Cigna Medical Coverage Policy

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Subject **Discography**

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Coverage Policy

Cigna covers lumbar provocative discography, including post discography computed tomography (CT) assessment as medically necessary for the preoperative evaluation of discogenic back pain, when ALL of the following criteria for a single level lumbar fusion have been met:

- unremitting pain with significant functional impairment of at least twelve months duration
- failure of at least six (6) consecutive months of structured*, physician-supervised conservative medical management, which includes **ALL** of the following components:
  - exercise, including core stabilization exercises
  - nonsteroidal and/or steroidal medication (unless contraindicated)
  - physical therapy, including passive and active treatment modalities
  - activity/lifestyle modification
- complex imaging studies (e.g., computerized tomography (CT) scan or magnetic resonance imaging (MRI) scan) do not conclusively demonstrate single level degenerative disc disease as the likely cause of pain
- documentation from a primary care physician, neurologist, physiatrist, psychiatrist or psychologist, indicating BOTH of the following:
  - the absence of untreated, underlying psychological conditions/issues (e.g., depression, drug and alcohol abuse) as a contributor to chronic pain
  - a statement indicating that the individual has completed a course of cognitive behavior therapy (e.g., 8-10 sessions, face-to-face interaction, may also include group sessions, is problem focused/ action oriented)

***Note: Structured medical management consists of medical care that is delivered through regularly scheduled appointments, including follow-up evaluation, with licensed healthcare professionals.**

Cigna does not cover lumbar discography (e.g., provocative discography, stimulation discography) with or without CT assessment, when performed in connection with or in anticipation of any procedure that has been determined to be experimental, investigational or unproven, including, but not limited to ANY of the following:

- intradiscal electrothermal therapy (IDET™)
- disc nucleoplasty, decompression nucleoplasty, or Coblation® Nucleoplasty™
- laser discectomy (e.g., percutaneous, laparoscopic)

Cigna does not cover lumbar provocative discography, with or without CT assessment, for ANY other indication because it is considered not medically necessary.

Cigna does not cover any of the following discography procedures, for ANY indication, because each is considered experimental, investigational or unproven (This list may not be all-inclusive):

- cervical discography
- thoracic discography
- functional anesthetic discography (FAD)
- contrast disc analysis mapping

General Background

Discography, also referred to as stimulation discography, or a discogram, is an invasive diagnostic tool used to characterize the anatomical structure of the intervertebral disc and determine if a specific disc is causing back pain. The procedure provides direct radiographic information concerning the nuclear morphological characteristics of the vertebral endplates and annulus. It provides a method of directly relating radiograph images to a patient's pain. Abnormalities of the vertebral disc and internal disruption of the annulus have been considered sources of low back pain. Authors propose that discography identifies the primary pain generator causing back pain when other spinal diagnostic procedures have failed to identify the source, and allows for targeted intervention.

Discography involves the injection of radiographic contrast into the nucleus of an intervertebral disc. The injection of contrast dye allows for the determination of intradiscal pressures. The pressures and volume of contrast can be used to determine the integrity of the inner and outer annuli. Changes in volume and pressure result in direct stimulation of the nerve endings within the fibers of the disc. Authors contend that discography induces pain as a result of the increased pressure from the contrast material, neurochemical stimulation and/or an increase in intervertebral pressure.

The standard for determining that a discogram is positive (i.e., abnormal discogram) is the occurrence of pain that is similar to or exactly like the patient's clinical pain provoked with the injection of dye, accompanied by an abnormal radiographic image of the disc (Guyer, Ohnmeiss, 2003). However, some published studies differ in the definition of an abnormal discogram; as a result, the technique and interpretation of the discogram must also be closely evaluated when assessing outcomes.

Discography is a provocative clinical test and is typically not used as a baseline imaging study; the procedure is indicated for assessment of pain that is chronic in nature and unresponsive to other conservative measures. The test is typically performed in combination with CT scans. Post-discography CT scanning provides additional information about the exact pattern of the spread of contrast through or out of the disc space. Combined with anteroposterior and lateral radiographs, CT scanning allows the disc to be viewed in three planes. Surgery should be precluded by failing to find a painful disc on discography, finding multiple painful discs or indeterminate results (Barna, 2005).

Discography has been proven to be a safe procedure although there are associated risks. Risks and complications include disc space infection (discitis), nerve root injury, urticaria, bleeding, nucleus pulposus pulmonary embolism, nausea, increased pain and spinal headache. Acute lumbar disc herniation as a result of discography has been reported (Poynton, et al., 2005). The procedure is contraindicated for patients with dye sensitivity, spinal cord compression, and who have current local infections.

In clinical practice, a majority of discograms are performed to evaluate the lower three lumbar discs (Peh, 2005). Provocative discography is less frequently performed to assess cervical or thoracic disc pain. The approach for thoracic discography is similar to lumbar. Cervical discography is approached anteriorly rather than posteriorly. The technique for cervical discography is the same as for thoracic and lumbar.

Cervical Discography
Cervical discography requires an anterior approach and has been recommended for patients with persistent neck pain without localized neurological findings when standard imaging studies are negative. Potential complications are related to the surrounding anatomy and include injury to the trachea, esophagus, carotid artery, discitis, spinal cord injury and pneumothorax.

There is limited evidence in the form of case series and published systematic reviews that lend some support to safety, low complication rates, and utility of cervical discography for the evaluation of discogenic pain in select patients (Ohnmeiss, et al., 2000; Grubb, et al., 2000; Zheng, et al., 2004; Shah, et al., 2005; Buenaventura et al., 2007). The results of a recent systematic review evaluating cervical discography indicates that despite a paucity of evidence and discrepancy among studies, the diagnostic accuracy of cervical discography has moderate validity and moderate predictive value based on modified United States Preventive Services Task Force (USPSTF) criteria (Manchikanti, et al., 2009a). This conclusion is based on Level II-2 evidence which is evidence obtained from at least one properly designed small diagnostic accuracy study. For this systematic review, the authors reviewed a total of 33 studies, three studies which met the inclusion criteria utilizing IASP (Association for the Study of Pain) criteria: provocation discography with control discs and involving patients with chronic pain of at least three months duration.

Professional Society/Organizations: The International Society of Interventional Pain Physicians published guidelines with recent updates for interventional techniques in the management of chronic spinal pain (Manchikanti et al., 2003; Boswell, et al., 2005, Boswell et al., 2007; Manchikanti, et al., 2009c [update]; Manchikanti, et al., 2013a).Within the most recent guideline among the diagnostic interventions, the authors note “false-positive results are a serious concern with cited prevalence rates exceeding 50%”. According to the guidelines “cervical discography is indicated to test the diagnostic hypothesis of discogenic pain of the cervical spine in individuals who have been properly selected and screened to eliminate other sources of cervical pain.”

The American College of Radiology (ACR) published guidelines for appropriateness of initial radiologic examinations for patients with chronic neck pain (Daffner, et al., 2005). The committee concluded that pain radiographs should be the initial study performed; MR imaging should be performed on all patients who have chronic neck pain and neurologic signs, and that CT myelography may be performed if MRI is contraindicated. The committee did not recommend discography.

The body of evidence evaluating cervical discography is limited. While there is some evidence in the form of case series and systematic reviews to support utility for cervical discography, evidence from well-designed controlled trials is lacking. There is much debate regarding false-positive results and concerns regarding safety. The current evidence in the published peer-reviewed scientific literature is insufficient and does not lead to strong conclusions regarding clinical utility. What effect, if any, cervical discography has on surgical treatment for discogenic type pain has yet to be proven.

Thoracic Discography
Thoracic discography is considered by some providers to be useful in clinical practice for the assessment of thoracic, chest and upper abdominal pain (Gardocki, Park, 2012). Similar to cervical, potential complications are related to the surrounding anatomy of the thoracic spine and include pneumothorax, spinal trauma, discitis and bleeding. The evidence supporting the safety and utility of thoracic discography is even more limited than cervical, consisting mainly of a few case series and systematic reviews (Wood, et al., 1999; Shah, et al., 2005; Buenaventura, et al., 2007).

Professional Societies/Organizations: The International Society of Interventional Pain Physicians has published guidelines for interventional techniques in the management of chronic spinal pain (Manchikanti et al., 2003; Boswell, et al., 2005 [update], Boswell et al., 2007 [update]; Manchikanti, et al., 2009c [update]; Manchikanti, et al., 2013a [update]). Within this practice guideline among the diagnostic interventions, the authors reported that the evidence supporting thoracic discography is limited and very few authors have studied the procedure; however the procedure may be indicated to determine if an intervertebral disc is painful or not. The evidence reviewed for the 2013 updated guideline was based on evidence from two moderate quality studies; there was no recent literature included in the review.

Similar to cervical discography, the evidence evaluating thoracic discography is limited and does not lead to strong conclusions regarding safety and clinical utility. Currently the evidence is insufficient to support the clinical value of thoracic discography.

Lumbar Discography
The clinical value of lumbar discography is also widely debated. The diagnosis of discogenic pain due to disc degeneration, internal disc disruption or annular tears, for example, is considered difficult and controversial by many authors. Not all patients with disc disease experience pain. In addition, it is reported that the ability of patients to separate spinal pain from nonspinal sources of lumbar pain may be questionable (Carragee, et al., 1999). Early published data showed high (37%) false-positive rates in a group of asymptomatic patients; however, recent authors have reported lower false-positive rates. Several systematic reviews and case studies have been published evaluating lumbar discography. Although there is no general consensus regarding validity of discography as a diagnostic tool, authors generally agree that lumbar discography is an appropriate diagnostic test with some clinical utility for patients with low back pain, particularly when lumbar surgery is being considered, and when noninvasive diagnostic tests are inconclusive.

The medical literature suggests the predictive value of provocative discography on surgical outcomes has not yet been firmly established. Discography is often performed prior to arthrodesis, minimally invasive surgery and other intradiscal surgeries. Arthrodesis (spinal fusion) is a surgical method of controlling low back pain attributable to abnormal or unstable vertebrae and pain due to mechanical degeneration and is indicated when degenerative disc disease is limited to a single level. However it has been reported there was no difference in operative outcome between groups of subjects who had preoperative discography and those who did not (Madan et al. (2002). Discography has also been recommended for use prior to minimally invasive surgeries for patients with contained disc herniation; discography may define disc containment for those candidates (Guyer, Ohnmeiss, 2003). Discography is also routinely performed in combination with intradiscal electrothermal therapy (IDET) as a treatment for disc pain; however, the long-term results of IDET remain unknown (AAOS, 2002; NASP, 2002).

Literature Review: Evidence in the published medical literature evaluating lumbar discography consists of systemic reviews, meta-analyses, technology assessments, prospective and retrospective clinical trials and published reviews (Manchikanti, et al., 2013a; Manchikanti, et al., 2013b; Manchikanti, et al., 2009a; ECRI, 2009; Wolfer, et al., 2008 ; ECRI, 2007; Buenaventura et al., 2007 ; Carragee, et al., 2006; Carragee, et al., 2005; Shah, et al., 2005; Cohen, et al., 2005; Guyer and Ohnmeiss, 2003). Many studies lack control groups and randomization. There is no general consensus regarding the clinical utility of lumbar discography; some authors have evaluated diagnostic accuracy and reported the evidence is strong to moderate for discography as an imaging tool for the evaluation of chronic low back pain (Manchikanti, et al, 2009a; Buenaventura et al., 2007; Shah, et al., 2005) although Carragee et al. (2005) reported diagnostic accuracy is not high and discography has a calculated positive predictive value of 50-60%. Cohen et al. (2005) reported discography is less accurate than MRI in diagnosing herniated nucleus pulposus, although comparable or slightly more sensitive in detecting degenerative disc disease. As demonstrated in a recent systematic review (Manchikanti, et al., 2013b) the evidence supporting diagnostic accuracy of provocation discography, after controlling for various factors which included methodological flaws, lack of standardization, and the absence of well-designed studies, is fair (according to USPSTF criteria: [good, fair, limited or poor]).

In other studies, authors have been concerned about reliability and false-positive results (Wolfer, et al., 2008; Carragee, et al., 2005); some authors have reported high false-positive rates, and others have reported zero false-positive rates. When performed in asymptomatic subjects, the pain provoked by discography cannot be compared to clinical or typical pain; therefore, some studies cannot address true false-positive rates. The

patients provoked pain must be similar to the patient's clinical pain for the test to be considered positive. In addition patients with severe pain sensitivity may be more likely to provide information that is not helpful in differentiating the disc as a pain generator (NASS, 2005).

Furthermore, the ability of discography to improve surgical outcomes has yet to be proven (Cohen, et al., 2005) and studies comparing surgical outcomes between patients who have had discography preoperatively with those who have not are few. Identification of a diseased disc as a generator of pain can improve clinical outcomes through better selection of candidates and therapies. In addition it can reduce the likelihood that discs which are not pain generators, are inappropriately treated (Manchikanti, et al., 2009b). When comparing outcomes of fusion procedures lumbar discography is sensitive but lacks specificity (Thiyagarajah, et al., 2009).

More recently, the effect of discography on progression of disc degeneration has gained interest. Carragee et al. (2009) published the results of a prospective matched cohort study evaluating disc degenerative progression over 10 years with (n=50) and without baseline discography (n=52, control). Magnetic resonance imaging was obtained at baseline and at 7-10 years follow-up. The authors noted more frequent and greater degenerative findings, including herniation, end-plate changes, disc grade progression, and annular fissures in the discography group when compared to the matched control group. The authors also noted greater loss of disc height and loss of disc signal in the discography group following annular puncture and injection. In the author's opinion, careful consideration of risk and benefit should be used when recommending procedures involving disc puncture.

In 2007 the ECRI Institute conducted a technology assessment evaluating the strength of evidence for the safety and efficacy of lumbar fusion for the treatment of degenerative disc disease (DDD) and the role of discography prior to lumbar fusion in this population of patients. In general, the studies available for review were of low quality; retrospective, nonrandomized and nonblinded. Due to varying definitions of positive discography, examination of different outcomes, and reporting of qualitatively different results, ECRI was not able to draw conclusions regarding prediction of surgical outcomes (ECRI, 2007). ECRI updated the discography portion of the evidence report in 2012 (2009, 2012) and evaluated additional literature; however ECRI noted the conclusions of the earlier report remain valid and unchanged.

Evidence in the medical literature does support the use of discography for the following selected conditions (Thiyagarajah, et al., 2009; Guyer and Ohnmeiss, 2003):

- for further evaluation of demonstrably abnormal discs when required to assess the extent of the abnormality or correlation of the abnormality with clinical symptoms
- for patients with persistent, severe symptoms in whom other diagnostic tests have failed to reveal clear confirmation of a suspected disc as the source of pain
- for assessment of patients who have failed to respond to previous surgical interventions (i.e., to detect pseudoarthrosis or a symptomatic disc in a posteriorly fused segment and to evaluate for recurrent disc herniation)
- for assessment of discs before fusion
- for assessment of minimally invasive surgical candidates to confirm a contained disc herniation or to investigate dye distribution pattern before chemonucleolysis or other percutaneous procedures

Professional Societies/Organizations: The American Pain Society introduced a clinical practice guideline (Chou, et al., 2009) for interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain. The guideline recommendations are based on a systematic review of evidence from randomized controlled trials. According to the guideline, based on moderate-quality evidence, in patients with nonradicular low back pain provocative discography was not recommended as a procedure for diagnosing discogenic low back pain. In addition the authors note the 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.

In June of 2010 the American Academy of Orthopedics approved the endorsement of the American Pain Society's guidelines on management of low back pain.

The International Society of Interventional Pain Physicians published guidelines for interventional techniques in the management of chronic spinal pain (Manchikanti et al., 2003; Boswell, et al., 2005[update], Boswell et al., 2007[update]; Manchikanti, et al., 2009c [update]; Manchikanti, et al., 2013b [update]). Based on the authors review of the evidence the recommendations for lumbar provocation discography include appropriate indications with patients with low back pain to prove the diagnostic hypothesis of the discogenic pain specifically after exclusion of other sources of lumbar pain only when a treatment is available.

The American College of Radiology (ACR) published guidelines of appropriateness criteria for low back pain (Bradley, et al., 2005). The committee recommended with regard to discography that there is additional risk to the procedure and that discography is not warranted in view of the efficacy of other less invasive imaging procedures. When other studies fail to localize the cause of pain, discography may be helpful. Furthermore, although the images often depict nonspecific aging or degenerative changes, the injection itself may reproduce the patient's own pain, which may have diagnostic value. Within an updated version of the guidelines 2011 (Davis, et al, 2011) the ACR stated" discography may have a role in localizing the source of back pain that is indeterminate with other less invasive studies as well as in patients with multifocal abnormalities on MRI."

In June 2005, the American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves published guidelines regarding the performance of fusion procedures for degenerative disease of the lumbar spine (Resnick, et al., 2005). According to one of these guidelines it is recommended that lumbar discography not be used as a stand-alone test on which treatment decisions are based for patients with low back pain. If discography is performed as a diagnostic tool to identify the source of the patient's low back pain, it is recommended that both a concordant pain response and morphological abnormalities be present at the pathological level prior to initiating any treatment directed at that level.

According to Pauza (2004) the Physiatric Association of Spine, Sports and Occupational Rehabilitation (PASSOR) (an official council of the American Academy of Physical Medicine and Rehabilitation) Educational Guidelines for the Performance of Spinal Injection Procedures, the International Association for the Study of Pain (IASP), and the International Spinal Injection Society (ISIS) all recommend that in order to be valid, provocation discography must be subjected to anatomical controls. Specifically, the diagnostic criteria for discogenic pain are that provocation of the target disc must reproduce the patient's pain, provided that provocation of adjacent discs does not reproduce pain.

Although it has not been updated since 1995, the North American Spine Society (NASS) published a position statement regarding discography. According to the position statement, this procedure is indicated for patients with persistent pain in whom disc abnormality is suspect but noninvasive tests have not provided sufficient diagnostic information or the images need to be correlated with clinical symptoms; for the assessment of discs in patients considering lumbar fusion who have previously undergone surgery but continue to experience significant pain; and to confirm contained disc herniation (Guyer, Ohnmeiss, [NASS], 1995).

Functional Anesthetic Discography (FAD)
Functional anesthetic discography is a diagnostic procedure that involves injecting an anesthetic agent directly into a spinal disc. Proponents suggest functional anesthetic discography can be used to confirm the presence of injured discs as the source of the patient's low back pain symptoms. According to the manufacturer, functional anesthetic discography is designed to diagnose and potentially treat low back pain caused by degenerative disc disease. Although techniques may vary, during this procedure, under light sedation and x-ray guidance, a small catheter is inserted into the suspected disc and anchored in place with a small balloon. After recovering from light sedation, the patient is asked to engage in physical activity to reproduce pain. Local anesthetic is then injected in the disc believed to be causing the patient's pain. In some cases, administration of intradiscal steroid injection has been proposed in addition to the anesthetic. Reduction in pain is considered diagnostic. If the injection into a specific disc relieves the patient's back pain, the disc can be further evaluated for potential treatment. If the test does not relieve the patient's pain, the physician can investigate other possible causes of pain.

The FAD™ System (originally developed by InnoSpine, Inc., Palo Alto, CA, and later acquired by Kyphon Inc., Sunnyvale, CA) received 510(k) approval through the U.S. Food and Drug Administration (FDA) in April 2005 (FDA, K043500) as a Class II device. According to the FDA, the intended use of the system is to deliver either

a single dose or continuous administration of radiopaque contrast, local anesthetics, and/or saline solution to the intradiscal space. In April 2007 the Discyphor Catheter System (Kyphon, Inc., Sunnyvale, CA), a more recent update to the FAD System, was cleared by the FDA.

Although researchers are presently investigating the use of functional anesthetic discography for diagnosing discogenic pain, there is insufficient evidence in the published, peer-reviewed scientific literature to support safety and efficacy at this time. Mankichanti and colleagues (2013b) published an update of the systematic review of the accuracy and utility of lumbar discography in chronic low back pain and reported there was limited evidence supporting FAD or provocation discography with local anesthetic injection. (For information on intradiscal steroid injections refer to the CIGNA Medical Coverage Policy Minimally Invasive Treatment of Back Pain).

Contrast Disc Analysis Mapping
The addition of 3-D image post-processing, reconstruction and/or mapping of data with markers have been investigated as a method of improving the accuracy and predictive value of discography. However, there is insufficient evidence in the peer-reviewed, published scientific literature to support improved diagnostic utility as compared to standard, established provocative discography.

Use Outside of the US: No relevant information found.

Summary
The evidence from systemic reviews, meta-analyses, technology assessments, and prospective and retrospective clinical trials supports the clinical utility of lumbar discography for a select group of patients. These patients include those with persistent back pain unresponsive to conservative therapy when the results of other diagnostic tests, such as magnetic resonance imaging (MRI) or computed tomography (CT) scanning are inconclusive, and/or if disc abnormality is suspected and surgery is anticipated. Evidence evaluating cervical and/or thoracic discography consists primarily of case series and systematic reviews and is insufficient to support clinical utility when used for evaluating cervical or thoracic pain. In addition, the clinical utility of functional anesthetic discography (FAD) and contrast disc analysis mapping remains under investigation and its role in the management of discogenic back pain remains unknown at this time.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Lumbar Discography

Covered when medically necessary:

CPT®* Codes	Description
62290	Injection procedure for discography, each level; lumbar
62292	Injection procedure for chemonucleolysis, including discography, intervertebral disk, single or multiple levels, lumbar
72295	Discography, lumbar, radiological supervision and interpretation

Experimental/Investigational/Unproven/Not Covered when used to report cervical or thoracic discography, functional anesthetic discography (FAD) or contrast disc analysis mapping:

CPT* Codes	Description
62291	Injection procedure for discography, each level; cervical or thoracic
64999	Unlisted procedure, nervous system
72285	Discography, cervical or thoracic, radiological supervision and interpretation
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or

	paraspinous diagnostic or therapeutic injection procedures (epidural, or subarachnoid)

***Current Procedural Terminology (CPT®) ©2012 American Medical Association: Chicago, IL.**

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