

HERC Coverage Guidance – Percutaneous Interventions for Low Back Pain Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
OHP Managed Care Medical Directors Oregon	1	“Define radiculopathy, and persistent radiculopathy in particular. Are their subgroups who benefit more or less from epidural steroid injection.	The evidence source included a total of 20 placebo controlled trials of epidural steroid injections that had mixed results. All populations were described as having radiculopathy or neurogenic claudication, with some requiring imaging evidence of a prolapsed disc. Regarding how radiculopathy or neurogenic claudication is defined: Of the five trials reviewed, none required objective findings on physical exam other than positive straight leg raising, and only two required imaging confirmation. The EbGS regrets that they are unable to provide more definition.
	2	Are there subgroups of folks with radiculopathy who do better, compared to those who don’t (i.e. for epidural steroid injections)?	The evidence source does not report on this, other than those trials for which the comparator was epidural saline or anaesthetic were more likely to be negative than those trials for which the comparator was a soft tissue injection.
Physician, Pain Management Eugene, OR	3	The proposed coverage guidance for percutaneous interventions for low back pain fails to serve the best interest of the patient in pain. The recommendations seem to be based on biased clinical practice guidelines and not on primary published literature. As these “literature reviews” form the basis for your recommendations, I will refer to this type of analysis as well.	The evidence source is the American Pain Society guideline on interventional therapies for LBP, which is supported by a systematic review of the evidence. This review includes the “primary published literature”. It is not clear why the commenter believes the APS guidelines are biased.
	4	The inclusion of a discussion about ‘shared decision-making’ in treatment recommendations is redundant and unnecessary. It seems the Commission recommendations for a procedure are not equal in strength to those against a procedure. If the commission is willing to support non-coverage of a procedure then they should also be willing to support coverage of a procedure. I note that the ‘shared decision making’ discussion is not (as it should be) included for non-covered procedures.	The EbGS disagrees that shared decision making is unnecessary when the evidence supporting the effectiveness of an intervention is conflicting. The patient should understand the lack of certainty regarding effectiveness, particularly when there are potential harms. When there is evidence that a treatment is ineffective, the treatment should not be offered, hence there is no need for shared decision making.
	5	Research into pain treatment is difficult; one of the most obvious is the absence of an objective verifiable measure of the experience of pain. Such a measure would allow for greater power from smaller studies. A type two error of publishing a negative result when a difference does not exist is particularly at risk of occurring in these studies. Very few trials of pain treatments are adequately powered to prevent type two errors.	There are numerous scales used to assess pain, and many studies have shown significant results, including in this evidence base. Seven of the 20 trials of epidural steroids included in the systematic review used validated pain measures and found positive results.
	6	I address specific recommendations in the order of your document.	In the referenced systematic review (Parr 2012), there were

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		1. Radicular low back pain. Extensive trials of moderate quality confirm a meaningful clinical response to transforaminal epidural injections. Good evidence also exists for the use of caudal epidural injections in the management of lumbar discogenic pain, spinal stenosis and post surgery syndrome. (Parr 2012) Based on this analysis, exclusion of spinal stenosis is not appropriate.	3 studies that addressed spinal stenosis, only one of which was a RCT. In this trial, the control comparator was bupivacaine injection, and the control group had a slightly better response than the steroid group in pain and functional status. There was no non-injection control group. The other two studies were case series.
	7	2. Nonradicular low back pain. Extensive level II evidence exists for lumbar and cervical diagnostic and therapeutic facet denervation procedures as well as caudal epidural injection of local anesthetic and steroids. (Manchikanti 2009)	The search dates for the stated reference are not specified, but publication date was 2009 (same as the Chou review). Without search dates, the EbGS is unable to evaluate the currency of the literature review. In addition, the guideline was reviewed at the time that the Oregon Guideline Development Group was developing the “Percutaneous Interventions for Low Back Pain Clinical Practice Guideline” and was rated poor quality.
	8	3. ‘Local injection’ is not adequately specific to include in your non covered list. If you intend to exclude ‘trigger point injections’ then you should state that and offer evidence, as there is an extensive literature on that technique.	Local injections in the evidence review are 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. <i>Clarification added to the guidance document.</i> The evidence review found insufficient evidence to draw conclusions for any type of local injection. Of the 4 trials identified, two addressed trigger point injections. None had follow up longer than 2 weeks, and the trial sizes ranged from 15 to 63.
North American Spine Society (NASS) Burr Ridge, IL	9	The North American Spine Society (NASS) wishes to comment on the Evidence Review Commission (HERC) draft coverage guidance regarding percutaneous interventions for low back pain (LBP), specifically regarding the non-coverage recommendation for epidural steroid injections (ESI) in the treatment of radicular pain due to spinal stenosis, in addition to sacroiliac injections and radiofrequency denervation for non-radicular LBP. NASS is a multispecialty medical organization dedicated to fostering the highest quality, evidence-based, ethical spine care. NASS has over 5,500 members from several disciplines, including orthopedic surgery, neurosurgery, physiatry, pain management and other spine professionals.	Thank you for your comment.
	10	Your policy states that there is insufficient evidence to adequately evaluate benefits and harms of ESIs for spinal stenosis. We strongly disagree with this assessment and present information to assist in a balanced review. Unfortunately, your HERC draft only sited three	The APS guideline is based on a full systematic review of the evidence.

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		references of which all are based on the controversial and criticized 2009 practice guidelines published by the American Pain Society.	
	11	Various organizations and professional medical societies have addressed the efficacy of ESIs for the treatment of radicular pain. Your draft actually states “ESIs should be covered for patients with persistent radiculopathy due to herniated lumbar disc”, however you should realize, herniated discs often cause stenosis contributing to the radicular symptoms which the HERC draft recommends coverage for.	The EbGS is aware that lumbar disc herniation may contribute to central spinal stenosis, but is also aware that other mechanical factors such as facet hypertrophy and spondylosis contribute as well. The presentation of spinal stenosis is distinct from that of radiculopathy due to herniated disc. Studies included in the evidence review generally included patients with unilateral sciatica with signs for nerve root irritation or compression. They did not include patients with the typical presentation of spinal stenosis (neurogenic claudication, often bilateral, relieved by change in posture). Spinal stenosis involves compression at the level of the spinal cord, while radiculopathy refers to compression of the nerve root. <i>To clarify this distinction, “central” was added to the guidance document.</i>
	12	Recently, the Washington State HTA committee voted to cover therapeutic lumbar (and cervical/thoracic) ESIs for the treatment of radicular pains due to stenosis and other etiologies. Coverage was supported and endorsed by 11 national and international specialty societies ¹ . Their decisions were based on an extensive, rigorous review, which took over a year to complete. The committee concluded, “The current evidence on spinal injections demonstrates that there is sufficient evidence to cover with conditions the use of therapeutic ESIs in the lumbar or cervical-thoracic spine for chronic pain”. They further stated “Based on the evidence about technologies’, safety, efficacy, and cost-effectiveness, therapeutic ESIs in the lumbar or cervical-thoracic spine is a covered benefit when all of the following conditions are met: <ol style="list-style-type: none"> 1. For treatment of radicular pain 2. With fluoroscopic guidance or CT guidance 3. After failure of conservative therapy 4. No more than two without clinically meaningful improvement in pain and function 5. Maximum of 3 in 6 months.” 	The EbGS disagrees that the current recommended guidance differs significantly from the WA HTA decision. This report specifically states that there is NO benefit of epidural steroid injections in either the short or long term in patients with spinal stenosis. The WA HTA does indeed recommend coverage of ESIs for patients with radicular pain, but does not specify the etiology of the radicular pain, nor do they state “radicular pains due to stenosis”.
	13	Additionally, NASS has published guidelines on degenerative spinal stenosis, which concluded there is evidence (Level II-III studies) demonstrating good short-term efficacy of	The reference cited is a guideline published in 2007, before the date of the Chou evidence review (2009), which also

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		fluoroscopically-guided transforaminal ESIs in the treatment of radicular pain due to stenosis ² . The guidelines also concluded that a multiple injection protocol of fluoroscopically-guided transforaminal ESIs can produce long-term relief of pain in patients with radiculopathy or intermittent neurogenic claudication due to lumbar spinal stenosis. The role of ESIs in the treatment of lumbar spinal stenosis was one question the NASS guideline addressed.	addressed ESIs for lumbar spinal stenosis.
	14	Other societies, including the American Society of Interventional Pain Physicians (ASIPP) have guidelines and reviews that evaluated the efficacy of epidurals for spine and radicular pain and concluded that the evidence for transforaminal epidurals is strong for short-term and moderate for long-term improvement in managing chronic LBP and sciatica ³ .	The reference cited is a guideline published in 2007, before the date of the Chou evidence review (2009), which also addressed ESIs for chronic LBP.
	15	There have been a number of randomized, prospective studies indicating good short and long-term efficacy of fluoroscopically-guided transforaminal ESIs in the treatment of radicular pain ⁴⁻⁹ . One such prospective, randomized, controlled, double-blinded study of 55 patients with > 6 weeks radicular pain with radiographically confirmed nerve root compression due to either herniated nucleus pulposus or foraminal stenosis, were treated with 1-3 fluoroscopically-guided transforaminal ESIs of bupivacaine, with or without steroid ⁶ . All were candidates and agreed to proceed with surgery. Follow-up was 13-26 months and over a mean of 23 months from injection, 71 percent of patients in treatment group cancelled surgery vs. 33 percent control group (p<.004). The study concluded that selective nerve root blocks (transforaminal epidural injections) with corticosteroids are more effective than bupivacaine alone, obviating the need for decompressive surgery and all patients with 1 or 2 level radiculopathy should be treated with selective nerve root blocks prior to considering surgery.	The EbGS does not disagree that ESIs can be effective for radiculopathy due to disc herniation, hence the permissive coverage guidance. In addition, the citations listed were published before the date of the Chou evidence review. The EbGS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded based on transparent, reproducible criteria; therefore the EbGS does not investigate individual studies. The EbGS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.
	16	A recent systematic review of ESIs in the treatment of chronic LBP concluded that a fluoroscopically-guided ESI is a reasonable treatment option in patients unresponsive to physical therapy and anti-inflammatory medications ¹⁰ .	The reference cited was published in 2008, before the date of the Chou evidence review (2009).
	17	This policy also does not address the diagnostic aspect of selective spinal nerve blocks that utilize the same CPT codes (64479-64484) as therapeutic transforaminal epidural injections. Anesthetizing a specific spinal nerve and subsequently measuring the amount of radicular pain relief can help provide diagnostic confirmation as to the source of a patient's limb (radicular) pain and which nerve root may need to be surgically decompressed in patients with radicular pain due to central and/or foraminal spinal stenosis. Diagnostic spinal nerve blocks are not only highly sensitive and specific at diagnosing radicular pain, but may be superior to imaging studies (e.g., MRI) alone in	The Chou review addressed this intervention; their comments are as follows: "because nerve root compression can usually be identified by non-invasive imaging, the main roles of diagnostic nerve root blocks are to evaluate the appropriate target level for interventions when multiple nerve roots are involved or to confirm radiculopathy when imaging is equivocal or when there is discordance between clinical findings and imaging. No reliable reference standard

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		predicting surgical outcomes ¹¹ .	<p>(such as electrophysiologic testing) is available for estimating diagnostic accuracy of selective nerve root blocks for identifying “true” nerve root pain in these situations. We therefore focused our review on evidence on whether use of selective nerve root blocks to select patients for procedures intended to relieve nerve root compression improves clinical outcomes compared to not using selective nerve root blocks to select patients.</p> <p>We identified one lower-quality systematic review on diagnostic accuracy of selective nerve root blocks. However, it included no studies that evaluated whether use of diagnostic selective nerve root blocks to identify patients for procedures intended to relieve nerve root compression improves clinical outcomes compared to relying only on imaging or other non-invasive diagnostic methods to select patients. From 381 potentially relevant citations, we identified no relevant studies.”</p> <p>The citation referenced was published before the date of the Chou review; see comment #15.</p>
	18	The main purpose of epidural injections in the treatment of radicular pain due to spinal stenosis is to reduce pain and morbidity while improving function and resumption of normal activities.	The evidence demonstrates that ESIs may be effective for radicular pain. It is not effective for central spinal stenosis.
	19	With respect to radiofrequency neurolysis (RFN) in the treatment of LBP secondary to facet-mediated pain, NASS disagrees with the HERC non-coverage decision. One study of LBP patients with facet-mediated pain diagnosed by controlled medial branch blocks, RFN demonstrated significant pain relief for at least 12 months in a majority of patients ¹² . A comprehensive review by Manchikanti et al gave a 1C/strong recommendation for RFN for the treatment of facet-mediated LBP ¹³ . A recent review by Bogduk, et al demonstrated that lumbar RFN had positive effects on pain and disability and that all valid, randomized controlled trials showed RFN to be more effective than sham treatment ¹⁴ .	Reference #12 was published before the date of the Chou review. Reference #13 was published in 2009, but does not list search dates for their evidence review. Without search dates, the EbGS is unable to evaluate the currency of the cited review. Reference #14 is a narrative review, no systematic search of the literature was undertaken.
	20	We strongly disagree with the exclusion of sacroiliac joint injections (SIJ) in the evaluation of LBP. Eleven specialty societies endorsed a statement on sacroiliac injections and	The Chou review identified only 1 trial that met inclusion criteria that evaluated SI joint injections. While there was

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		submitted it to the Washington HTA as part of a technology review ¹ . The Washington HTA committee voted to cover sacroiliac intra-articular injections. We hope that this information will assist in formation of a reasonable coverage policy.	improvement in median pain scores at one month, it included only 24 patients. This was the same evidence included in the WA HTA technology review.
<i>International Spine Intervention Society (ISIS)</i> San Rafael, California	21	The International Spine Intervention Society (ISIS), a multi-specialty association of 3,000 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain would like to comment on the Draft Coverage Guidance for Percutaneous Interventions for Low Back Pain. We commend the Oregon Health Evidence Review Commission (HERC) on incorporating a number of the ISIS guidelines in the draft coverage guidance; however, we would like to bring attention to several issues of concern:	Thank you for your comment.
	22	1. Sacroiliac Joint Steroid Injections for Non-radicular Pain We strongly disagree with the exclusion of sacroiliac joint injections for non-radicular pain and are enclosing information to assist in a balanced and diligent review. 11 national medical specialty societies* endorsed a statement on SI joint injections ¹ (see attachment) and submitted it to the Washington State Health Technology Assessment (HTA) Program, as part of a technology review. Upon extensive review, the WA HTA committee voted to cover sacroiliac intra-articular injections of steroids. ²	See comment #20. The clinical committee of the WA HTA elected to make a coverage decision based on one trial of only 24 patients.
	23	2. Radiofrequency Denervation for Non-radicular Low Back Pain We strongly disagree with the proposal to exclude from coverage radiofrequency (RF) denervation for non-radicular low back pain. Diagnostic lumbar medial branch blocks, which are allowed under this policy, are concordant for lumbar facet joint mediated pain. Hence, RF neurotomy should, naturally, also be covered. Other treatment options, such as surgery, are certainly much more invasive and costly.	It is not clear why the commenter believes that diagnostic lumbar medial branch blocks for non-radicular LBP are allowed under this guidance. <i>The word “therapeutic” has been deleted from medial branch block in guidance box.</i>
	24	The first controlled study, which clearly showed that RF neurotomy was not a placebo, in the lumbar region, was by Van Kleef, ³ though its limited effect was attributed to the sub-optimal placement (not parallel to the nerves) of the electrode. A subsequent yearlong study ⁴ of carefully screened patients diagnosed as having lumbar zygapophyseal joint pain who underwent denervation by RF neurotomy in which the electrodes were correctly placed parallel to the target nerves, found that, after one year, some 60% of patients can expect to have at least 80% relief of their pain and 80% of patients can expect more than 60% relief. Therefore, this study showed that for patients with lumbar zygapophyseal joint pain, diagnosed by controlled medial branch blocks, lumbar radiofrequency medial branch neurotomy offers a good chance of obtaining worthwhile relief of pain sustained for at least 12 months.	The citations were published before the date of the Chou review. The EbGS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded based on transparent, reproducible criteria; therefore the EbGS does not investigate individual studies. The EbGS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.

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	25	In addition, Manchikanti et al. ⁵ performed a comprehensive review of therapeutic interventions in managing chronic spinal pain and determined that, for lumbar RF, based on criteria by Guyatt et al., ⁶ the recommendation is 1C (strong recommendation).	This is the same review cited by the prior commenter. This review was rated poor quality when evaluated during the development of the Oregon “Percutaneous Interventions for Low Back Pain Clinical Practice Guideline”. See comment #19.
	26	<p>3. Epidural Injections for Spinal Stenosis</p> <p>We encourage HERC to reconsider the proposal not to cover Epidural Steroid Injections (ESIs) for spinal stenosis. Studies evaluation the efficacy ESIs for LSS without fluoroscopic guidance should not be considered, although all showed a short-term benefit ranging from 1 week to 2 months of relief, and one demonstrated a longer term benefit with up to 10 months of relief.^{7,8,9,10} The more recent studies, which used fluoroscopic guidance,^{11,12,13,14} all demonstrated some short-term benefit; while the Botwin study¹², the only prospective evaluation, showed a substantial long-term benefit as well. This study evaluated 34 patients with unilateral radicular symptoms secondary to LSS with fluoroscopically guided transforaminal ESIs. A mean of 1.9 injections per patient was performed. Subjects were evaluated at 2 and 12 months when compared to the pre-injection baseline. The patient satisfaction scale revealed that 62% of patients at 2 months and 64% of patients at 12 months felt somewhat or completely better. Briggs et al.¹⁵, in an evaluation of injection treatment in lumbar spinal stenosis in older adults, reported significant alleviation of pain after injection treatment under fluoroscopy.</p>	See comments # 6 and #24. The only citation that was published after the Chou review is Briggs, which is a case series, N=62. Case series are a type of evidence with high susceptibility to bias.
	27	<p>The NASS 2007 clinical guidelines¹⁶ stated that a study by Riew et al.¹⁷ provided “level II treatment evidence that transforaminal ESI can decrease the likelihood that a patient with radicular leg pain and spinal stenosis will undergo an operation.” They also stated that there was grade B recommendation (fair evidence for recommending the intervention) for the statement that “a single radiographically-guided transforaminal epidural steroid injection can produce short-term relief in patients with radiculopathy from lumbar spinal stenosis.</p> <p>ISIS appreciates the opportunity to comment.</p>	Both the guideline and the trial cited were published before the date of the Chou review. See comment #24.