

Physician Advisory Committee

PROPOSED OKLAHOMA TREATMENT GUIDELINES – SPINE

As Submitted to the Governor and Legislature for Review Pursuant to 85 O.S., §373

INTRODUCTION

BACKGROUND: The Physician Advisory Committee (PAC) is a statutorily created advisory body to the Oklahoma Workers’ Compensation Court. It is composed of nine physicians from various practice areas as specified by law. The Governor, President Pro Tempore of the State Senate, and the Speaker of the Oklahoma House of Representatives each appoint three members.

The PAC was directed by statute, 85 O.S., §373, to develop and adopt Oklahoma Treatment Guidelines (OTG) for injuries to the cervical, thoracic and lumbar spine covering treatment not addressed by the current edition of the Work Loss Data Institute’s *Official Disability Guidelines* (ODG) or addressed but not recommended by the ODG. The OTG - Spine are subject to a state mandated review process involving the Physician Advisory Committee, Advisory Council on Workers’ Compensation, Workers’ Compensation Court Administrator and the State Legislature. The OTG - Spine become operative thirty (30) days following adjournment of the Legislature to which submitted, unless disapproved as provided by law. For OTG - Spine status, go to the Workers’ Compensation Court’s website at <http://www.owcc.state.ok.us> or contact the Court’s Counselor Program at 405-522-8760 (Oklahoma City), 918-581-2393 (Tulsa) or in-state toll free at 1-800-522-8210.

DEVELOPMENT OF THE GUIDELINES: The Committee reviewed input from a wide variety of sources including employers, insurance carriers, health care providers, and the legal profession. Appropriate scientifically based and nationally peer reviewed literature, and statutory provisions, were reviewed, together with the *Official Disability Guidelines* published by the Work Loss Data Institute.

APPLICATION OF THE GUIDELINES: These Oklahoma Treatment Guidelines (OTG) - Spine concern only the low back, neck and upper back, and govern matters specifically covered therein. Matters not covered by the OTG - Spine are governed by the Work Loss Data Institute’s *Official Disability Guidelines*.

Pursuant to 85 O.S., §326, compliance with treatment guidelines applicable by law is mandatory, unless the medical treatment was provided in a medical emergency, the medical treatment was preauthorized by the employer or insurance carrier, or the medical treatment is approved by the Workers’ Compensation Court based on a determination that medical treatment according to either the ODG or OTG is not in the best interest of the employee.

Procedure Summary – Low Back	
Procedure/Topic	Summary of Medical Evidence
Bone-morphogenetic protein (BMP)	Currently, two BMPs have been approved by the FDA. rhBMP-2 (InFUSE®) has been approved as an allograft replacement in anterior interbody fusions and for treatment of open tibial fractures. rhBMP-7 (OP-1®) has been approved under the Humanitarian Device Exemption (HDE) process as an autograft

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	<p>substitute of long bone nonunion and for revision posterolateral fusion, for which autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion. All other applications are considered off label and not FDA approved.</p> <p>There is a lack of clear evidence of improved outcomes with the off-label use of BMP, and there is inadequate evidence of safety and efficacy to support routine use. (Carragee, 2009) The use of BMP may be off-label in clinical practice in up to 85% of procedures. (Ong, 2010) Complications are significant with off-label use, and application in the cervical spine has been associated with significant complications including respiratory and swallowing. (Mroz, 2010) There is a strong association between treatment with BMP and the incidence of a wide variety of cancers, based on a large lumbar fusion trial. (Carragee, 2011) See also the Neck Chapter.</p> <p>Recommendation:</p> <ul style="list-style-type: none"> - rhBMP-2 (InFUSE®): Anterior Lumbar Interbody Fusion - rhBMP-7 (OP-1®): Revision Posterolateral Fusion when Autograft bone is unavailable or a substantial hardship to the patient
Discography	<p>Recommended for the approved indications described below. Not recommended unless patient has been identified as a potential candidate for surgical fusion. Additionally, thoracic discography is not recommended; it is very rarely indicated as a diagnostic option, and remains challenging from a technical point of view. (Sing, 2004)</p> <p>While an MRI can detect disc degeneration, it cannot confirm if a disc is symptomatic and responsible for the patient's pain. Lumbar discography (also known as lumbar provocative discography and provocative lumbar discography) is usually carried out when MRI and other diagnostic tests have failed to identify the cause of Lower Back Pain (LBP). (Derby, 2005)</p> <p>Discography involves the injection of a water-soluble, radiopaque contrast material (1 to 3 ml) into the intervertebral disc to examine disc abnormality. (Aetna, 2011) Both routine x-ray imaging during the injection and post-injection CT examination of the injected discs are usually performed as part of the study. Information is recorded about: the pressure in the disc at the initiation and completion of injection, the amount of dye accepted, the configuration and distribution of the dye in the disc, the quality and intensity of the patient's pain experience and the pressure at which that pain experience is produced.</p> <p>There are two diagnostic objectives for performing discography: (1) to evaluate radiographically the extent of disc damage on discogram and (2) to characterize the pain response on disc injection to see if it compares with the typical pain symptoms the patient has been experiencing. Discography can provide radiographical evaluation of the integrity of the nucleus pulposus and annular</p>

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	<p>rings to determine tears or other lesions that could be the cause of Lower Back Pain (LBP). (Tomecek, 2002) It can measure disc nociception -- a normal disc should not cause pain when injected; however, a disc that is physiologically compromised can mimic the pain experienced by the patient. (Pneumaticos, 2006) A symptomatic degenerative disc is considered one that disperses injected contrast in an abnormal, degenerative pattern, extending to the outer margins of the annulus and at the same time reproduces the patient’s lower back complaints (concordance) at a low injection pressure. Criteria exist to grade the degree of disc degeneration from none (normal disc) to severe. (American Society of Neuroradiology, 2001)</p> <p>Discography is not a sensitive test for radiculopathy and has no role in its confirmation. It is, rather, a confirmatory test in the workup of axial back pain and its validity is intimately tied to its indications and performance. As stated, discography is appropriately performed during the final stages of a diagnostic workup, for patients who have failed conservative care, remain highly symptomatic, and are potential candidates for surgical fusion. (Pneumaticos, 2006) The validity of discography is enhanced if an MRI demonstrates both dark and bright discs. The presence of normal discs is needed as an internal validity measure in discography. Discography should be performed according to contemporary diagnostic criteria. See also Functional anesthetic discography (FAD).</p> <p>It is critical that discography serve as an adjunct or compliment in patient evaluation, and that strict patient selection criteria are adhered to when determining if discography is indicated. As stated by Pneumaticos et al.: “Diskography should be considered when all other treatment modalities have failed and surgery is being contemplated. A position statement of the North American Spine Society advocates the use of discography within strict guidelines.” This is particularly true because, despite the benefits of discography, its value and safety have been debated. Criticisms include a high false-positive rate, increased risk of complications, and the potential for iatrogenic disk injury and degeneration. (Chou, 2009) (Ohtori, 2009) However, low false positive rates have been associated with discography when strict patient selection criteria are applied (i.e., in subjects with normal psychometric profiles and without chronic pain). (Carragee, 2000)</p> <p>Discography has been historically associated with certain risks including infection (including diskitis and epidural abscess) vascular and spinal cord injury. (Guyer, 1995) (Walker, 2007) Most occurrences of these serious adverse events were reported during the early days of discography and improved discography injection technique, imaging, and contrast materials have led to decreased complication rates. (Walker, 2007)</p>

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Procedure Summary – Low Back	
Procedure/Topic	Summary of Medical Evidence
	<p>Patient selection criteria for Discography:</p> <ul style="list-style-type: none"> o Back pain of at least 4-6 months duration. o Failure of recommended conservative treatment including active physical therapy. o An MRI demonstrating one or more degenerated discs as well as one or more normal appearing discs to allow for an internal control injection (injection of a normal disc to validate the procedure by a lack of a pain response to that injection). o Satisfactory results from detailed psychosocial assessment (discography in subjects with emotional and chronic pain problems has been linked to reports of significant back pain for prolonged periods after injection, and therefore should be avoided). o Intended as a diagnostic tool to assist surgical decision making, i.e., the surgeon feels that lumbar spine fusion may be appropriate and is looking for this to help rule in or rule out the need for surgery. (Carragee, 2006) NOTE: In a situation where the selection criteria and other surgical indications for fusion are conditionally met, discography can be considered in preparation for the surgical procedure. Discography should not be ordered for a patient who does not meet surgical criteria. o Briefed on potential risks and benefits from discography and surgery.
Fusion (spinal)	<p><u><i>Lumbar fusion in workers' compensation patients:</i></u> In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. However, workers' compensation patients with chronic low back pain should not be excluded from lumbar spinal fusion if they meet the Patient Selection Criteria for Lumbar Spinal Fusion. (ISASS, 2011) (<i>NOTE: Except as otherwise noted, ODG text of this section remains unchanged.</i>)</p>

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Procedure Summary – Neck & Upper Back

Procedure/Topic	Summary of Medical Evidence
Discography	<p>Recommended for indications below. Conflicting evidence exists in this area, though some recent studies do not support its use as a preoperative indication for IDET or Fusion, and indicate that discography may produce symptoms in control groups more than a year later, especially in those with emotional and chronic pain problems. (Carragee, 2000) (Carragee2, 2000) (Bigos, 1999) (Grubb, 2000) (Zeidman, 1995) (Manchikanti, 2009) Cervical discography has been used to assist in determining the specific level or levels causing neck pain and, potentially, which levels to fuse; however, controversy regarding the specificity of cervical discograms has also been debated and more research is needed. (Wieser, 2007) Although discography, especially combined with CT scanning, may be more accurate than other radiologic studies in detecting degenerative disc disease, it should be considered as part of the diagnostic tool kit and not a sole indicator of surgical outcomes. It is routinely used before IDET, yet only occasionally used before spinal fusion. (Cohen, 2005)</p> <p>See also the Low Back Chapter.</p> <p>Patient selection criteria for Discography:</p> <ul style="list-style-type: none"> o Neck pain of 3 or more months o Failure of recommended conservative treatment o An MRI demonstrating one or more degenerated discs as well as one or more normal appearing discs to allow for an internal control injection (injection of a normal disc to validate the procedure by a lack of a pain response to that injection) o Satisfactory results from psychosocial assessment (discography in subjects with emotional & chronic pain has been associated with reports of significant prolonged back pain after injection, and thus should be avoided) o Should be considered a candidate for surgery o Should be briefed on potential risks and benefits both from discography and from surgery

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**PHYSICIAN ADVISORY COMMITTEE PROPOSED OTG – SPINE
AS SUBMITTED TO THE GOVERNOR AND LEGISLATURE FOR REVIEW PURSUANT TO 85 OS §373**