

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: PERCUTANEOUS INTERVENTIONS FOR LOW BACK PAIN

Initial HERC approval 10/11/2012
Reaffirmed 11/13/2014

This coverage guidance was created under HERC's 2012 coverage guidance process and does not include strength of recommendation, a GRADE-informed framework or coverage guidance development framework.

As a part of the normal evidence review process, the Evidence-based Guidelines Subcommittee elected in September, 2014 (see Appendix A) to deter action on this coverage guidance until a planned updated version of the original source review is completed. However, the guidance's recommendation language has been altered to be consistent with that of more recent guidances.

HERC Coverage Guidance

For radicular low back pain, epidural steroid injections are recommended for coverage for patients with persistent radiculopathy due to herniated lumbar disc; it is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. If an epidural steroid injection does not offer benefit, repeated injections are not recommended for coverage.

Epidural steroid injections are not recommended for coverage for central spinal canal stenosis.

For radicular low back pain, the following treatments are not recommended for coverage:

- coblation nucleoplasty
- radiofrequency denervation

For nonradicular low back pain, the following treatments are not recommended for coverage:

- facet joint corticosteroid injection
- prolotherapy
- intradiscal corticosteroid injection
- local injections (including trigger point injections)
- botulinum toxin injection
- epidural steroid injection
- intradiscal electrothermal therapy (IDET)
- medial branch block
- radiofrequency denervation
- sacroiliac joint steroid injection
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation

RATIONALE FOR GUIDANCE DEVELOPMENT

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

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

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

EVIDENCE SOURCES

Chou, R., Loesser, J.D., Owens, D.K., Rosenquist, R.W., Atlas, S.J., Baisden, J., et al. (2009). Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. *Spine*, 34(10), 1066-1077. – Accompanied by:

Chou, R., Atlas, S.J., Stanos, S.P., & Rosenquist, R.W. (2009). Nonsurgical interventional therapies for low back pain: A review of the evidence for an American Pain Society clinical practice guideline. *Spine*, 34(10), 1078-1094.

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

SUMMARY OF EVIDENCE

CLINICAL BACKGROUND

Low back pain is the fifth most common reason for all physician visits in the United States. Approximately one quarter of US adults reported having low back pain lasting at least one whole day in the past three months, and 7.6% reported at least one episode of severe acute low back pain within a 1-year period. Low back pain is also very costly. Total incremental direct health care costs attributable to low back pain in the US were estimated at \$26.3 billion in 1998. In addition, indirect costs related to days lost from work are substantial, with approximately 2% of the US work force compensated for back injuries each year.

Many patients have self-limited episodes of acute low back pain and do not seek medical care. Among those who do seek medical care, pain, disability, and return to work typically improve rapidly in the first month. However, up to one third of patients report persistent back pain of at least moderate intensity one year after an acute episode, and one in five report substantial

limitations in activity. Approximately 5% of the people with back pain disability account for 75% of the costs associated with low back pain.

Many options are available for evaluation and management of low back pain. However, there has been little consensus, either within or between specialties, on appropriate clinical evaluation and management of low back pain. Numerous studies show unexplained, large variations in use of diagnostic tests and treatments. Despite wide variations in practice, patients seem to experience broadly similar outcomes, although costs of care can differ substantially among and within specialties.

EVIDENCE REVIEW

RADICULOPATHY DUE TO HERNIATED LUMBAR DISC

For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed. Although some higher-quality trials found epidural steroid injection associated with moderate short-term (through up to 6 weeks) benefits in pain or function, others found no differences *versus* placebo injection. Reasons for the discrepancies between trials is uncertain, but could be related to the type of comparator treatment, as trials that compared an epidural steroid injection to an epidural saline or local anesthetic injection tended to report poorer results than trials that compared an epidural steroid injection to a soft-tissue (usually interspinous ligament) placebo injection. Regardless of the comparator intervention, there is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. Although serious complications following epidural steroid injection are rare in clinical trials, there are case reports of paralysis and infections. There is insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid injection, or on use of fluoroscopic guidance. In addition, insufficient evidence exists to recommend how many epidural injections to perform, though one higher-quality trial found that if an initial epidural steroid injection did not result in benefits, additional injections over a 6-week period did not improve outcomes.

Decisions regarding use of epidural steroid injection should be based on a shared decision-making process that includes a discussion of the inconsistent evidence for short-term benefit, lack of long-term benefit, potential risks, and costs. Patient preferences and individual factors should also be considered. For example, epidural steroid injection may be a reasonable option for short-term pain relief in patients who are less optimal surgery candidates due to comorbidities. There is insufficient evidence to guide specific recommendations for timing of epidural steroid injection, though most trials enrolled patients with at least subacute (greater than 4 weeks) symptoms.

Evidence on efficacy of epidural steroid injection for spinal stenosis is sparse and shows no clear benefit, though more trials are needed to clarify effects. Although chymopapain chemonucleolysis is effective for radiculopathy due to herniated lumbar disc, it is less effective than discectomy and is no longer widely available in the United States, in part due to risk of severe allergic reactions. Three trials suggest that intradiscal steroid injection has similar efficacy to chemonucleolysis, although none were placebo controlled.

NONRADICULAR LOW BACK PAIN

Injections and most interventional therapies for nonradicular low back pain target specific areas of the back that are potential sources of pain, including the muscles and soft tissues (botulinum toxin injection, prolotherapy, and local injections), facet joints (facet joint steroid injection, therapeutic medial branch block, and radiofrequency denervation), degenerated intervertebral discs (intradiscal steroid injection, IDET, and related procedures), and sacroiliac joints (sacroiliac joint injection). There is no convincing evidence from randomized trials that injections and other interventional therapies are effective for nonradicular low back pain. Facet joint steroid injection, prolotherapy and intradiscal steroid injections are not recommended because randomized trials consistently found them to be no more effective than sham therapies.

LOCAL INJECTIONS

For local injections¹, there is insufficient evidence to accurately judge benefits because available trials are small, lower-quality, and evaluate heterogeneous populations and interventions. Trials of IDET and radiofrequency denervation reported inconsistent results. There were a small number of higher quality trials, and in the case of radiofrequency denervation, the trials had technical or methodologic shortcomings, making it difficult to reach conclusions about benefits. For other interventional therapies, data are limited to one to two small placebo-controlled randomized trials (botulinum toxin injection, epidural steroid injection for nonradicular low back pain, PIRFT and sacroiliac joint steroid injection), or there are no placebo-controlled randomized trials (therapeutic medial branch block, coblation nucleoplasty....or other medications).

OVERALL SUMMARY

For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed, with some trials finding moderate short-term benefits and others finding no differences. There is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. For nonradicular low back pain, there is likewise no convincing evidence that injections and other interventional therapies are effective, while there is consistent evidence that facet joint steroid injection, prolotherapy and intradiscal steroid injections are no more effective than sham therapies.

PROCEDURE

- Epidural steroid injection
- Botulinum toxin injection
- Local injections
- Facet joint steroid injection
- Therapeutic medial branch block
- Radiofrequency denervation
- Intradiscal steroid injection
- Intradiscal electrothermal therapy (IDET)

¹ Defined as placement of a local anesthetic into the muscles or soft tissues of the back via a catheter. One type of local injection is trigger point injection.

Sacroiliac joint injection
 Chymopapain chemonucleolysis
 Coblation nucleoplasty
 Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)

DIAGNOSES

Low back pain

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
720.1	Spinal enthesopathy
720.2	Sacroiliitis, not elsewhere classified
721.3	Lumbosacral spondylosis without myelopathy
721.42	Spondylosis with myelopathy, lumbar region
721.5	Kissing spine
721.6	Ankylosing vertebral hyperostosis
721.7	Traumatic spondylopathy
721.8	Other allied disorders of spine
721.9	Spondylosis of unspecified site
722.1	Displacement of thoracic or lumbar intervertebral disc without myelopathy
722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.32	Schmorl's nodes, lumbar region
722.39	Schmorl's nodes, other region
722.5	Degeneration of thoracic or lumbar intervertebral disc
722.6	Degeneration of intervertebral disc, site unspecified
722.70	Intervertebral disc disorder with myelopathy, unspecified region
722.72	Intervertebral disc disorder with myelopathy, thoracic region
722.73	Intervertebral disc disorder with myelopathy, lumbar region
722.80	Postlaminectomy syndrome, unspecified region
722.82	Postlaminectomy syndrome, thoracic region
722.83	Postlaminectomy syndrome, lumbar region
722.90	Other and unspecified disc disorder, unspecified region
722.92	Other and unspecified disc disorder, thoracic region
722.93	Other and unspecified disc disorder, lumbar region
724	Other and unspecified disorders of back
724.0	Spinal stenosis other than cervical
724.00	Spinal stenosis, unspecified region
724.01	Spinal stenosis, thoracic region
724.02	Spinal stenosis, lumbar region, without neurogenic claudication
724.03	Spinal stenosis, lumbar region, with neurogenic claudication
724.09	Spinal stenosis, other region
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.7	Disorders of coccyx

5 Percutaneous interventions for low back pain

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CODES	DESCRIPTION
724.70	Unspecified disorder of coccyx
724.71	Hypermobility of coccyx
724.79	Other disorders of coccyx
724.8	Other symptoms referable to back
724.9	Other unspecified back disorders
730.2	Unspecified osteomyelitis
732.0	Juvenile osteochondrosis of spine
733.0	Osteoporosis
737.2	Lordosis (acquired)
737.30	Scoliosis [and kyphoscoliosis], idiopathic
737.39	Other kyphoscoliosis and scoliosis
737.4	Curvature of spine associated with other conditions
737.8	Other curvatures of spine
737.9	Unspecified curvature of spine
738.4	Acquired spondylolisthesis
738.5	Other acquired deformity of back or spine
739.2	Nonallopathic lesions, thoracic region
739.3	Nonallopathic lesions, lumbar region
739.4	Nonallopathic lesions, sacral region
754.2	Congenital musculoskeletal deformities of spine
756.1	Congenital anomalies of spine
846	Sprains and strains of sacroiliac region
847.1	Sprain of thoracic
847.2	Sprain of lumbar
847.3	Sprain of sacrum
847.4	Sprain of coccyx
847.9	Sprain of unspecified site of back
ICD-9 Volume 3 (procedure codes)	
87.24	Other x-ray of lumbosacral spine
88.38	Other computerized axial tomography
88.93	X-ray, other and unspecified
CPT	
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance; lumbar or sacral, single level
0217T	second level
0218T	third and any additional level(s)
20552	Injection, single or multiple trigger point(s), 1 or 2 muscle(s)
20553	Injection, single or multiple trigger point(s), 3 or more muscle(s)
20600	Arthrocentesis, aspiration and /or injection; small joint or bursa (eg, fingers, toes)
20605	intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa)
20610	major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa)
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	1 or more additional levels
27096	Injection procedure for sacroiliac joint, anesthetic steroid, with image guidance (fluoroscopy or CT) including arthrography when performed
62292	Injection procedure, arterial, for occlusion of arteriovenous malformation, spinal
64412	Injection, anesthetic agent; spinal accessory nerve

CODES	DESCRIPTION
64483	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level
64484	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level
64493	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
64494	second level
64495	third and any additional level(s)
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural or subarachnoid)
77021	Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
HCPCS Codes	
M0076	Prolotherapy
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

Note: Inclusion on this list does not guarantee coverage

APPENDIX A

SCANNING RESULTS

One AHRQ review that addresses percutaneous interventions for low back is expected to be published in early-to-mid 2015.

Agency for Healthcare Research and Quality (2014). Pain Management Injection Therapies for Low-Back Pain. Evidence-based Practice Center Review Protocol. Pacific Northwest Evidence-based Practice Center. Project ID: ESIB0813. May 29, 2014. Retrieved from <http://www.ahrq.gov/research/findings/ta/topicrefinement/injection-protocol.pdf>

SUMMARY

The Evidence-based Guidelines subcommittee will perform a search of trusted sources and update the coverage guidance upon completion of the report referenced above.