared to controls</td>
<td>●●○○ (<em>Low confidence, based on 2 RCTs, N=171</em>)</td>
</tr>
<tr>
<td>Change in utilization of other therapies (Important outcome)</td>
<td>No difference in analgesic or opioid use at up 2 years compared to controls</td>
<td>●●○○ (<em>Low confidence, based on 2 RCTs, N=204</em>)</td>
</tr>
<tr>
<td>Adverse events (Important outcome)</td>
<td>Few harms or serious adverse events compared to controls</td>
<td>●●○○ (<em>Low confidence, based on 10 RCTs, N=823</em>)</td>
</tr>
</tbody>
</table>

**Balance of benefits and harms:** We have low confidence that facet joint corticosteroid injections for low back pain do not affect functional outcomes or use of analgesics compared to controls. We have insufficient evidence to determine whether they affect rates of surgery.

**Rationale:** Based on evidence of no benefit, the availability of effective alternatives, and the cost of the procedures relative to evidence-based conservative care, we make a **strong recommendation** for noncoverage of these procedures.

**Recommendation:** Facet joint corticosteroid injections are not recommended for coverage for low back pain (**strong recommendation**).
Coverage question: Should sacroiliac joint corticosteroid injections be recommended for the treatment of low back pain?

<table>
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<tr>
<td><strong>Long-term function</strong> <em>(Critical outcome)</em></td>
<td>Insufficient data</td>
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<tr>
<td><strong>Long-term risk of surgery</strong> <em>(Critical outcome)</em></td>
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</tr>
<tr>
<td><strong>Short-term function</strong> <em>(Important outcome)</em></td>
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</tr>
<tr>
<td><strong>Change in utilization of other therapies</strong> <em>(Important outcome)</em></td>
<td>Insufficient data</td>
</tr>
<tr>
<td><strong>Adverse events</strong> <em>(Important outcome)</em></td>
<td>Insufficient data</td>
</tr>
</tbody>
</table>

**Balance of benefits and harms:** There is insufficient evidence to determine whether sacroiliac joint corticosteroid injections are effective or whether any benefits would outweigh potential harms for the treatment of low back pain.

**Rationale:** We recommend against coverage because of the unproven benefit and unknown harms and moderate costs. Although future evidence could change the recommendation, the benefit of sacroiliac joint injections is unproven.

**Recommendation:** Sacroiliac joint corticosteroid injections are not recommended for coverage for low back pain *(strong recommendation)*.

Note: GRADE framework elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.
Evidence Overview

Clinical background

Low back pain is the leading cause of disability in individuals under 45 years of age in the United States and globally (The American Academy of Pain Medicine, n.d.) (Bicket et al., 2013). Approximately 80% of adults experience low back pain at some point in their lifetimes. In one large survey, more than 25% of adults reported low back pain during the past three months (National Institute of Neurological Disorders and Stroke, 2015). Furthermore, the impact of low back pain on health in the U.S. has increased in recent years. A 1990 study ranked low back pain as the sixth most burdensome condition in the U.S. in terms of mortality or poor health. In a 2010 reproduction of the study, back pain was ranked as the third most burdensome condition, following ischemic heart disease and chronic obstructive pulmonary disease (National Institute of Neurological Disorders and Stroke, 2015). Low back pain is also associated with high economic costs: annual cost estimates are upward of $100 billion in the United States (Bicket et al., 2013).

A majority of low back pain is defined as acute, lasting a few days to a few weeks, and resolves on its own with self-care. However, about 20% of people affected by low back pain develop chronic low back pain and have persistent symptoms at one year. Many cases of low back pain are the result of a mechanical disruption influencing the way in which components of the back fit together and move. Low back pain is also often associated with spondylosis, which refers to general spinal wear and tear that typically occurs as people age. However, in rare cases, low back pain is related to more serious underlying conditions requiring immediate medical attention, such as infections, tumors, cauda equina syndrome, and abdominal aortic aneurysms (National Institute of Neurological Disorders and Stroke, 2015).

A variety of treatment options are used to address low back pain. Conservative treatment for low back pain includes rest, physical therapy, advice regarding posture and exercise, analgesics, and anti-inflammatory medications (Hayes, 2013). If symptoms persist, epidural steroid injections (ESIs), facet joint injections, and sacroiliac joint injections provide additional nonsurgical options to treat low back pain. Surgical options for treating low back pain include decompression, total disc arthroplasty, total facet arthroplasty, and fusion (Balgia et al., 2015).

Indications

Low back pain is the fifth most common reason for all physician visits in the United States (American Academy of Family Physicians, 2016). Among the available procedural interventions for low back pain, ESIs are the most widely used. Facet and sacroiliac joint injects also may involve the injection of corticosteroids, but are less commonly practiced. Both ESI and surgery utilization rates have doubled in the last decade. Despite this increase in utilization, disability rates continue to rise as well (Bicket et al., 2013). Given the high costs, morbidity, and lack of certainty regarding the long-term benefits of operative interventions, steroid injections are often employed with the intention to not only reduce pain, but also to avoid surgical interventions (Bhatia et al., 2016).
Technology description

Corticosteroids are a class of drugs commonly used to reduce swelling or inflammation. Injectable corticosteroids include methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone (United States Food & Drug Administration, 2014). Injecting corticosteroids into the epidural space might inhibit inflammation and thus reduce low back pain. ESIs expose spinal nerve roots to higher concentrations of medications for a longer time period than a systemic administration technique does (Hayes, 2013).

There are three primary routes used to administer an ESI: caudal, interlaminar, and transforaminal. The origin of the patient’s pain can determine the selection of the route. Caudal injections involve delivering the needle through the sacrococcygeal ligament and sacral hiatus into the caudal epidural space, which communicates with the posterior lumbar epidural space. An interlaminar approach entails guiding the injection fluid into the posterior epidural compartment, without assurance that it will flow into the anterior epidural compartment. Transforaminal injections are directed to the anterior epidural space and spinal nerve as it exits the neural foramen. Transforaminal injections are considered the most “targeted” injections and allow for the lowest use of steroid concentrations (Hayes, 2013).

Facet joint injections and sacroiliac joint injections are related techniques for administering corticosteroids to relieve a patient’s pain. These approaches would be considered for patients with low back pain and a clinical suspicion that the pain is due to facet joint arthropathy or sacroiliitis. Both types of injections involve the insertion of a needle through a selected site of entry until it reaches the bone. Minor manipulation may be required to locate the needle into the joint space (Althoff, et al., 2015; Peh, 2011).

At some point prior to administration of corticosteroid injections, it is common for patients to receive an imaging test (e.g., CT or MRI) to identify potential causes of back pain. The procedure is then generally completed using fluoroscopic or ultrasound guidance with the patient lying prone, although it can also be done with the patient in the lateral position. After the injection, the patient is monitored before being discharged, and normal activity can usually be resumed the next day.

Key Questions and Outcomes

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods, please see Appendix C.

1. What is the comparative effectiveness of corticosteroid injection therapies for low back pain?
2. Does the effectiveness of corticosteroid injection therapies for low back pain vary based on:
   a. Duration of back pain
   b. Etiology of back or radicular pain
   c. Choice of corticosteroid, dose, or frequency
   d. Anatomic approach
   e. Use of imaging guidance
   f. Previous back surgery
3. What are the harms of corticosteroid injections for low back pain?

Critical outcomes selected for inclusion in the GRADE table are long-term function, and long-term risk of undergoing surgery. Important outcomes selected for inclusion in the GRADE table are short-term function, adverse events and change in utilization of comparators (e.g., opioids, surgery).

Evidence review

Chou et al., 2015 (AHRQ Report)

This is a comprehensive, good-quality systematic review of randomized controlled trials (RCTs) of corticosteroid injection therapies for patients with low back pain. The review includes 78 RCTs of epidural steroid injections, 13 trials of facet joint injections, and one trial of sacroiliac injections. The included RCTs span adult patients with non-radicular low back pain; lumbosacral radiculopathy, a term that is not consistently defined in the included trials, but which Chou and colleagues define as “presence of leg pain (typically worse than back pain), with or without sensory deficits or weakness, in a nerve root distribution”; spinal stenosis; or post-surgical back pain. The trials compared steroid injection therapies to placebo or active controls (commonly local anesthetics). In their meta-analysis, the authors treated the various control treatments as placebos. An analysis by which type of control was used found no difference in effects. Specified outcomes of the review include pain, function, and the risk of back surgery at various time points. Those time points and their respective definitions were immediate (1 week to ≤2 weeks), short (2 weeks to ≤3 months), intermediate (3 months to <1 year), and long (>1 year). Several subgroup analyses and meta-regressions were performed to ascertain whether the evidence supported differential effects stemming from a variety of intervention, patient, and provider characteristics.

The authors of the review highlighted several general limitations of the evidence base including the small number of trials for epidural injections outside of the radiculopathy population; methodological limitations of the included studies (only nine were rated good quality); inconsistent control interventions; inconsistent blinding procedures; and the small number of trials that directly compared patient characteristics, steroid type and dose, or various techniques (including anatomic approach and imaging guidance).

Key Question 1: What is the comparative effectiveness of corticosteroid injection therapies for low back pain?

Outcomes for Epidural Steroid Injections

Long-term Function – Radiculopathy

In seven trials of ESIs compared with placebo interventions for patients with radiculopathy, there was low-strength evidence of no difference in long-term function (SMD -0.23, 95% CI -0.55 to 0.10). Similarly, in three trials of ESIs compared with placebo interventions for patients with radiculopathy, there was
low-strength evidence of no difference in long-term likelihood of a successful functional outcome (RR 1.15, 95% CI 0.97 to 1.35).

In one trial of ESIs compared to minimally invasive lumbar decompression for patients with radiculopathy, there was low-strength evidence that steroid injections improve long-term function as measured by a ≥ 13 point improvement on the ODI (RR 0.34, 95% CI 0.34 to 0.95). There was no difference in the long-term risk of undergoing surgery (RR 0.45, 95% CI 0.09 to 2.19).

**Long-term Function – Spinal Stenosis**
In two trials of ESIs compared with placebo interventions for patients with spinal stenosis, there was low-strength evidence of no difference in long-term function (WMD 2.78, 95% CI -0.24 to 6.79). Similarly, in two trials of epidural ESIs compared with placebo interventions for patients with spinal stenosis, there was low-strength evidence of no difference in the long-term likelihood of a successful functional outcome (RR 0.95, 95% CI 0.71 to 1.26).

**Long-term Function – Non-radicular Low Back Pain**
In two trials of ESIs compared with epidural local anesthetics for patients with non-radicular low back pain, there was low-strength evidence of no difference in long-term function (no meta-analysis was performed).

**Long-term Risk of Surgery – Radiculopathy**
In 14 trials of ESIs compared with placebo interventions for patients with radiculopathy, there was moderate-strength evidence of no difference in the long-term risk of surgery (RR 0.97, 95% CI 0.75 to 1.25).

**Long-term Risk of Surgery – Spinal Stenosis**
In one trial of ESIs compared with placebo interventions for patients with spinal stenosis, there was low-strength evidence of no difference in the long-term risk of surgery (RR 0.76, 95% CI 0.38 to 1.54).

**Short-term Function – Radiculopathy**
In 11 trials of ESIs compared with placebo interventions for patients with radiculopathy, there was moderate-strength evidence of no difference in short-term function (SMD -0.03, 95% CI -0.20 to 0.15). Similarly, in six trials of ESIs compared with placebo interventions for patients with radiculopathy, there was low-strength evidence of no difference in short-term likelihood of a successful functional outcome (RR 1.01, 95% CI 0.74 to 1.38).

In one trial of transforaminal ESIs compared to etanercept for patients with radiculopathy, there was low-strength evidence that steroid injections improve short-term function as measured by the Oswestry Disability Index (ODI) at one month (difference -16 [of 100], 95% CI -26 to -6.27), but there was no difference in the long-term risk of undergoing surgery (RR 0.45, 95% CI 0.09 to 2.19).
**Short-term Function – Spinal Stenosis**

In five trials of ESIs compared with placebo interventions for patients with spinal stenosis, there was moderate-strength evidence of no difference in short-term function (SMD -0.03, 95% CI -0.31 to 0.26). Similarly, in three trials of ESIs compared with placebo interventions for patients with spinal stenosis, there was low-strength evidence of no difference in short-term likelihood of a successful functional outcome (RR 0.91, 95% CI 0.70 to 1.18).

In one trial of ESIs compared to minimally invasive lumbar discectomy for patients with spinal stenosis, there was low-strength evidence of no difference in function at six weeks. In one trial of ESIs compared to intensive physical therapy for patients with spinal stenosis, there was low-strength evidence of no difference in function at two weeks to six months. In one trial of ESIs compared to etanercept for patients with spinal stenosis, there was low-strength evidence of no difference in function at one month.

**Change in Utilization of Comparators**

Aside from the risk of surgery reported above, changes in the utilization of other treatments were not consistently reported in the included studies. In two trials of ESIs compared with epidural local anesthetics for patients with non-radicular low back pain, there was low-strength evidence of no difference in opioid use at two years (no meta-analysis was performed).

**All Outcomes – Chronic Post-surgical Pain**

The authors found insufficient evidence to draw conclusions about the effectiveness of ESIs compared to placebo or active controls in patients with chronic post-surgical back pain.

**Other Outcomes**

The authors found moderate-strength evidence for immediate-term improvement in pain (WMD -7.55 on a 100 point scale, 95% CI -11.4 to -3.74), low-strength evidence for immediate-term improvement in function (SMD -0.33, 95% CI -0.56 to -0.09), and low-strength evidence of a reduced short-term risk of surgery (RR 0.62, 95% CI 0.41 to 0.92) for ESIs in patients with radiculopathy. The authors observed that the differences in pain and function did not meet pre-specified thresholds of minimal clinically important differences and were not sustained at longer-term follow-up (as indicated above).

**Outcomes for Facet Joint Injections (including medial branch injections)**

**Long-term Function**

In two trials of medial branch steroid injection compared to medial branch local anesthetic injections, there was low-strength evidence of no difference in function at 12 to 24 months (no meta-analysis was performed).

**Short-term Function**

Two trials of facet joint steroid injections compared to a saline placebo found low-strength evidence of no difference in function at one to three months. One trial of facet joint steroid injections compared to intramuscular steroid injections found low-strength evidence of no difference in function at up to six
months. One trial of facet joint steroid injections compared to hyaluronic acid found low-strength evidence of no difference in function at one month. In one trial that compared facet joint steroid injection plus sham neurotomy to medial branch radiofrequency neurotomy plus local anesthetic injection, there was low-strength evidence of no difference in pain at up to six months.

Change in Utilization of Comparators

In two trials of medial branch steroid injection compared to medial branch local anesthetic injections, there was low-strength evidence of no difference in opioid use at 12 to 24 months. In one trial that compared facet joint steroid injection plus sham neurotomy to medial branch radiofrequency neurotomy plus local anesthetic injection, there was low-strength evidence of no difference in analgesic use at up to six months (no meta-analysis was performed).

Outcomes for Sacroiliac Joint Injections

The authors judged that there was insufficient evidence from a single, small (n=24) trial of sacroiliac steroid injections compared to local anesthetic injections to draw conclusions about the effectiveness of this procedure.

KQ2: Does the effectiveness of corticosteroid injection therapies for low back pain vary based on:

- Duration of back pain
- Etiology of back or radicular pain
- Choice of corticosteroid, dose, or frequency
- Anatomic approach
- Use of imaging guidance
- Previous back surgery
- Response to previous diagnostic injections
- Response to previous injection therapies

The authors identified six trials in which it was possible to compare the effectiveness of ESIs based on the duration of symptoms. In five of those trials, there was no association between the duration of symptoms and the likelihood of responding to treatment. In the sixth study, a longer duration of symptoms was associated with a poorer response to injection therapies. This conclusion was based on low strength of evidence. The authors observed that most of the available evidence was for patients with back pain that lasted more than three months, and the number of studies of patients with pain of less than four weeks duration is very limited.

The effectiveness of ESIs for different types of back pain (radicular, non-radicular, and spinal stenosis) is discussed in KQ1. Inconsistent evidence from four trials led the authors to conclude that there was insufficient evidence to determine whether the etiology of radicular symptoms was associated with responsiveness to steroid injection therapies.

In the meta-regression of trials comparing epidural steroids to placebo, there was no apparent effect of steroid type on outcomes for pain, function, or risk of surgery. Four trials that directly compared different types of steroids for epidural injection in patients with radiculopathy found low-strength
evidence that there are “few differences” between steroid types, although some inconsistency in the results could have stemmed from differences in the steroid dose used. Similarly, the authors concluded that there was low-strength evidence of no clear difference in effectiveness of steroid injections for radiculopathy based on the steroid dose or number of injections. For patients with spinal stenosis, there was insufficient evidence to determine whether the effects of epidural steroid injections varies by type, dose, or frequency of injections (no meta-analysis was performed).

In three trials that directly compared a transforaminal approach to an interlaminar approach for ESIs, there was low-strength evidence of no difference in short-term function (SMD 0.39, 95% CI -.036 to 1.13). Similarly, in the one trial that reported on long-term function, there was no difference between the transforaminal and interlaminar approach (WMD -2.00, 95% CI -8.77 to 4.77). Although the long-term risk of surgery was not reported, in two trials there was low strength of evidence of no difference in intermediate-term risk of surgery based on the approach. There was low-strength evidence from mostly single trials that other approaches (caudal, oblique interlaminar, lateral parasagittal) did not offer clear comparative benefit. One trial that compared a ganglionic transforaminal approach to a preganglionic transforaminal approach provided low strength of evidence that the preganglionic approach was associated with greater likelihood of treatment success at one month, but no differences were found beyond five months. There were no trials of patients with spinal stenosis that randomly compared different approaches for ESIs. For facet joint injection, there was insufficient evidence from one trial to determine whether an intra- or extra-articular injection approach was more effective.

The authors found no trials that directly compared the use of image-guided ESIs to non-image-guided injections, and indirect comparisons were not possible because of the correlation between the use of imaging and the type of approach that was used. The authors noted that there was low-strength evidence from one trial that ESIs guided by MRI findings were no more effective than those based on history and physical exam with respect to outcomes of function and medication use.

In the meta-regression of trials of ESIs compared to placebo, there was no association between a history of lumbar surgery and the effectiveness of the treatment. In this review, the authors did not address whether response to prior diagnostic or therapeutic injection trials was associated with a difference in outcomes.

Testimony and public comments indicated that ESIs are most effective when performed on patients with radicular pain in a dermatomal distribution and the injections are performed using imaging guidance with a transforaminal approach. Many of the studies included in this evidence review had less restrictive patient selection criteria, did not use imaging guidance, or used other approaches. The table below summarizes results from the studies of patients with radicular pain in which the injections were performed using imaging guidance and a transforaminal approach. Although some studies showed a statistically significant benefit for pain or function at certain intervals, none reached commonly accepted thresholds of minimal clinically important difference. Table 1 summarizes these studies.
Table 1. Summary of selected studies for back pain with radiculopathy

Studies selected included only patients with low back pain with radiculopathy with imaging correlates; all used a transforaminal approach and were performed using imaging guidance.

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention(s) vs. Comparator(s)</th>
<th>N</th>
<th>Quality Assessment</th>
<th>Imaging Correlates</th>
<th>Imaging Guidance</th>
<th>Anatomic Approach</th>
<th>Results: Function</th>
<th>Results: Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burgher et al., 2011</td>
<td>Triamcinolone and lidocaine vs. clonidine with lidocaine</td>
<td>26</td>
<td>Fair</td>
<td>Disc encroachment confirmed by MRI or CT</td>
<td>Yes</td>
<td>Transforaminal</td>
<td>Mixed: No statistically significant differences at 2 weeks, but small statistically significant benefit of ESI over clonidine at 4 weeks</td>
<td>No statistically significant differences</td>
</tr>
<tr>
<td>Cohen et al., 2012</td>
<td>Methyldaprednisolone and bupivacaine vs. etanercept and bupivacaine vs. sterile water and bupivacaine</td>
<td>84</td>
<td>Good</td>
<td>MRI evidence of pathologic disc condition</td>
<td>Yes</td>
<td>Transforaminal</td>
<td>No statistically significant difference for comparison of steroid with sterile water; statistically significant benefit of steroid over etanercept</td>
<td>No statistically significant differences</td>
</tr>
<tr>
<td>Cohen et al., 2014</td>
<td>Depomethylprednisolone and bupivacaine injection + placebo vs. Sham injection + gabapentin</td>
<td>145</td>
<td>Fair</td>
<td>MRI demonstrated HNP or spinal stenosis</td>
<td>Yes</td>
<td>Interlaminar or transforaminal</td>
<td>No statistically significant differences</td>
<td>No statistically significant differences for mean pain score. Statistically significant benefit for positive composite outcome in favor of ESI over comparator</td>
</tr>
<tr>
<td>Study</td>
<td>Intervention(s) vs. Comparator(s)</td>
<td>Quality Assessment</td>
<td>Imaging Correlates</td>
<td>Imaging Guidance</td>
<td>Anatomic Approach</td>
<td>Results: Function</td>
<td>Results: Pain</td>
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<tr>
<td><strong>Gerstzen et al., 2010</strong></td>
<td>Corticosteroid (various types and doses at clinician discretion) vs. Plasma disc decompression N=90</td>
<td>Fair</td>
<td>Imaging evidence of focal lumbar disc protrusion</td>
<td>Yes</td>
<td>Transforaminal</td>
<td>No statistically significant difference or benefit in favor of plasma disc decompression over ESI</td>
<td>No statistically significant difference or benefit in favor of plasma disc decompression over ESI</td>
<td></td>
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<tr>
<td><strong>Ghahreman et al., 2011</strong></td>
<td>Triamcinolone and bupivacaine vs. bupivacaine vs. saline vs. IM triamcinolone vs. IM saline N=150</td>
<td>Good</td>
<td>Imaging correlate required</td>
<td>Yes</td>
<td>Transforaminal</td>
<td>No statistically significant differences</td>
<td>Statistically significant benefit of ESI over comparators</td>
<td></td>
</tr>
<tr>
<td><strong>Karpinnen et al., 2001</strong></td>
<td>Methylprednisolone and bupivacaine vs. saline N=163</td>
<td>Good</td>
<td>MRI scans at baseline</td>
<td>Yes</td>
<td>Transforaminal</td>
<td>No statistically significant differences or benefit of saline over ESI</td>
<td>No statistically significant differences or benefit of saline over ESI</td>
<td></td>
</tr>
<tr>
<td><strong>Lee et al., 2016</strong></td>
<td>Dexamethasone and bupivacaine vs. pulsed radiofrequency treatment of the dorsal root ganglion N=44</td>
<td>Poor</td>
<td>Imaging findings of intervertebral disc pathology</td>
<td>Yes</td>
<td>Transforaminal</td>
<td>No statistically significant differences</td>
<td>No statistically significant differences</td>
<td></td>
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<tr>
<td><strong>Manchikanti et al., 2014</strong></td>
<td>Betamethasone and lidocaine vs. saline and lidocaine N=120</td>
<td>Fair</td>
<td>Imaging evidence of L4-L5 or L5-S1 disc herniation</td>
<td>Yes</td>
<td>Transforaminal</td>
<td>No statistically significant differences</td>
<td>No statistically significant differences</td>
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<tr>
<td>Study</td>
<td>Intervention(s) vs. Comparator(s)</td>
<td>Quality Assessment</td>
<td>Imaging Correlates</td>
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<tr>
<td><strong>Riew et al., 2006</strong></td>
<td>Betamethasone and bupivacaine vs. bupivacaine N=55</td>
<td>Fair</td>
<td>Disc herniation or spinal stenosis by MRI or CT</td>
<td>Yes</td>
<td>Transforaminal</td>
<td>Not reported</td>
<td>Not reported</td>
<td></td>
</tr>
<tr>
<td><strong>Tafazal et al., 2009</strong></td>
<td>Methylprednisolone and bupivacaine vs. bupivacaine N=150</td>
<td>Fair</td>
<td>Disc herniation or foraminal stenosis by MRI</td>
<td>Yes</td>
<td>Transforaminal</td>
<td>No statistically significant differences</td>
<td>No statistically significant differences</td>
<td></td>
</tr>
</tbody>
</table>
KQ3: What are the harms of corticosteroid injections for low back pain?

In general, the authors found low- to moderate-strength evidence of few harms being associated with epidural or facet joint steroid injections, but noted that reporting of harms was sparse and inconsistent in this literature. However, the authors noted that observational studies of harms of steroid injections also found a low risk of serious adverse effects.

Additional Studies

The following are randomized controlled trials that fit the inclusion criteria for the AHRQ systematic review (Chou et al., 2015) but were published after the search dates of that systematic review.

Chun et al., 2015

This is a poor-quality randomized trial of different volumes of injectate used for epidural steroid injection. In this trial, 66 patients with lumbar radicular pain for at least six weeks despite conservative treatment and clinical and radiologic evidence of a herniated disc or spinal stenosis were randomized to receive lidocaine and 4 mg dexamethasone in either a 3 mL or 8 mL injectate. All injections were performed via the transforaminal route under fluoroscopy. The investigator who performed the injections was aware of the treatment assignments. There were baseline differences between the two groups at the beginning of the trial with respect to the duration of pain and history of laminectomy. The main outcome of interest was improvement in the Roland-Morris Disability Questionnaire (RMDQ) score at four weeks. Both groups showed statistically significant improvement in the mean RMDQ score (approximately three to four points) compared to baseline, but there were no between-group differences. The authors reported no serious adverse events in either group.

Cohen et al., 2015

This is a fair-quality randomized trial comparing epidural steroid injections plus oral placebo to sham injections plus oral gabapentin. In this trial, 145 patients with lumbosacral radicular pain of greater than six weeks but less than four years and imaging findings of a herniated disc or spinal stenosis were randomized to undergo imaging-guided interlaminar or transforaminal ESI with 60 mg depotmethylprednisolone and bupivacaine, followed by an oral placebo or a sham injection with saline, and then oral gabapentin titrated to a daily dose of 1,800 to 3,600 mg. At the beginning of the trial, there were more women in the ESI group, and there were high rates of attrition in both arms at three months. There were no statistically significant differences between the two groups in the ODI score at one or three months. Similarly, there was no difference in opioid doses, incidence of surgery at one year, or adverse events between the two groups.

Denis et al., 2015

This is a poor-quality randomized trial comparing the use of equipotent doses of betamethasone or dexamethasone for ESI. In this trial, 56 patients with lumbosacral radicular pain and CT or MRI findings of a herniate disc or foraminal stenosis were randomized to 6 mg of betamethasone or 7.5 mg of dexamethasone delivered by transforaminal injection under fluoroscopy. There were baseline
differences between the two groups with respect to type of occupation (manual vs. non-manual) and smoking status. Both groups showed improvement in the ODI compared to baseline. At one month and three months follow-up, there was no difference between the two groups, but at six months the patients in the dexamethasone group showed greater improvement in the ODI. There were no significant adverse events in either arm. The authors acknowledged that the study was underpowered to detect a difference a between the two steroids.

_Evansa et al., 2015_
This is a fair-quality single-center, single-operator randomized trial comparing ultrasound and fluoroscopically guided ESIs. In this trial, 112 patients (predominantly women) with chronic axial low back pain or lumbosacral radiculopathy for more than three months despite conservative treatment were randomized to interlaminar ESI with 80 mg methylprednisolone and lidocaine delivered under ultrasound or fluoroscopic guidance. The investigators and patients were not blinded. The patients were similar at baseline. Both groups showed improvement in the ODI compared to baseline. There were no significant between-group differences. Dizziness, injection-site pain, and flushing were similar in both groups.

_Ghai et al., 2015_
This is a poor-quality single-center randomized trial comparing injections of lidocaine alone and lidocaine plus steroid. In this trial, 69 patients under the age of 60 with more than three months of chronic low back or lumbosacral radicular pain despite conservative treatment were randomized to receive either lidocaine or lidocaine plus 80 mg methylprednisolone in equal volumes delivered via parasagittal interlaminar approach under fluoroscopy. Groups appeared to be similar at baseline. There were differences between the two groups with respect to the number of patients receiving more than three injections during the trial. There was also differential loss to follow-up at 12 months; more patients were lost in the lidocaine-only arm. With respect to functional outcomes, both arms showed improvement in the Modified Oswestry Disability Questionnaire (MODQ) compared to baseline. Patients in the lidocaine plus steroid arm showed statistically significantly greater improvement in the MODQ score at 3, 6, 9, and 12 months, although the magnitude of difference appears to be less than 10 points, a level of improvement that might not be clinically significant. One patient in the lidocaine-only group had a vagal reaction to the injection that was treated with atropine.

_Kamble et al., 2016_
This is a poor-quality single-center randomized trial of three approaches to ESIs. In this trial, 90 patients with lumbosacral radicular pain and clinical and radiologic correlates for nerve root compression were randomized to receive 40 mg triamcinolone with bupivacaine and lidocaine delivered by transforaminal, caudal, or interlaminar approach (1:1:1). The investigators did not report on baseline characteristics, other treatments received, or attrition. All groups showed improvement in the mean ODI compared to baseline, but the improvements were statistically significantly greater in the patients who had received transforaminal injections. The crude number of patients requiring repeat injection or proceeding to surgery were similar in all three groups. Adverse events were not reported.
**Karamouzian et al., 2014**

This is a poor-quality randomized trial comparing caudal and transforaminal ESIs in patients with a history of back surgery. In this trial, 30 patients with a history of previous open lumbar discectomy and recurrent radicular pain that had not responded to six weeks of conservative treatment were randomized to receive 40 mg methylprednisolone with bupivacaine and lidocaine by either a caudal or transforaminal approach. All patients in this trial also received treatment with tizanidine, celecoxib, and nortriptyline. Fluoroscopic guidance was only used for the transforaminal injections. Functional outcomes were assessed using the Prolo index (an instrument only validated to measure back surgery outcomes), and no statistically significant difference was observed between the two groups at two or six months after the treatment.

**Lee et al., 2016**

This is a poor-quality randomized trial comparing pulsed radiofrequency treatment and transforaminal ESI. In this trial, 44 patients under age 70 with cervical or lumbar radicular pain and imaging findings of a herniated disc who had previously undergone ESI with unsatisfactory results were randomized to receive pulsed radiofrequency treatment or repeat transforaminal ESI with 5 mg dexamethasone and bupivacaine under fluoroscopic guidance. At baseline there were more women in the pulsed radiofrequency group. Both groups showed statistically significant improvement in ODI scores compared to baseline, but there were no statistically significant between-group differences at 2, 4, 8, or 12 weeks after the procedure. One patient in the radiofrequency group reported exacerbation of pain, but there were no other adverse events reported in either arm.

**Manchikanti et al., 2014**

This is a fair-quality single-center, single-operator randomized trial comparing injection of lidocaine with saline to lidocaine with steroid. In this trial, 120 patients who had chronic low back pain for at least six months with L4-L5 or L5-S1 disc herniation and unilateral radiculitis were randomized to undergo fluoroscopically guided transforaminal injection of either lidocaine with saline or lidocaine with 3 mg betamethasone. At baseline, there were more women, a higher average body mass index, and a higher mean ODI score in the lidocaine with saline group. There was a 25% loss to follow-up at two years. At 3, 6, 12, 18, and 24 month follow-up, both groups showed statistically significant improvement over baseline ODI score, but there was no significant difference between the two groups. Both groups also showed significant reductions in opioid dose at three months and beyond (generally on the order of a 15-30 mg morphine equivalent dose), but there were no differences between the two groups. The authors reported that about 5% of injections resulted in intravascular infiltration, and 1.5% led to nerve root irritation.

**Manchikanti et al., 2015**

This is a fair-quality single-center, single-operator randomized trial comparing injections with lidocaine alone and lidocaine plus steroid. In this trial, 120 patients over the age of 30 with radiologically documented central spinal stenosis and radicular pain for at least six months despite conservative treatment were randomized to receive fluoroscopically guided interlaminar injection of either lidocaine
or lidocaine and 6 mg betamethasone. At baseline there were more women and a higher mean weight in the lidocaine-only group. At two years of follow-up, the average number of injections was between five and six in both groups. At 3, 6, 12, 18, and 24 months of follow-up, there were statistically significant improvements in the ODI compared to baseline, but no statistically significant difference between the two groups. Both groups also showed significant reductions in opioid dose compared to baseline at three months and beyond (generally on the order of a 15-30 mg morphine equivalent dose), but there were no between-group differences. The authors reported 14 subarachnoid entries out of 644 procedures performed.

Ökmen & Ökmen, 2016
This is a poor-quality single-center randomized trial comparing injection of bupivacaine with saline to bupivacaine with steroid and saline. In this trial, 120 patients with low back pain and radicular symptoms for more than six months and MRI findings of disc bulge not responding to conservative treatment were randomized to undergo fluoroscopically guided interlaminar injection of bupivacaine with saline or bupivacaine with 40 mg methylprednisolone and saline. Methods for adequate randomization, allocation concealment, and blinding were not described. Both groups showed statistically significant improvement over baseline ODI scores at 1, 3, 6, and 12 months. In addition, there was statistically significantly greater improvement in the ODI score in the steroid group at each follow-up point. The magnitude of the difference in the ODI score between groups was 10 to 30 points depending on the follow-up period, and those differences would generally be regarded as clinically significant. The authors did not report on adverse events.

Spijker-Huijges et al., 2014
This is a fair-quality pragmatic randomized trial comparing usual care to usual care plus ESI. In this trial, 73 adults under the age of 60 with a clinical diagnosis of lumbosacral radicular back pain of greater than two but less than four weeks duration were randomized to receive care as usual or care as usual plus non-imaging guided lumbar interlaminar injection of 80 mg triamcinolone with saline. There were baseline differences between groups, including differences in the severity of symptoms, which were adjusted for in covariate analysis. Both groups experienced significant improvement in function as measured by the RMDQ score at any endpoint through one year of follow-up; the ESI group showed a statistically significantly greater improvement in RMDQ score, although that difference did not rise to the pre-established minimal clinically important difference of greater than 30% improvement. Patients in the ESI group were statistically significantly more likely to express satisfaction with their treatment.

Staats et al., 2016
This is a poor-quality randomized trial comparing minimally invasive lumbar decompression (MILD) to ESI. In this trial, 302 Medicare patients over the age of 65 with neurogenic claudication for more than three months in spite of physical therapy and analgesics and radiologically demonstrated spinal stenosis due to ligamentum flavum hypertrophy were randomized to undergo MILD or fluoroscopically guided interlaminar injection with 40 or 80 mg of triamcinolone or methylprednisolone (up to four treatments per year). At baseline, there were more women and more people with facet arthropathy in the ESI
group. During the trial, more patients in the ESI group also received aquatic therapy. The primary functional outcome of greater than 10-point improvement in ODI at six months was achieved in 62% of patients undergoing MILD and 36% of patients receiving ESI. Procedure-related adverse events were 1.3% in both groups, and there were no serious adverse events in either group.

Summary of additional studies

In general, the evidence from the additional studies would not be likely to substantially alter the conclusions from the AHRQ review. Most of the additional studies demonstrated functional improvements compared to baseline, but the use of corticosteroids in particular does not offer additional clinically important benefit beyond that of active controls in most studies.

Effectiveness of epidural steroid injections for reducing pain—low back pain with radiculopathy caused by herniated discs or foraminal stenosis

Based on public testimony, the subcommittee requested information on the effectiveness of ESIs for reducing pain in patients with low back pain and radiculopathy caused by herniated discs or foraminal stenosis. The following section summarizes the evidence on pain outcomes that were reported in the sources used in the Evidence Review above.

Chou et al., 2015

There was moderate-quality evidence from six trials that ESI was associated with greater improvement in immediate-term pain scores compared to placebo in patients with low back pain and radiculopathy (WMD -7.55 [0 to 100 scale], 95% CI -11.4 to -3.74), however, this did not meet the predefined threshold for a minimum clinically important difference. There was low- to moderate-quality evidence of no statistically significant differences between the groups for mean pain improvement at short-, intermediate- or long-term follow-up.

For categorical pain outcomes, there was low- to moderate-quality evidence of no difference in the likelihood of a successful pain outcome at short-, intermediate-, or long-term follow-up.

Cohen et al., 2015

This trial randomized patients with lumbosacral radicular pain and MRI-demonstrated HNP or spinal stenosis to receive either image-guided ESI and placebo pills or a sham injection and gabapentin. For the outcomes of average pain score at one and three months, there were no statistically significant differences between the two groups. For the secondary outcomes, the ESI group reported lower worst leg pain scores at one month, but there were no differences between the groups at three months. More patients in the ESI group (66%) reported a positive composite outcome (defined as >2 point decrease in average leg pain on a 10-point scale and positive perceived global effect) at one month compared to the gabapentin group (46%) (p=0.02). There were no statistically significant differences in the positive composite outcome at three months.


**Ghai et al., 2015**
This trial randomized patients with lumbosacral radicular pain with MRI-demonstrated HNP to receive an image-guided interlaminar epidural injection of lidocaine or lidocaine and methylprednisolone. For the primary outcome of effective pain relief (defined as >50% reduction from baseline pain score) at three months, a significantly greater percentage of patients in the steroid with local anesthetic group attained that result compared to the local anesthetic-only group (86% vs. 50%, p=0.002). Those differences were maintained through 12 months of follow-up.

**Lee et al., 2016**
This trial randomized patients with lumbar radicular pain with imaging findings of intervertebral disc pathology who had not attained satisfactory relief from a first transforaminal ESI to receive repeat image-guided ESI or pulsed radiofrequency treatment of the dorsal root ganglion. Pain scores, as measured by the visual analogue scale (VAS), showed significant decreases compared to baseline in both groups at 2 to 12 weeks of follow-up, but there were no between-group differences.

**Manchikanti et al., 2014**
This trial randomized patients with lumbosacral radicular pain of at least six months duration and imaging findings of HNP at L4-L5 or L5-S1 to receive an imaging-guided transforaminal epidural injection of lidocaine with saline or lidocaine with betamethasone. For the outcome of mean pain score as reported by the Numeric Rating Scale (NRS), both groups showed significant improvement compared to baseline scores at 3 to 24 months of follow-up, but there were no statistically significant differences between the two groups. The proportion of patients reporting significant pain relief (>50% improvement in NRS from baseline) was higher in the lidocaine with saline group at 3 to 24 months of follow-up, but between-group tests of statistical significance were not reported for this outcome.

**Ökmen & Ökmen, 2016**
This trial randomized patients with low back pain and radiculitis with MRI-demonstrated disc pathology to receive an imaging-guided interlaminar epidural injection of bupivacaine and saline or bupivacaine and methylprednisolone. For the outcome of mean pain score as measured by the VAS, there were significantly greater improvements for patients in the steroid group at 1 to 12 months of follow-up (mean between-group differences in VAS ranged from 0.9 to 2 [10-point scale] at various follow-up times, p<0.05 for all between-group comparisons).

**Spijker-Huiges et al., 2014**
This pragmatic trial randomized patients with clinically diagnosed lumbosacral radicular pain to receive care as usual (CAU) or CAU with a non-imaging-guided interlaminar injection of triamcinolone and saline. In the mixed-model analysis that accounts for between-group differences at various time points during 52 weeks of follow-up, there was a statistically significant improvement in the NRS back pain score (estimated mean difference 1.12 [10-point scale], 95% CI 0.26 to 1.98, p=0.01) favoring the patients who received ESI; there were no statistically significant between-group differences with respect to the NRS leg pain score or the NRS total pain score.
Summary of findings on pain outcomes

Based on the AHRQ review, there is moderate-quality evidence of a small but statistically significant improvement in immediate-term pain for patients with lumbosacral radicular pain who receive ESI; however, those improvements were not maintained at a later follow-up period and did not meet the pre-specified threshold for minimal clinically important difference.

The additional RCTs comparing ESI with various control treatments for lumbosacral radicular pain reached mixed conclusions. However, the most methodologically and technically rigorous of these subsequent trials found no significant differences in pain outcomes between patients who received ESI and those who received sham injections plus gabapentin (Cohen et al., 2015) or local anesthetic injections alone (Manchikanti et al., 2014).

Evidence summary

Overall, low- to moderate-strength evidence demonstrates no difference in short- or long-term function for patients treated with epidural steroid injections, facet joint steroid injections, or medial branch steroid injections when compared to control treatments. For patients with radiculopathy, epidural steroid injections have been shown to produce immediate-term improvements in pain (moderate confidence) and function (low confidence) compared to control treatments, but the magnitude of those improvements does not rise to pre-specified thresholds of clinical significance. Epidural steroid injections in patients with radiculopathy may reduce the risk of undergoing surgery in the short-term, but the evidence does not support any difference in the long-term risk of surgery compared to control treatments. There was insufficient evidence to draw conclusions about the effectiveness of sacroiliac joint steroid injections. Harms and serious adverse events associated with these procedures are inconsistently reported in the trials, but appear to be rare.

Other decision factors

Resource allocation

The actual prices of the various corticosteroid injections are highly variable depending on the setting and plan. Prices appear to range from hundreds to thousands of dollars. If these injections were effective, then they could potentially be comparable to an extended course of conservative therapy, and some patients would prefer more rapid relief of their symptoms. If these injections decreased future risk of surgery, they would likely be cost saving. However, there is insufficient evidence supporting a decreased use of conservative treatments, and there is moderate confidence that ESIs are ineffective at reducing the risk of surgery for radiculopathic pain. Given the lack of proven benefit on the predefined outcomes, various corticosteroid injections for back pain are unlikely to be cost-effective.

Values and preferences

Patients with back pain would highly value having effective treatments to improve their symptoms, and would likely prefer interventions that are less invasive, less time consuming, less risky, and less
demanding on the patient. Given the variety of frequently used interventions for low back pain, patient preferences would likely be highly variable.

**Other considerations**

There are many proven evidence-based treatments for low back pain that are widely available to patients through most insurers.

**Policy Landscape**

**Quality measures**

A search of the National Quality Measures Clearinghouse did not identify any measures directly related to the use of ESI. The National Quality Measures Clearinghouse does include a number of quality measures that address assessment and collaborative decision-making regarding low back pain. For example, one quality measure is “Percentage of patients with non-specific low back pain diagnosis who have had collaborative decision-making with regards to referral to a specialist” (Institute for Clinical Systems Improvement, 2012).

**Payer coverage policies**

**Private payers**

*Coverage policy for ESIs*

Coverage policies were assessed for Aetna, Cigna, Moda, and Regence. Aetna, Cigna, and Moda provide coverage for ESIs when considered medically necessary according to set criteria. No coverage policy regarding ESIs for low back pain was identified for Regence. The criteria included in Aetna, Cigna, and Moda coverage policies for the treatment of low back pain with ESIs is described below.

*Criteria for ESI diagnosis and origin of pain*

Moda covers ESIs for patients with spinal pain (i.e., cervical, thoracic, or lumbar) who have physical examination findings consistent with radicular pain. Aetna and Cigna cover ESIs for patients with radiculopathy. Cigna additionally covers ESIs for certain patients with radiculitis or radicular pain and certain patients with evidence of symptomatic spinal stenosis as an initial trial. Moda and Cigna may require physical exam findings consistent with radicular pain, such as a positive leg raising test. All three of these payers require a failed response to a reasonable course of conservative therapy (e.g., physical therapy, chiropractic care, rest, systemic analgesics) prior to treatment with ESIs. Furthermore, all three payers include criteria for the origin of the pain. Aetna and Moda explicitly exclude patients with non-specific back pain or failed back syndrome.

*Criteria for administration of ESI treatment*

Aetna and Moda do not cover ultrasound guidance for administration of ESIs for any indication. Cigna states that ESIs should be administered under fluoroscopic guidance, with few exceptions. Cigna does not cover caudal ESIs because this injection route is not target specific. Cigna only covers ESIs as part of a comprehensive approach to pain, stating “based on the limited long-term benefit of performing an ESI
as an isolated intervention with regard to pain and improved function, all ESIs should be performed in conjunction with active rehabilitative care/therapeutic exercise.” Aetna requires that ESIs are provided as part of a comprehensive pain management program following the first set of three injections.

Criteria for repeated use of ESIs
All three private payers set criteria for continued use of ESIs. Aetna states that it is not medically necessary to employ ESIs more frequently than every seven days, and that it is rarely medically necessary more than every two months following an established therapeutic effect of the treatment. Treatment exceeding 12 months may be reviewed by Aetna for continued medical necessity. Cigna permits repeated use of ESIs given 50% pain relief, an increase in function, or a reduction in utilization of medication or additional medical services. Cigna further specifies that administration of ESIs should be limited to three per episode of pain and four per region in a year. Moda covers up to four injections in a 12-month period if the preceding injection resulted in 50% pain relief for at least six weeks.

Coverage policy for facet joint injections
Aetna and Cigna do not cover therapeutic facet joint injections for the treatment of low back pain. Moda covers therapeutic joint injections for certain patients with back pain when facet joint syndrome is suspected and the patient has tried and failed three months of conservative treatment. No coverage policy regarding facet joint injections for the treatment of low back pain was identified for Regence.

Coverage policy for sacroiliac joint injections
Aetna, Moda, and Cigna cover therapeutic sacroiliac joint injections for certain patients with back pain. No coverage policy regarding the therapeutic use of sacroiliac joint injections was identified for Regence. Both Aetna and Moda require that the patient has chronic low back pain for a period of at least three months prior to treatment. Aetna and Cigna only permit sacroiliac joint injections as part of a comprehensive pain management program. Moda and Cigna only cover sacroiliac joint injections for patients who have been nonresponsive to a reasonable course of conservative treatment.

Medicaid
The Washington Medicaid program covers ESIs in the cervical, thoracic, or lumbar spine for the treatment of patients with chronic radicular pain who have failed to respond to at least six weeks of conservative therapy or for patients with radiculopathy who have failed to respond to at least two weeks of conservative therapy. Fluoroscopic, CT, or ultrasound guidance must be used in the administration of ESIs. Additionally, Washington Medicaid requires documentation of the patient’s baseline level of function.

The Washington Medicaid program also covers sacroiliac joint injections when completed with fluoroscopic or CT guidance for patients with chronic sacroiliac joint pain who have not shown sufficient improvement in response to at least six weeks of conservative therapy. Washington Medicaid states there must be no more than one injection without medical record documentation of at least 30% improvement in function and pain, when compared to the baseline documented before the injections started. Washington Medicaid requires clinical review of requests for more than two injections.
Medicare

No National Coverage Determination was identified for ESIs for low back pain. Three Medicare Local Coverage Determinations (LCDs) were identified for the treatment of low back pain with ESIs. The LCD for South Carolina, Virginia, West Virginia, and North Carolina (effective 3/17/2016) and the LCD for Kentucky and Ohio (effective 10/01/2015) cover ESIs for patients with suspected radicular pain, neurogenic claudication, post laminectomy syndrome, or low back pain with substantial imaging abnormalities, or a documented Visual Analog scale or Numeric Pain Rating Scale indicating moderate to severe pain with functional impairment in daily living activities. These LCDs require a failed response to at least four weeks of non-surgical, non-injection care. The LCD for Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania (effective 10/01/2016) states that the therapeutic use of transforaminal epidural injections performed under imaging guidance may be appropriate for certain patients when other therapeutic measures are ineffective or contraindicated and when the low back pain is not associated with myofascial pain syndrome.

No National Coverage Determination was identified for facet joint injections for low back pain. Ten Medicare LCDs were identified for the treatment of low back pain with facet joint injections for certain patients. All 10 LCDs only cover facet joint injections for patients with low back pain that has persisted for at least three months. Additionally, all 10 LCDs state that facet joint injections must be performed with imaging guidance (e.g., fluoroscopy, CT). All 10 LCDs set criteria for continued treatment with facet joint injections. One LCD states that if the first set of injections fails to produce the desired effect, the provider should proceed to the next indicated treatment option. A second LCD states that long-term multiple facet joint injections are not an effective method for chronic pain management and recommends limiting injections to four per region, per year. The remaining eight LCDs state that facet joint injections of corticosteroids are associated with adverse health events, and thus “ongoing coverage requires outcomes reporting as described in this LCD to allow future analysis of clinical efficacy.”

No National Coverage Determination was identified for sacroiliac joint injections for low back pain. Two Medicare LCDs were identified for the treatment of low back pain with sacroiliac joint injections. Both the LCDs for Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania (effective 10/01/2016) and the LCDs for Florida, Puerto Rico, and Virgin Islands (effective 10/01/2015) state that therapeutic sacroiliac injections of steroids may be used to treat low back pain and recommend the use of imaging guidance to ensure the success of this procedure.

Professional society guidelines

Each of the guidelines summarized below addresses the treatment of low back pain and recommends ESIs for specific patient populations.

- The Toward Optimized Practice (TOP) 2015 clinical practice guideline, Evidence-informed primary care management of low back pain, states that there is inconclusive evidence to recommend for or against ESIs in the presence of radiculopathy and recommends “do not use epidural steroid injections for acute low back pain in the absence of radiculopathy” (Toward Optimized Practice, 2015).
The North American Spine’s Society’s (NASS) 2014 guideline, *An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy*, recommends transforaminal ESI to provide short-term pain relief in some patients with lumbar disc herniation with radiculopathy. The guideline additionally recommends contrast-enhanced fluoroscopy to guide ESIs in order to improve accuracy. However, the guideline concludes that there is insufficient evidence to recommend for or against the 12-month efficacy of transforaminal ESI to treat this patient population. Moreover, there is insufficient evidence to recommend for or against one injection approach over another in administering ESIs to this patient population (Kreiner et al., 2014).

The American Society of Interventional Pain 2013 guideline, *An update of comprehensive evidence-based guidelines for intervention techniques in chronic spinal pain*, recommends caudal, interlaminar, and transforaminal epidural injections for disc herniation and for spinal stenosis, as well as caudal or interlaminar epidural injections for axial or discogenic pain without disc herniation, radiculitis, or facet joint pain (Manchikanti et al., 2013).

The Canadian Pain Society Task Force 2012 guideline, *Evidence-based guideline for neuropathic pain intervention treatments: Spinal cord stimulation, intravenous infusions, epidural injections, and nerve blocks*, recommends that clinicians consider a trial of ESI for patients with lumbar radiculopathy or with neuropathic pain arising from the cervical spine who failed to respond adequately to conservative treatment. However, the guideline states there is insufficient, limited, or conflicting data to support the use of ESIs to treat spinal stenosis, failed back surgery syndrome, complex regional pain syndrome type I, and postherpetic neuralgia (Mailis and Taenzer, 2012).

The following guideline addresses facet joint injections:

- The American Society of Interventional Pain 2013 guideline, *An update of comprehensive evidence-based guidelines for intervention techniques in chronic spinal pain*, states that the evidence is limited for therapeutic lumbar intraarticular facet joint injections and fair to good for lumbar facet joint nerve blocks (Manchikanti et al., 2013).

The following guidelines address sacroiliac joint injections:

- The Toward Optimized Practice (TOP) 2015 clinical practice guideline, *Evidence-informed primary care management of low back pain*, states that there is inconclusive evidence to recommend for or against intra-articular sacroiliac injections (Toward Optimized Practice, 2015).

- The American Society of Interventional Pain 2013 guideline, *An update of comprehensive evidence-based guidelines for intervention techniques in chronic spinal pain*, states that the evidence is limited for therapeutic sacroiliac joint injections (Manchikanti et al., 2013).

**Food and Drug Administration safety announcement**

The injection of corticosteroids into the epidural space of the spine is a widespread medical practice. However, this use of injectable steroids is not currently approved by the FDA because its effectiveness and safety has not been established. In response to concerns of medical professionals regarding the risk
of severe neurological adverse events associated with the use of ESIs for back pain, the FDA initiated an ongoing investigation of the safety issue and has acted to raise awareness of the risks. In 2014, the FDA released a safety announcement regarding the use of ESIs:

“The U.S. Food and Drug Administration (FDA) is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating pain in the arms and legs. We are requiring the addition of a Warning to the drug labels of injectable corticosteroids to describe these risks. Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments” (FDA, 2014).

REFERENCES

Evidence Sources


**Other Citations**


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.

## Appendix A. GRADE Informed Framework – Element Descriptions

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Balance of benefits and harms</td>
<td>The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.</td>
</tr>
<tr>
<td>Quality of evidence</td>
<td>The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted</td>
</tr>
<tr>
<td>Resource allocation</td>
<td>The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted</td>
</tr>
<tr>
<td>Values and preferences</td>
<td>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</td>
</tr>
<tr>
<td>Other considerations</td>
<td>Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.</td>
</tr>
</tbody>
</table>

### Strong recommendation

**In Favor:** The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

**Against:** The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

### Weak recommendation

**In Favor:** The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors, but further research or additional information could lead to a different conclusion.

**Against:** The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

### Confidence in estimate rating across studies for the intervention/outcome

**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 estimate of effect: 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...
Low Back Pain – Corticosteroid Injections
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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 estimate of effect 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 estimate of effect: 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.
### APPENDIX B. GRADE EVIDENCE PROFILES

#### Quality Assessment (Confidence in Estimate of Effect) – Epidural steroids for radiculopathy

<table>
<thead>
<tr>
<th>No. of Studies</th>
<th>Study Design(s)</th>
<th>Risk of Bias</th>
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<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Factors</th>
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### Quality Assessment (Confidence in Estimate of Effect) – Facet joint injections

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<td>Harms (Important)</td>
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APPENDIX C. METHODS

Scope Statement

Populations

Adults with acute, subacute, or chronic low back pain with or without radiculopathy

*Population scoping notes: None*

Interventions

Epidural, facet joint, or sacroiliac corticosteroid injections

*Intervention exclusions: None*

Comparators

Other injection therapies (e.g., local anesthetics, hyaluronic acid, or saline), physical therapy, home exercise programs, medications (e.g., oral corticosteroids, opioids, nonsteroidal anti-inflammatory drugs), complementary and alternative therapies (e.g., acupuncture, yoga, chiropractic therapy, Alexander technique), soft tissue injections, ablative interventions, surgery, no treatment

Outcomes

**Critical:** Long-term function, long-term risk of undergoing surgery

**Important:** Short-term function, adverse events, change in utilization of comparators (e.g., opioids, surgery)

*Considered but not selected for the GRADE table: intermediate-, short- and long-term pain, immediate-term function*

Key Questions

KQ1: What is the comparative effectiveness of corticosteroid injection therapies for low back pain?

KQ2: Does the effectiveness of corticosteroid injection therapies for low back pain vary based on:

a. Duration of back pain
b. Etiology of back or radicular pain (e.g., stenosis, disc herniation)
c. Choice of corticosteroid, dose, or frequency
d. Anatomic approach
e. Use of imaging guidance
f. Previous back surgery
g. Response to previous diagnostic injections
h. Response to previous injection therapies

KQ 3: What are the harms of corticosteroid injection therapies for low back pain?
Contextual Questions

1. Does the use of these therapies influence subsequent utilization of health care resources (e.g., chiropractic, opioids, acupuncture, physical therapy)?

2. Does the effectiveness of these interventions depend on prior treatments the patient has received?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using the terms (epidural OR spine OR spinal OR sacroiliac OR medial branch OR radiculopathy) AND (inject* OR steroid* OR corticosteroid). Searches of core sources were limited to citations published after 2011.

The core sources searched included:
- Agency for Healthcare Research and Quality (AHRQ)
- Blue Cross/Blue Shield Health Technology Assessment (HTA) program
- BMJ Clinical Evidence
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Cochrane Library (Wiley Interscience)
- Hayes, Inc.
- Institute for Clinical and Economic Review (ICER)
- Medicaid Evidence-based Decisions Project (MED)
- National Institute for Health and Care Excellence (NICE)
- Tufts Cost-effectiveness Analysis Registry
- Veterans Administration Evidence-based Synthesis Program (ESP)
- Washington State Health Technology Assessment Program

A MEDLINE® search was then conducted to identify systematic reviews, meta-analyses, and technology assessments. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the AHRQ systematic review (Chou et al., 2015). The search was limited to publications in English published after October 2014 (the end search date for the AHRQ systematic review, which was judged to be the most comprehensive review on this topic).

Searches for clinical practice guidelines were limited to those published since 2011. A search for relevant clinical practice guidelines was also conducted, using the following sources:
- Australian Government National Health and Medical Research Council (NHMRC)
- Centers for Disease Control and Prevention (CDC) – Community Preventive Services
- Choosing Wisely
- Institute for Clinical Systems Improvement (ICSI)
- National Guidelines Clearinghouse
- New Zealand Guidelines Group
- NICE
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DOD)

Inclusion/Exclusion Criteria
Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, or clinical practice guidelines. Additionally, studies that reported only on data that had been previously published were excluded.
# Appendix D. Applicable Codes

<table>
<thead>
<tr>
<th>CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td><strong>CPT Codes</strong></td>
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</tr>
<tr>
<td>Paravertebral facet with ultrasound guidance</td>
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<tr>
<td>0216T</td>
<td>Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level</td>
</tr>
<tr>
<td>0217T</td>
<td>... lumbar or sacral; second level (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0218T</td>
<td>... lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0230T</td>
<td>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level</td>
</tr>
<tr>
<td>0231T</td>
<td>... lumbar or sacral; each additional level (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td><strong>Sacroiliac</strong></td>
<td></td>
</tr>
<tr>
<td>27096</td>
<td>Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed</td>
</tr>
<tr>
<td>62322</td>
<td>Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance</td>
</tr>
<tr>
<td>62323</td>
<td>... lumbar or sacral (caudal); with imaging guidance</td>
</tr>
<tr>
<td>64483</td>
<td>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level</td>
</tr>
<tr>
<td>64484</td>
<td>... lumbar or sacral, each additional level</td>
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<tr>
<td><strong>Paravertebral facet with fluoroscopy or CT guidance</strong></td>
<td></td>
</tr>
<tr>
<td>64493</td>
<td>Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level</td>
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<tr>
<td>64494</td>
<td>... lumbar or sacral; second level (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>64495</td>
<td>... lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)</td>
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</tbody>
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Note: Inclusion on this list does not guarantee coverage