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**Health Technology Clinical Committee****Findings and Coverage Decision****Date: February 15, 2008****Topic: Discography****Final Adoption: August 15, 2008****Number and Coverage Topic**

20080215B – Discography

**HTCC Coverage Determination**

Discography for patients with chronic low back pain and lumbar degenerative disc disease is **not a covered benefit**. This decision does not apply to patients with the following conditions:

- Radiculopathy
- Functional neurologic deficits (motor weakness or EMG findings of radiculopathy)
- Spondylolisthesis (>Grade 1)
- Isthmic spondylolysis
- Primary neurogenic claudication associated with stenosis
- Fracture, tumor, infection, inflammatory disease
- Degenerative disease associated with significant deformity

**HTCC Reimbursement Determination****❖ Limitations of Coverage**

Not applicable.

**❖ Non-Covered Indicators**

Not applicable.

**❖ Agency Contact Information**

<b>Agency</b>	<b>Contact Phone Number</b>
Labor and Industries	1-800-547-8367
Uniform Medical Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

**Health Technology Background**

Low back pain is the most common cause of disability and loss of productivity in patients under age 45. Disabling, chronic low back pain impacts 1.2 million patients in the United States. One difficulty in treating chronic low back pain is the lack of a precise and agreed clinical definition or diagnosis for the cause of certain back pain.

Some clinicians believe that the source of pain is the intervertebral disc, and if appropriately identified, treatments to reduce the disc-related pain will be effective. Discography's premise

is to diagnose the source of pain as coming from the disc itself (i.e., a diagnosis of discogenic pain) through two findings: a CT image aided by injection of contrast material to identify disc morphology or shape, and the provocation of pain by the injection that reproduces the pain typically felt by the patient.

Controversy in using the test exists because the clinical importance of these two test results is unknown and there is significant evidence of false positive test results. Some clinicians believe that the high false positive rate more accurately identifies patients with psychological co-morbidities rather than discogenic abnormalities.

The potential impact on the health system is unknown. Potential benefits include an accurate identification of individuals with degenerative disc disease and discogenic pain, which can potentially lead to effective interventions and a reduction in back pain and disability. Where other clinical findings are lacking, discography results are sometimes used to justify the need for surgical and other interventions. Theoretically, if the test accurately identifies a condition that will respond to surgical intervention, it will lead to better outcomes. The potential burden to the health system is the patient discomfort and relatively high cost of the diagnostic test, and the cost of unnecessary treatments and burden to the patient associated with a misdiagnosis (either due to false positives or due to the underlying clinical relevance not being accurate).

### **Summary of Committee Findings**

The HTCC reviewed and considered the discography technology assessment report, information provided by the Administrator, and public and agency comments. The overall question about the benefit of discography that the committee members focused on was whether or not do patients receiving discography have better treatment and health outcomes (surgical or otherwise). Key factors were related to the impact that discography had on either the therapeutic decision or the surgical success. Three low quality studies that addressed prediction of surgical success and outcomes were found to be not favorable in two studies; no study addressed impact on therapeutic decisions. Current evidence does not demonstrate that the test produces reliable results, even though expert opinion evidence supported the use of discography to rule out surgery. Based on the evidence presented on safety, efficacy and cost-effectiveness, the committee voted for non-coverage.

**Effectiveness:** A majority of committee members found that current scientific evidence is lacking in key areas or is of insufficient quality to draw conclusions about discography's effectiveness. Outcomes on efficacy and effectiveness were the primary focus of the discography discussion. Three key efficacy factors included specificity; subjective findings related primarily to pain provocation; and reliability. The available evidence on specificity is of low quality and focuses on a secondary result of whether the same reader can later read the test in the same way; instead of the more substantive data on whether administering the test at different times produces the same results. The second issue is that the primary outcome relied upon in the test is the replication of normal pain. There is wide clinical debate on the ability to measure accurately, and the meaning of, the subjective pain response. The relevance is made more unclear by findings that there is no established clinical case definition for degenerative disc disease other than radiographic and other imaging descriptions. The issue of false positives and reliability (percent agreement) are also a key concern raised by several studies, including the Carragee studies that demonstrated a high rate of positive discography findings in asymptomatic individuals. Patients may be subject to additional tests and risks of invasive therapies unnecessarily.

**Safety:** A majority of committee members found that the current scientific evidence is of insufficient quality to permit a conclusion on key health outcomes on the safety of Discography. Primary issues of concern here include the lack of a gold standard diagnosis and re-operation risk. The diagnostic test itself does include a small risk of infection and radiation common to any injection related test. The study results did not focus on safety concerns, and no other evidence on safety was presented. However, the committee did not have significant concern related to the performance of the test itself and acknowledged small risks as similar to other similar tests. The re-operation risk from surgeries performed as a result of the test is significant, especially where the test did not accurately identify the appropriate site. Appropriateness of surgery is a high concern that is unaddressed in the current trials. The substantial false positive rate of the test, discussed in efficacy, also contributes to this concern.

**Cost:** Half the committee members found that discography is less cost effective than the alternative tests, and half the committee members found that the evidence was insufficient to reach a conclusion on cost. The procedure fee itself and the need for referral for other tests were identified as key cost considerations. The cost of the procedure (agency average about \$2000 and \$8 million per year) is very high compared to alternatives and does not include any additional testing, treatments performed as a result of the test, or complications. Also, this is an additional test, not a replacement test. Discography is currently not used as a definitive test and it cannot replace other tests. Given high reliability concerns, more tests to confirm or refute findings can be required. No formal cost effectiveness evaluations and no long term costs were addressed.

The committee found that Medicare does not have a national coverage decision on discography. No professional guideline recommends discography as a stand alone or pre-operative diagnostic test. MRI is recommended as the diagnostic test of choice. Several guidelines do not recommend its use at all, while several advocate its use in addition to other tests.

### **Committee Authority**

The Washington State [Health Technology Clinical Committee \(HTCC\)](#), an independent committee of 11 health practitioners, determines how selected health technologies are covered by several state agencies. RCW 70.14.080-140. These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Evidence includes a report concerning the technology provided by a company specializing in objective reviews of pertinent scientific literature; information submitted by the affected state agencies; and public comment. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be reviewed at the determination of the HCA Administrator.