Washington State Health Care Authority

Health Technology Assessment Program

Health Technology Clinical Committee
Discography Topic

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Provocative discography

- Diagnostic procedure to identify if the disc itself the source of pain by injection of dye directly into the spinal disc
- Typical pain reproduced?
  - Subjective response
  - An emphasis on “typical” pain
  - Considered by most practitioners to be the key discography finding
- Abnormal morphology?
  - Integrity of the disc annulus
  - Dye leakage

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Selection
Lumbar Fusion/Discography

Primary Criteria	
Potential patient **harm/safety** concerns:	High
Concerns about therapeutic **efficacy or diagnostic accuracy** and appropriateness of outcomes for patients:	High
Estimated total direct **cost** per year (estimated increase/decrease):	High
Secondary Criteria	
Number of persons affected per year:	Med Low
Severity of condition treated by technology:	Med
Policy related urgency/diffusion concern:	Med
Potential or observed variation:	High
Special populations/ethical concerns:	Low

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Lumbar Fusion and Discography Background

- Discography Topic Concern
  - **Concern relates to using discography results to select or "confirm" a patient for fusion surgery**
    - There is no clear case definition of presence/absence of degenerative disc disease
    - Association between disease presence, pain, surgical benefit not established
    - Unclear that positive discogram patients undergoing surgery do better
    - The test is usually cumulative, not a replacement
    - Significant false positive rate ("normal" patients who experience pain/positive result)
  - **Discography premise is to diagnose source of pain as from disc through**:
    - Injection of contrast material to aid imaging of disc
    - Injection should provoke pain (look for a corresponding facial / subjective response)
  - **Diagnostic "gold standard" not established – generally**:
    - not recommended for uncomplicated cases, or
    - MRI or plain radiograph

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Discography Key Questions

Reliability

4) In patients being considered for lumbar fusion surgery, what is the reliability of discography?

- Test-retest reliability
- Inter-reader reliability

Prediction

5) In patients undergoing lumbar fusion surgery, do the results of pre-surgical discography predict the degree of pain reduction or improvement in functional status/quality of life after lumbar fusion surgery?

Impact

6) In patients being considered for lumbar fusion surgery, do patients who receive discography that influences the treatment choice have better treatment outcomes than patients who do not receive discography?

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Discography Reliability Results

- No studies reported any of the following:
  - Reliability of discography result when different people perform the injection
  - Reliability of discography on the same disc at different times
  - Reliability of patients' reports of pain provocation
- Three small studies exist on whether a given discogram is judged to have the same morphology grade:
  - By the same reader at different times (1 study, N=72).
  - By different readers (2 studies, N=72 and N=45)

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Inter-Rater Reliability Data

Study	Discs	System	Kappa (95% CI)
Agorastides (2002)	133	Adams classification	0.77 (0.66 to 0.87)
Milette (1999)	132	DDD degeneration	0.67 (0.55 to 0.78)
Milette (1999)	132	DDD disruption	0.66 (0.56 to 0.76)

Test-Retest Reliability Data

Study	Discs	Test-retest kappa (95% CI)		
		Rater 1	Rater 2	Rater 3
Agorastides (2002)	133	0.80 (0.71 to 0.89)	0.85 (0.77 to 0.93)	0.80 (0.70 to 0.90)

Not enough data to permit a conclusion

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Discography Prediction Results

- 3 studies, all Low quality
- Different definitions of a positive test:
  - Willems (2007) had 2 groups, based on pain provocation in adjacent discs (total N=82)
  - Gill (1992) had 3 groups, based on morphology of suspected disc (total N=53)
  - Colhoun (1988) had 4 groups, based on both pain provocation and morphology of suspected disc (total N=195).

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Discography Prediction Results

- Different results were found:
  - Willems (2007): No difference in surgical outcomes between those with positive discography (+) and those with negative discography (-)
  - Gill (1992) : Inconclusive findings
  - Colhoun (1988): Surgical outcomes were better among those with positive discography (+)

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Discography Impact

- Do patients receiving discography and fusion have better outcomes?
- Only one study: N=32 who received discography and N=41 who did not
  - All patients received fusion
  - Retrospective, non-concurrent, non-randomized, unblinded, poor matching at baseline
  - Very low quality

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Committee Decision
Lumbar Fusion and Discography

Medicare Coverage, Guidelines, Agency Experience

- Committee determination must either:
  - be consistent with the identified Medicare decisions and expert guidelines or
  - specify the reason (s) for the decision and the evidentiary basis

WAC 182-55-035: Committee coverage determination process

- Committee must consider:
  - Information submitted by the Administrator

WAC 182-55-035: Committee coverage determination process

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Discography Guidelines
Medicare Coverage

- CMS has no national medicare coverage policy on spinal fusion or discography

- American Society of Interventional Pain Physicians (2007)
- Work Loss Data Institute (2006)
- American Association of Neurological Surgeons (2005)
- Guyer and Ohnmeiss, Texas Back Institute (2003)
- Washington State Department of Labor & Industries (2002)

Evidence relied upon not explicit/variable quality

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Discography Guidelines

- No guideline recommends discography as stand-alone preoperative diagnostic test for back surgery
- MRI is recommended as diagnostic test of choice
- Discography Specifics
  - Three guidelines indicate that discography be reserved for patients with equivocal or inconclusive MRI findings
  - WLDI does not recommend use at all
  - AANS recommends against surgery where MRI normal, even if positive discography
  - Wa L&I does not consider positive discography a definitive indication for fusion

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Lumbar Fusion/Discography

Questions

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Agency Medical Director's Group
Provocative discography

- Injection of dye under pressure at multiple disc levels
- Follow up CT to look at anatomic abnormalities consistent with DDD-most can be seen on MRI
- Subjective response to injection-1) How much does it hurt (1-10)?, and 2) Does it reproduce your usual pain (concordant pain)?

Agency Medical Director's Group
Discography Performance

- **Carragee studies**

  Spine 2000; 25: 1373-80: In persons with NO LBP, discography (+) in 10% of pain-free, 40% of chronic cervical pain, and 83% of somatization disorder

Agency Medical Director's Group Discography Performance

Spine 2004; 29: 1112-1117: In asymptomatic persons undergoing discography, future LBP episodes predicted by psychometrics but not by anatomic abnormalities or painful response to injection

Curr Rev Pain 2000; 4: 301-8: pain reproduction primarily related to dye leakage through outer annulus

Agency Medical Director's Group DLI Discography Experience

- 10-15% of all fusion requests associated with discography
- DLI fusion guideline-fusion cannot be based on discography
- Nearly all of the disputed fusion cases appear to be based largely on discography
- Typical case-chronic LBP with multilevel DDD-(+) discogram is used to decide 1) whether to do fusion, and 2) at what level(s)

Lumbar Fusion and Discography

Current Agency Policy

- Coverage: Agencies have a general coverage policy including discography without specific indications or limitations
  - Currently includes patients with chronic low back pain and degenerative disc disease
  - L&I policy on fusion indicates that positive discogram is not sufficient alone as indicator for surgery
- Alternatives: The agencies cover discography alternatives, including:
  - Physical examination
  - MRI
  - Plain Radiograph (x-ray)

Agency Utilization (SFY06)

*L&I Discography prior to fusion		
137	$305,000	$2,230

* A total of 358 discographies were done. Of these, 221 injured workers did not go on to have fusion

*UMP Discography prior to fusion		
4	$8,800	$2,200

* A total of 15 discographies were done. Of these, 11 members did not go on to have fusion

*DSHS Discography prior to fusion		
7	$9,800	$1,400

* A total of 45 discographies were done. Of these, 38 clients did not go on to have fusion

Agency Medical Director's Group UW Discography Research

- Juratli et al, Lumbar fusion outcomes in Washington State workers' compensation, Spine 2006; 31: 2715-2723
  - Reoperation in 22% (N=1950) within 2 years
  - Receipt of discography, even after adjustment for important covariates, doubled the reoperation risk (OR-1.98, 95% CI 1.45-2.72)

Agency Medical Director's Group Summary of Our View

- Provocative discography is a subjective test with a high false positive rate
- Provocative discography is more likely to be (+) in the presence of psychosocial risk factors than anatomic findings

Agency Medical Director's Group Summary of Our View

- Provocative discography is not useful in predicting the outcome of fusion.
- Provocative discography does appear to independently increase the risk for reoperation, and thus the test may be indirectly harmful

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HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards. [2]

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.[3]

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

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Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	Safety Evidence
Efficacy/Effectiveness Outcomes	**Efficacy/Effectiveness Evidence**
Specificity (true negative, false negative)	
Pain Provocation- subjective finding	
Morphology	
Cost Outcomes	**Cost Evidence**
-Procedure Fee and timing	
- Referral to additional tests	
Other Factors	**Evidence**
- Impact on therapeutic decision	
- Impact on surgical success	

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
Medicare	N/A	No national coverage decision		
American Society of Interventional Pain Physicians	2007	Reserve for patients with equivocal or inconclusive MRI	Y	N/A
Work Loss Data Institute	2006	Not recommended	Y	N/A
American Association of Neurological Surgeons	2005	Recommends against surgery if MRI normal, even if positive discography Reserve for patients with equivocal findings or inconclusive MRI	Y	N/A
Guyer and Ohnmeiss, Texas Back Institute	2003	Includes in diagnostic tests	Y	N/A
Washington State Department of Labor & Industries	2002	Positive discography not a definitive indication for fusion	Y	N/A

Clinical Committee Evidence Votes

First voting question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Inconclusive (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not covered. _____ Covered Unconditionally. _____Covered under certain conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover With Conditions
If covered with conditions, the Committee will continue discussions.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence of a diagnostic tests' accuracy
    - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does the scientific evidence confirm that use of the technology can effectively replace other tests?
- Does use of the test change treatment choices
- What is the evidence that use of the technology results in a more beneficial outcome
    - Direct outcome or surrogate measure
    - Short term or long term effect
    - Magnitude of effect
    - Impact on pain, functional restoration, quality of life
    - Disease management

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?