

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria Discography (Discogram) for Low Back Pain

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, <i>Discography (Discogram) for Low Back Pain</i> , for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Low back pain is a great and growing problem in the Western countries as well as other parts of the world. It is the most common cause of disability in patients younger than 45 years old, and the loss of work, medical and disability costs can add up to at least \$50 billion per year in the Unites States. Many factors are associated with back pain, but the exact causes of severe pain are unclear especially in the absence of a diagnosed anatomic pathology such as infection, tumor, deformity, or instability (Carragee 2001, 2004, Willems 2007).

Currently, there is no clinical test that could be used as a diagnostic gold standard for discogenic pain, and it is not possible to determine with absolute certainty that a particular disc is the spinal pain generator. Imaging methods such as radiography, magnetic resonance imaging (MRI), and computed tomography (CT) may detect disc degeneration but cannot confirm if it is symptomatic and relevant to the patient's pain syndrome. Plain radiographs provide data on bony alignment and deformity, signs of instability, and the general state of lumbar degeneration. Nuclear medicine scans may exclude tumors, fractures and infection, and magnetic resonance imaging (MRI) is used for the diagnosis lumbar degenerative disorders. MRI is considered the morphological imaging study of choice in patients with low back pain. It is non-invasive and allows assessment of more levels in one test. MRI findings might also provide some information to indicate that a positive test increases the likelihood of the disc as a source of patients' symptoms, yet the current evidence is insufficient to allow making an accurate prediction (Saal 2002, Hancock 2007, Willems 2007). Surgical exposure can confirm the presence of disc degeneration but cannot definitely confirm that it is the source of discogenic pain.

Lumbar discography was first introduced in the late 1940s as a morphologic test. The term discography used to describe the technology, implies a strictly anatomic evaluation. Discograms do not image pain and hence do not provide insight into which neural pathways mediate discogenic pain. Imaging of intervertebral discs morphology usually does not change within a short interval, but discographic images may change after only 2 weeks. Concerns about the invasiveness of discography, radiation exposure, risk of infection, and the recent advances made in the high-resolution multi-detector CT and MRI of the disc, minimized the role of discography as an imaging tool. However, the frequent recurrence of familiar back pain during the discography led to the use of the test in evaluating lumbar discs as the origin of chronic low back pain, as well as pain in the cervical spine. Currently discography is used as a provocative test alleged to correlate symptoms with pathology (Buenaventura 2007).

Provocative discography is an invasive diagnostic procedure performed by the injection of a nonirritating radio-opaque dye, under x-ray guidance, into the nucleus of one or more lumbar discs. The dye is slowly injected into the center of the nucleus pulposus by a 22-25-gauge needle. The patient must be awake and cooperative and is supposed to be blinded to the time and level of injection. The distribution of the dye is noted, and the patient is asked whether each injection seems painful, and if the pain is similar "concordant" to the usual back pain he experiences. The patient is also asked to rate the pain on a visual analogue scale (VAS) or pain thermometer from 0-10 (or 0 to 5), with 0 denoting no pain and the higher end being unbearable pain. A completely intact disc will retain the dye in a central globular pattern, and is usually not very uncomfortable, even at high pressures. With more advanced disc degeneration on the other hand, patients may experience varying degrees of discomfort and pain as the dye is injected. A post discogram CT scan is often performed, and allows for a more thorough visualization, assessment, and identification of disc abnormalities (Saal 2002, Carragee 2001, Cohen 2005, Rowles 2005).

Discography has always been described as one of the most controversial tests in the management of degenerative painful lumbar spine conditions. Unlike MRI or CT scans, discography is used as a provocative test alleged to correlate symptoms with pathology. It seeks to confirm an impression that the back pain is discogenic and originating from a certain intervertebral disc. Some researchers found that healthy, previously pain free, patients can develop both back and leg pain from a provocative discogram as a result of the injection of irritants at different sites in motion segments. They also found that placement of the needle and injecting contrasts in the annulus fibrosus rather than the nucleus pulposus may induce back pain which should be regarded as false positive discography. Also, pain response to the discograms may vary widely among patients with chronic pain and somatization disorders. According to several investigators, psychological distress and pre-existing chronic pain processes may be stronger predictors of low-back pain than painful disc injections (Saal 2002, Carragee 2004, and Lander 2005).

One of the most feared complications of discography is discitis because of the poor blood supply of the intervertebral discs. Other reported adverse events include injury to the intervertebral disc, headache due to neuroaxial leak of the contrast, convulsions, meningitis, subdural or epidural abscesses, intrathecal hemorrhage, and others. Also, as indicated earlier discography may cause or worsen low back pain especially in patients with somatization disorder (Cohen 2005).

The suggested clinical indications for discography are wide-ranging and highly individualized (Carragee 2004). Guidelines published by specialized groups recommend that discography be reserved for use in patients with equivocal or inconsistent findings from MRI or other tests. Some investigators suggest its use for the evaluation of patients with chronic back pain for whom a surgical intervention is being considered.

Discography is being reviewed by MTAC based on a request from Dr. Kyle Kim. Considered as a procedure, discography is not regulated by the FDA; however, the devices and agents used for the test require FDA approval. Several of these devices and contrast material have been approved by the FDA.

Medical Technology Assessment Committee (MTAC)

Discography

10/01/2007: MTAC REVIEW

Evidence Conclusion: Reliability of discography for patients with chronic lumbar disc disease: There is no current consensus in the spine community of what constitutes a positive disc injection (Carragee & Hannibal 2004). In general, a positive discogram depends mainly on the production of the usual or concordant pain, which is a subjective measure and might not be a proper validation tool. Observer variability and bias in reading a discogram, as well as inter and intraobserver validation of pain response were evaluated only in a few studies. In a prospective trial involving 47 patients (Carragee 2000), the authors found that patients with abnormal

psychological profiles have significantly higher rates of positive disc injections than either asymptomatic volunteers or symptomatic subjects with normal psychological screening. Agorastides and colleagues (2002) found an excellent interobserver and intraobserver agreement in applying Adams classification for discogram morphology but did not study the reliability of the test in diagnosing discogenic pain. These, as well as other published studies were small, had methodological flaws, and do not provide sufficient evidence to determine the reliability of discography. Diagnostic accuracy of discography: As indicated earlier there is no clinical test that could be used as a diagnostic gold standard for discogenic pain. Several studies investigated the accuracy of discogram and/or CT discograms in detecting disc disease based on surgical confirmation of the pathology. Other researchers evaluated the technology by comparing, and /or correlating its results with those obtained by various other techniques including CT, myelography, and MRI. Small series where experimental discograms (with no surgical confirmation) were performed on asymptomatic patients showed that the test might be associated with high false positive rates. Accuracy based on surgical confirmation of findings: Results of studies with surgical confirmation of disc degeneration (Jackson 1989, Bernard 1994, and others) showed that CT discography was more accurate than standard discography in identifying disc herniation. CT discography had a sensitivity ranging from 74% to 92% and specificity ranging from 60% to 80%, versus sensitivity around 80% and specificity as low as 31% for standard discography. Compared to other diagnostic modalities, CT discography seemed to be more accurate in identifying disc abnormalities. Combining it with MRI improved its sensitivity, but not the specificity in Bernard's study (See attached appendix table 1). Birney et al, 1992 (See evidence table) compared the findings of discography with MRI using surgical confirmation of disc herniation/degeneration as a gold standard among 90 patients (264 discs). All participants underwent an awake discogram by one radiologist and an MRI exam by another radiologist. 57 patients with 76 discs underwent surgical intervention. The study had its advantages and limitations. The authors evaluated discography as a morphologic test to examine the disc abnormality, but not as the cause of discogenic pain. The results of the study show 86% agreement between MRI and discogram. MRI was found to be more accurate in detecting disc herniation, while discogram was more accurate in detecting disc degeneration. The authors concluded that MRI and discography are equivalent in detecting degenerative disc disease; however, the study was not designed nor powered to detect equivalence. These studies determined the accuracy of discography in diagnosing disc pathology but did not confirm that the disc is the source of discogenic pain. Identifying a disc abnormality is not equal to identifying the cause of pain or that the disc is suitable for surgical intervention. Correlation of discography with MRI without surgical confirmation: Studies that compared discography with MRI showed a varying agreement between the two tests. (See appendix table 2) Lim and colleagues (2005) studied the correlation between MRI and CT discography findings with pain response at provocative discography in 47 patients with discogenic back pain. MRI and discogram findings were analyzed based on concordant pain at discography. The study was small and had several limitations. Overall the authors reported a 68-89% accuracy of MRI in predicting pain, vs. 61% for discograms. Earlier in 1998, Ito and colleagues showed a 57% correlation between the two technologies in predicting pain. Several other investigators e.g. Gibson 1986, Linson 1990, Simmons 1991, Osti 1992, (See appendix table 2) as well as others studied the correlation between MRI and discograms in diagnosing a disc abnormality. The studies were small and had their limitations. Agreement rates were reported per patients, and/ or per discs. For patients it ranged from 55-75%, and for discs it ranged between studies from 71-94%. It is hard to determine if the lack of agreement between the tests was due lack of sensitivity (false negatives) or lack of specificity (false positives) in one or the other test. Diagnostic and therapeutic impact of discography on health outcomes: There were a number of published prospective and retrospective studies that aimed at correlating discography findings to surgical outcomes. The population sizes in these studies were small, and the mean duration of follow-up ranged from <2-6 years. Abnormal discogram was the basis for surgery, which was mainly spinal fusion, a procedure which is considered by many investigators as a controversial treatment. Willems and colleagues' (2007) study (see evidence table) evaluated whether preoperative status of the adjacent discs, as determined by provocative discography, had an impact on the clinical outcome of lumbar fusion in patients with chronic low back pain (LBP). The study included 209 patients with chronic LBP. They underwent outpatient routine diagnostic tests including radiography, MRI, CT, and provocative discography to determine the levels considered for lumbar fusion. The patients then underwent temporary external transpedicular fixation trial which was the final decisive factor for fusion. The latter was performed on 82 patients. They were followed up for a mean of 80 months and the primary outcome was the individual changes in pain on a visual analog scale (VAS), and patient satisfaction. A successful outcome was defined as 30% or more pain reduction. This rate was arbitrary, and according to the authors debatable. The study had other methodological flaws, and its overall results indicate that provocative discography had no significant impact on the clinical outcome after lumbar fusion. Carragee (2006) compared 5-year outcomes of two cohorts: 1 Discography (presumed discogenic pain) cohort, n=30, and 2: Unstable spondylolisthesis cohort of 32 patients used as a control group. The gold standard used for the diagnosis of discogenic pain by discography was clinical outcome after surgical intervention. Outcome measures included VAS for back and leg pain, Modems Lumbar Questionnaires, analgesic usage, work status, reoperation, and complications. The results show a surgical success rate of 27% among the patients with discography positive test, compared to a 72% success rate in the control group. The calculated positive predictive value of discography for achieving at least the minimum © 2007 Kaiser Foundation Health Plan of Washington. All Rights Reserved. Back to Top

acceptable outcome was 43%. Earlier in 2002, Madan and colleagues studied the outcome of spinal arthrodesis among 73 patients with discogenic low back pain refractory to nonoperative management. Chronologically the first 41 patients had not undergone discography while the following 32 patients underwent surgery based on discographic findings. The primary outcome was satisfactory clinical outcome based on a visual analogue scale and other questionnaires including the Oswestry Disability Questionnaire after a mean follow-up of 2.4-2.8 years. The results showed that 75.6 % of the patients in the discography group had satisfactory outcomes versus 81% of those who did not have a preoperative discography. This observed difference in improvement was not statistically significant. The other published studies had their limitations, had potential selection, spectrum and observation bias, and used subjective measures as their outcomes. They also had conflicting results all of which makes it hard to determine if preoperative discography is of value in selecting patients for surgical intervention and/or predicting surgical outcomes. Conclusion: There is insufficient evidence to determine the reliability of discography in the diagnosis of discogenic pain among patients with chronic low back pain. There is insufficient evidence to conclude whether or not the use of discography can improve selection of patients, predict or improve surgical outcomes in those with discogenic chronic low back pain.

Articles: The search yielded over 500 articles some of which dated back to 1966. There were three systematic reviews of the literature with no meta-analyses, and several small prospective or retrospective studies that aimed at determining the reliability, calculating the diagnostic accuracy, comparing, or correlating the findings of discography with MRI, CT scanning, myelograms or radiographs in symptomatic or asymptomatic patients. The search also revealed several relatively small studies that utilized health outcomes as a method for assessing the efficacy of discography. The ideal study would be a blinded independent comparison of discogram with a gold standard. However, to date, there is no known gold standard for discogenic pain. Some researchers determined the accuracy of discography by comparing it to other diagnostic modalities. Others used surgical findings and pathological disc morphology as their standard to confirm discographic results. These can confirm the presence of disc degeneration but cannot definitely confirm that it is the source of discogenic pain. Other groups suggested using clinical results of fusion as a gold standard to confirm whether the positive discogram injections were in fact true positives. Still many disagree on using a "controversial "treatment as the spinal fusion as a gold standard for a diagnostic test. One study that correlated discogram findings with MRI, and another that sought to measure its efficacy based on health outcomes were presented in evidence tables. Several other studies were grouped in table forms (see appendix tables 1 and 2) and/or discussed in the reviewer's evidence summary section. The studies critically appraised in evidence tables are Birney TJ, White JJ, Berens D, et al. Comparison of MRI and in the diagnosis of lumbar degenerative disc disease. J Spinal Disord 1992;5:417-423 See Evidence Table. Willems PC, Elmans L, Anderson PG, et al. Provocative discography and lumbar fusion. Is preoperative assessment of adjacent discs useful? Spine 2007;32:1094-1099 See Evidence Table.

The use of discography in the treatment of lower back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Discography

12/14/2011: MTAC REVIEW

Evidence Conclusion: In 2007 we reviewed the evidence for lumbar provocative discography, and there was insufficient evidence to determine the benefits of the procedure. A quick literature search did not reveal any good quality or large studies on analgesic discography. The only more recent study discussed in that article is the Cooper et al's study presented in a meeting and not published in a peer reviewed journal.

There was a systematic review with no meta-analysis of studies on lumbar discography (Manchianti 2009) that concluded that the level of evidence on the technology is II-2 (i.e. evidence obtained from at least one properly designed small diagnostic accuracy study). The review indicated that there is a lack of literature, poor methodological quality and very few studies using IASP criteria. Carragee (2006) compared 5-year outcomes of two cohorts: 1 Discography (presumed discogenic pain) cohort, n=30, and 2: Unstable spondylolisthesis cohort of 32 patients used as a control group. The gold standard used for the diagnosis of discogenic pain by discography was clinical outcome after surgical intervention. Outcome measures included VAS for back and leg pain, Modems Lumbar Questionnaires, analgesic usage, work status, reoperation, and complications. The results show a surgical success rate of 27% among the patients with discography positive test, compared to a 72% success rate in the control group. The calculated positive predictive value of discography for achieving at least the minimum acceptable outcome was 43%.

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Applicable Codes

Considered Not Medically Necessary

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CPT® or	Description	
HCPC		
Codes		
62290	Injection procedure for discography, each level; lumbar	
62291	Injection procedure for discography, each level; cervical or thoracic	
62292	Injection procedure for chemonucleolysis, including discography, intervertebral disc, single or multiple levels, lumbar	
72285	Discography, cervical or thoracic, radiological supervision and interpretation	
72295	Discography, lumbar, radiological supervision and interpretation	

^{*}Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/18/2007	10/01/2007, 10/15/2007 MDCRPC, 1/3/2012 MDCRPC, 2/7/2012 MDCRPC,	05/02/2017
	09/01/2015 ^{MPC} , 07/05/2016 ^{MPC} , 05/02/2017 ^{MPC} , 03/06/2018 ^{MPC} , 02/05/2019 ^{MPC} , 02/04/2020 ^{MPC} , 02/02/2021 ^{MPC} , 02/01/2022 ^{MPC} , 02/07/2023 ^{MPC}	

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
05/02/2017	Adopted KPWA policy for Medicare members

^{**}To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.