**Procedure Summary – Low Back**

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<tr>
<td><strong>Bone-morphogenetic protein (BMP)</strong></td>
<td>Not recommended. 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 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. 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.</td>
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<td><strong>Discography</strong></td>
<td>Not recommended. 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</td>
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**Recommendation:**
- 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
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<td><strong>challenging from a technical point of view.</strong> (Sing, 2004)</td>
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<td>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)</td>
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| In the past, discography has been used as part of the pre-operative evaluation of patients for consideration of surgical intervention for lower back pain. However, the conclusions of recent, high-quality studies on discography have significantly questioned the use of discography results as a preoperative indication for either IDET or spinal fusion. These studies have suggested that reproduction of the patient's specific back complaints on injection of one or more discs (concordance of symptoms) is of limited diagnostic value. (Pain production was found to be common in non-back pain patients, pain reproduction was found to be inaccurate in many patients with chronic back pain and abnormal psychosocial testing, and in this latter patient type, the test itself was sometimes found to produce significant symptoms in non-back pain controls more than a year after testing.) Also, the findings of discography have not been shown to consistently correlate well with the finding of a High Intensity Zone (HIZ) on MRI. Discography may be justified if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion (but a positive discogram in itself would not allow fusion). (Carragee-Spine, 2000) (Carragee2-Spine, 2000) (Carragee3-Spine, 2000) (Carragee4-Spine, 2000) (Bigos, 1999) (ACR, 2000) (Resnick, 2002) (Madan, 2002) (Carragee-Spine, 2001) (Carragee2, 2001) (Maghout-Juratli, 2006) (Pneumaticos, 2006) (Airaksinen, 2006) (Manchikanti, 2009) Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. (Derby, 2005) (Derby2, 2005) (Derby, 1999) Positive discography was not highly predictive in identifying outcomes from spinal fusion. A recent study found only a 27% success from spinal fusion in patients with low back pain and a positive single-level low-pressure provocative discogram, versus a 72% success in patients with a well-accepted single-level lumbar pathology of unstable spondylolisthesis. (Carragee, 2006) The prevalence of positive discogram may be increased in subjects with chronic low back pain who have had prior surgery at the level tested for lumbar disc herniation. (Heggeness, 1997) Invasive diagnostics such as provocative discography have not been proven to be accurate for diagnosing various spinal conditions, and their ability to effectively guide therapeutic choices and improve ultimate patient outcomes is uncertain. (Chou, 2008) Although discography,
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especially combined with CT scanning, may be more accurate than other radiologic studies in detecting degenerative disc disease, its ability to improve surgical outcomes has yet to be proven. It is routinely used before IDET, yet only occasionally used before spinal fusion. (Cohen, 2005) Provocative discography is not recommended because its diagnostic accuracy remains uncertain, false-positives can occur in persons without low back pain, and its use has not been shown to improve clinical outcomes. (Chou2, 2009) This recent RCT concluded that, compared with discography, injection of a small amount of bupivacaine into the painful disc was a better tool for the diagnosis of discogenic LBP. (Ohtori, 2009) Discography may cause disc degeneration. Even modern discography techniques using small-gauge needle and limited pressurization resulted in accelerated disc degeneration (35% in the discography group compared to 14% in the control group), disc herniation, loss of disc height and signal and the development of reactive endplate changes compared to matched-controls. These finding are of concern for several reasons. Discography as a diagnostic test is controversial and in view of these findings the utility of this test should be reviewed. Furthermore, discography in current practice will often include injecting discs with a low probability of being symptomatic in an effort to validate other disc injections, a so-called control disc. Although this strategy has never been confirmed to increase test validity or utility, injecting normal discs even with small-gauge needles appears to increase the rate of degeneration in these discs over time. The phenomenon of accelerated adjacent segment degeneration adjacent to fusion levels may be, in part, explained by previous disc puncture if discography was used in segments adjacent to the fusion. Similarly, intradiscal therapeutic strategies (injecting steroids, sclerosing agents, growth factors, etc.) have been proposed as a method to treat, arrest or prevent symptomatic disc disease. This study suggests that the injection procedure itself is not completely innocuous and a recalculation of these demonstrated risks versus hypothetical benefits should be considered. (Carragee, 2009) More in vitro evidence that discography may cause disc degeneration. (Gruber, 2012)

Discography involves the injection of a water-soluble imaging material directly into the nucleus pulposus of the disc, 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 then recorded about the pressure in the disc at the initiation and completion of injection, about the amount of dye accepted, about the configuration and distribution of the dye in the disc, about the quality and intensity of the patient's pain experience and about the pressure at which that pain experience is produced. 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.

There are two diagnostic objectives for performing discography: (1) to evaluate radiographically the extent of disc damage on discogram and (2) to characterize...
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<td>Discography</td>
<td>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, it is the end discography is appropriately performed during the final stages of a diagnostic workup in a patient, for patients who have failed all reasonable conservative care and remain highly symptomatic. Its validity is enhanced (and only achieves potential meaningfulness) in the context of an MRI showing both dark discs and bright, normal discs -- both of which need testing as an internal validity measure. And the discogram needs to, 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—namely, a positive response should be low pressure, concordant at equal to or greater than a VAS of 7/10 and demonstrate degenerative changes (dark disc) on MRI and the discogram with negative findings of at least one normal disc on MRI and discogram. See also Functional anesthetic discography (FAD).</td>
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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.: “Discography 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...
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<td>Discography</td>
<td>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) <strong>Discography is Not Recommended in ODG.</strong></td>
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<td>Patient selection criteria for Discography if provider &amp; payor agree to perform anyway:</td>
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<td>o Back pain of at least 4-6 months duration.</td>
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<td>o Failure of recommended conservative treatment including active physical therapy.</td>
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<td>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).</td>
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<td>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).</td>
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<td>o Intended as screening a diagnostic tool to assist surgical decision making, i.e., the surgeon feels that lumbar spine fusion may be appropriate but and is looking for this to determine if it is not indicated (although discography is not highly predictive) help rule in or rule out the need for surgery. (Carragee, 2006)</td>
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<td>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. However, all of the qualifying conditions must be met prior to proceeding to discography as discography should be viewed as a non-diagnostic but confirmatory study for selecting operative levels for the proposed surgical procedure. Discography should not be ordered for a patient who does not meet surgical criteria.</td>
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<td>o Briefed on potential risks and benefits from discography and surgery.</td>
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<td>o Single level testing (with control) (Colorado, 2001)</td>
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<td>o Due to high rates of positive discogram after surgery for lumbar disc herniation, this should be potential reason for non-certification</td>
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<tr>
<td>Fusion (spinal)</td>
<td><strong>Lumbar fusion in workers' comp patients:</strong> In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that</td>
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| Low Back        | may affect overall success of the procedure, which should be considered. Until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis, and this treatment for this condition remains “under study.” 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) It appears that workers’ compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes in subgroups of patients who were receiving compensation or involved in litigation. (Fritzell-Spine, 2001) (Harris-JAMA, 2005) (Maghout-Juratli, 2006) (Atlas, 2006) Despite poorer outcomes in workers’ compensation patients, utilization is much higher in this population than in group health. (Texas, 2001) (NCCI, 2006) Presurgical biopsychosocial variables predict patient outcomes from lumbar fusion, which may help improve patient selection. Workers’ compensation status, smoking, depression, and litigation were the most consistent presurgical predictors of poorer patient outcomes. Other predictors of poor results were number of prior low back operations, low household income, and older age. (DeBerard-Spine, 2001) (DeBerard, 2003) (Deyo, 2005) (LaCaille, 2005) (Trief-Spine, 2006) Obesity and litigation in workers’ compensation cases predict high costs associated with interbody cage lumbar fusion. (LaCaille, 2007) A recent study of 725 workers’ comp patients in Ohio who had lumbar fusion found only 6% were able to go back to work a year later, 27% needed another operation, and over 90% were in enough pain that they were still taking narcotics at follow-up. (Nguyen, 2007) A recent case-control study of lumbar fusion outcomes in worker’s compensation (WC) patients concluded that only 9% of patients receiving WC achieved substantial clinical benefit compared to 33% of those not receiving WC. (Carreon, 2009) This large historical cohort study suggests that lumbar fusion may not be an effective operation in workers’ compensation patients with disc degeneration, disc herniation, and/or radiculopathy, and it is associated with significant increase in disability, opiate use, prolonged work loss, and poor RTW status. (Nguyen, 2011) After controlling for covariates known to affect lumbar fusion outcomes, patients on workers' comp have significantly less improvement. (Carreon, 2010) The presidents of AAOS, NASS, AANS, CNS, and SAS issued a joint statement to BlueCross BlueShield recommending patient selection criteria for lumbar fusion in degenerative disc disease. The criteria included at least one year of physical and cognitive therapy, inflammatory endplate changes (i.e., Modic changes), moderate to severe disc space collapse, absence of significant psychological comorbidities (e.g. depression, somatization disorder), and absence of litigation or compensation issues. The criteria of denying fusion if there are compensation issues may apply to workers' compensation patients. (Rutka, 2011) On the other hand, a separate policy statement from the International Society for the Advancement of Spine Surgery disagrees that...
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<td>worker’s compensation should be a contraindication for lumbar fusion. (ISASS, 2011) (NOTE: Except as otherwise noted, ODG text of this section remains unchanged.)</td>
<td></td>
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#### REFERENCE SUMMARIES


- **Carragee EJ, Lincoln T, Parmar VS, Alamin T. A gold standard evaluation of the "discogenic pain" diagnosis as determined by provocative discography.** Spine. 2006 Aug 15;31(18):2115-23. Rating: 3a


Washington State Department of Labor and Industries, Medical Treatment Guidelines, Date Introduced: Nov. '95.


**Colorado Division of Workers' Compensation,** Medical Treatment Guidelines, Rule XVII. Low Back Pain, 12/1/01. Rating: 7a


## Procedure Summary – Neck & Upper Back

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| Discography     | Not recommended. **Recommended for indications below.** Conflicting evidence exists in this area, though some recent studies **condemn 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 the 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](#)) Assessment tools such as discography lack validity and utility. ([Haldeman, 2008](#)) Although discography, especially combined with CT scanning, may be more accurate than other radiologic studies in detecting degenerative disc disease, its ability to improve surgical outcomes has yet to be proven; 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](#)) **Discography is Not Recommended in ODG.** See also the **Low Back Chapter**. Patient selection criteria for Discography **if provider & payor agree to perform anyway:**
  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
  o Due to high rates of positive discogram after surgery for disc herniation, this should be potential reason for non-certification

#### REFERENCE SUMMARIES


