

HERC Coverage Guidance – Lumbar Discography Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
<p><i>North American Spine Society</i> Burr Ridge, IL</p>	1	<p>The North American Spine Society (NASS) appreciates the opportunity to review the Health Evidence Review commission (HERC) draft coverage guidance: Lumbar Discography.</p> <p>Concerning the proposed discography policy, we agree that discography is controversial. Lumbar discography is a diagnostic procedure in which contrast material is injected into the nucleus pulposus of a lumbar disc, with the intent to determine whether the disc itself is the source of the patient’s low back pain. The results of this diagnostic test are typically used to determine whether or not subsequent treatment options, including surgical fusion, disc replacement or other interventions are indicated.</p> <p>Your statement that discography yields two types of results: pain provocation (whether the patient’s typical pain was reproduced by the injection), and morphology (whether the dye images an abnormal pattern in the disc, often based on CT scan), is not entirely correct. It is true that the presence or lack thereof, of pain provocation and disc morphology are two components of the test which are measured and evaluated.</p> <p>However, there are other factors that are often assessed in formulating the physician’s interpretation and overall impression or results of the study. Some of these other components of lumbar discography include the volume and/or pressure at which a pain response is produced, whether or not the pain response is concordant to the patient’s typical pain with respect to location, character and perhaps severity. Another, and often overlooked, diagnostic component is the presence of any inappropriate illness behavior or inconsistencies exhibited during the test that may be a sign of non-organic reasons for their chronic back pain complaints. All these factors are included in the physicians overall impression and results of the test for each disc studied.</p>	<p>The HTAS realizes that the two types of results are a generalization for the additional components mentioned.</p>
	2	<p>We agree that similar to most diagnostic tests, false positive results can occur. In patients with diffuse, chronic pain syndromes (i.e. fibromyalgia) and/or abnormal psychometric findings, the risks of obtaining a false positive study are increased.^{1,2,3} NASS does not recommend discography as a valid test in this patient population or in patients with significant psychiatric co-morbidities.</p>	<p>The citations listed were published before the date of the WA HTA report (last search date Aug 2007). The HTAS 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 HTAS does not investigate individual studies. The HTAS 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</p>

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			not attempt to re-review the entire body of evidence to reach its own conclusions.
	3	However, discography is suggested as a valid diagnostic test for the evaluation of discogenic low back pain in patients without diffuse, chronic pain syndromes and/or abnormal psychometric findings. False positive tests in patients without chronic pain syndromes and abnormal psychometric findings are low. Discography has a low false positive rate in patients without somatization or psychosocial disorders. ^{4,5}	See comment #2
	4	It is NASS' opinion that chronic discogenic low back pain (i.e. pain > 3 months) is a medically appropriate indication for lumbar discography, provided the patient does not have somatization or psychosocial disorders. Despite its limitations, provocative lumbar discography in the appropriately selected patients noted above, is the only test available to discriminate non-painful from painful, symptomatic discs in patients suffering from chronic discogenic low back pain.	This opinion is not supported by the evidence.
	5	We believe, non-coverage policies, as currently recommended in the Oregon HERC draft will decrease the availability of appropriate diagnostic testing and limit the physicians' consideration as to whether or not surgery is indicated. Without the information obtained by discography, patients may inappropriately undergo surgery based on imaging studies alone. Many patients deemed a surgical candidate on this limited information would have been excluded based on the discography results, such as those whose tests are negative, inconclusive, demonstrate significant evidence of inappropriate pain behavior or demonstrate multilevel symptomatic discs that would not respond favorably to surgery. The associated costs and morbidity associated with these patients undergoing surgery, who would have otherwise been excluded from receiving surgery based on the discography results, out-weighs the low risk of a false-positive study.	The evidence does not support the utility of discography in identifying patients appropriate for surgery.
	6	We understand that discography is a subjective test relying on the interaction between the patient and the provider. We also understand that the study has its limitations, but a blanket "non-coverage" policy is inappropriate. NASS continually reviews the literature on discography and we continue to update our recommendations with the latest evidence based medicine (EBM).	The HTAS respectfully disagrees.
	7	It is our recommendation that discography be limited to: <ul style="list-style-type: none"> • Patients with chronic low back pain who have not responded to conservative treatments, including physical therapy and are being considered for lumbar fusion and disc replacement. • Patients with chronic pain syndromes and significant psychiatric co-morbidities should be excluded. <p>Thank you for extending the opportunity to NASS to review and comment on this corporate medical policy.</p>	See comment #5

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<i>Neurological Surgeon</i> Portland, OR	8	Page 2, paragraph 2: The concept of discogenic pain is itself controversial. The imaging findings noted in the draft to be associated with discogenic back pain, including disc space collapse, endplate sclerosis, vacuum disc phenomenon on plain films and dehydration, high intensity zones, and endplate edema on MRI are all found in asymptomatic individuals and are therefore not strongly associated with localization of the source of pain.	Thank you for pointing out this controversy.
	9	Page 2, paragraph 4: In addition to pain provocation (both axial and radicular) and disc morphology (including architecture and leakage), comprehensive discography as advocated by Dr. Karasek and others also includes measurement of intradiscal pressure (including opening and maximum pressures and pressure above opening required to produce pain), response to local anesthetic injection, and the presence of normal findings at adjacent levels (International Spinal Injection Society protocols 1994).	Thank you for this information.
	10	Studies that I have found influential come mainly from the Stanford discography project and include: <ol style="list-style-type: none"> 1. Carragee EJ et al, Spine 25:1373-80, 2000 – volunteers without back pain had positive lumbar discography in 10% of pain free individuals, 40% of those with chronic neck pain, and 83% of those with somatization disorder, indicating that false positive discography is very common in patients with any pre-testing pain or psychological disorder. 2. Carragee EJ, et al, Spine 24:2542-7, 1999 – 50% of patients with pain known to arise from an iliac crest graft site and not the lumbar spine had positive discograms. 3. Resnick DK et al, JNeurosurg Spine 2:662-9, 2005 – a guidelines paper from the AANS determined that “there is insufficient evidence to recommend a treatment standard” for lumbar fusion based upon discography. The authors recommended that fusion only be considered when discography and MRI findings were concordant and not when discography alone was positive. 4. Carragee EJ et al, Spine 31:2115-23, 2006 – 32 patients with strongly positive discograms underwent lumbar fusion and were compared to 34 patients undergoing fusion for unstable spondylolisthesis. In the latter group, 72% had a good outcome, but in the discography group, only 27% had a good outcome. The conclusions state that if the gold standard for discography is that it leads to a meaningful surgical outcome, then discography does not meet this standard. 5. Carragee EJ et al: International Society for the Study of the Lumbar Spine Meeting, Miami, 2009 – discography may result in accelerated degenerative changes at injected levels when compared to matched controls. 	Thank you for providing this additional information; HTAS appreciates the perspective provided. The HTAS 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 HTAS does not investigate individual studies published before the date of the source document. The HTAS 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. HTAS notes that four of the citations listed were published before the date of the WA HTA report (last search date Aug 2007), and the fifth is a meeting abstract, which would not meet inclusion criteria for the evidence source.
	11	Taken together, I interpret these studies to indicate that discography has a high false positive rate, does not lead to successful surgery, and may provoke accelerated degenerative changes and increased back pain in some tested individuals. I do not order or recommend discography in my own	Thank you for this information.

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		practice.	
	12	To be fair, Dr. Karasek and others have argued passionately for discography. He often states that the results of Dr. Carragee’s work stem from improperly performed discography and that in his hands, it is safe and effective. Much of the literature he cites, however, is old and predates the work cited above.	Thank you for this information.
	13	Discussions with colleagues who perform the procedure lead to two other interesting observations. One observed that he views the procedure as having negative rather than positive predictive value. If a surgeon is considering fusion but a discogram is positive at multiple levels, then he would recommend strongly against the surgery. If the discogram is positive at a single level, he does not consider this predictive of a good surgical outcome as noted above. Another surgeon noted that he does not order discograms because no procedures are currently paid for based upon it – since he cannot fuse someone or do an IDET procedure based upon discography, then the test leads to no meaningful outcome.	Thank you for providing this perspective.