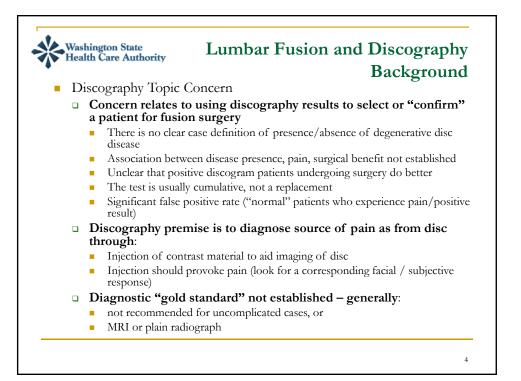
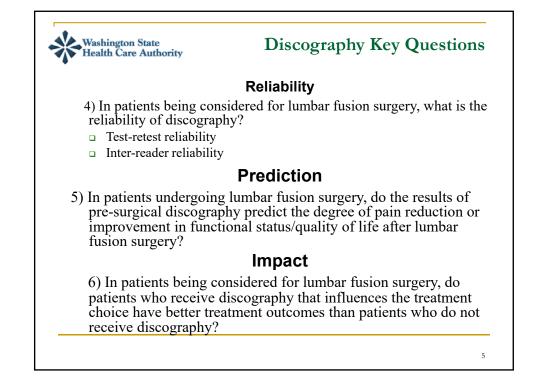
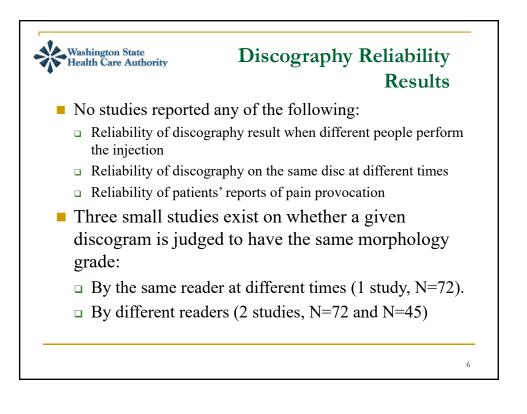


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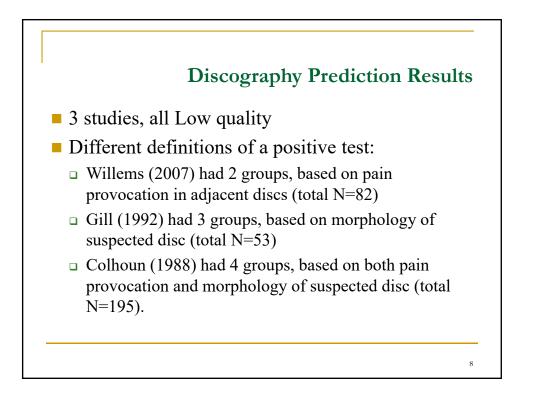
lealth Care Authority Lumbar Fusion/	Discogra
Primary Criteria	
Potential patient harm/safety concerns:	High
Concerns about therapeutic efficacy or diagnostic accuracy and appropriateness of outcomes for patients:	High
Estimated total direct cost per year (estimated increase/decrease):	High
Secondary 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

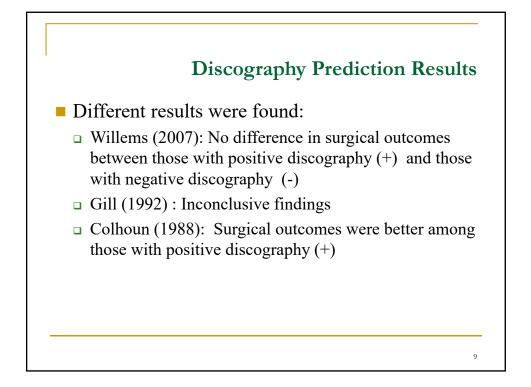


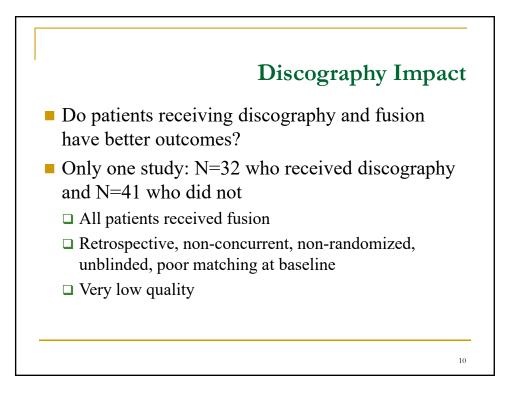


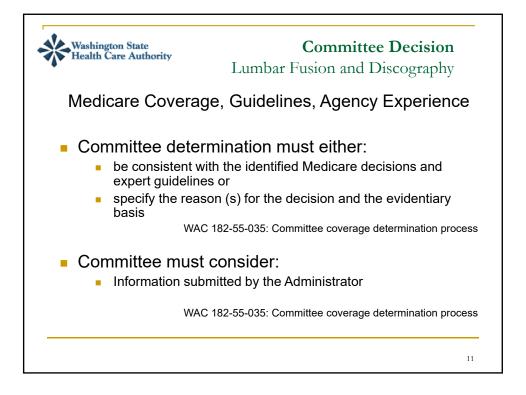


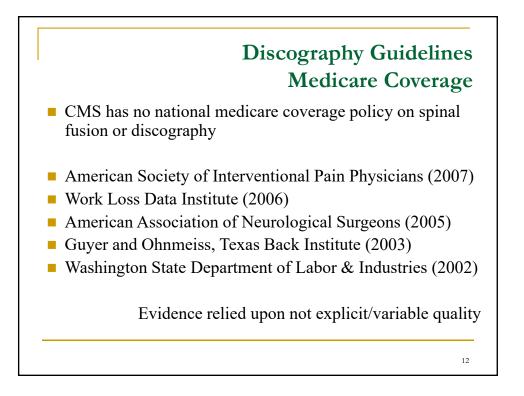
Study		Discs		System	K	appa (95% Cl)	
Agorastides (2	2002)	133		Adams classification		0.77	
		100				(0.66 to 0.87)	
Milette (1999)		132		DDD degeneration		0.67	
MIL 11 (1000)		100				(0.55 to 0.78)	
Milette (1999)		132		DDD disruption		0.66	
						(0.56 to 0.76)	
		Т	est-Retest	Reliability Da			
		T		Test-retest kappa	(95% CI)		
Study	Discs	T	Rater 1	Test-retest kappa Rater 2	(95% CI)	Rater 3	
Study Agorastides (2002)	Discs	T		Test-retest kappa Rater 2 0.85	(95% CI)	Rater 3 0.80 (0.70 to 0.90)	
		Т	est-Retest				

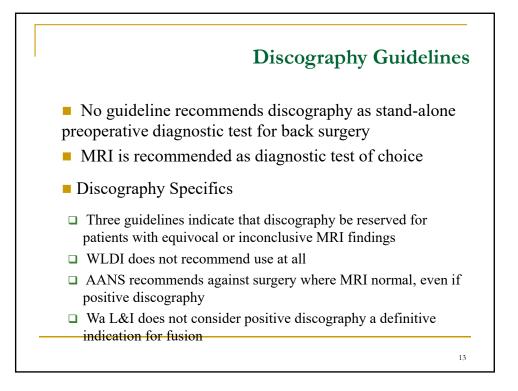


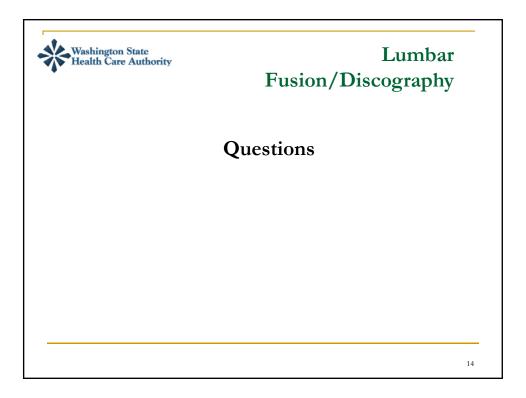






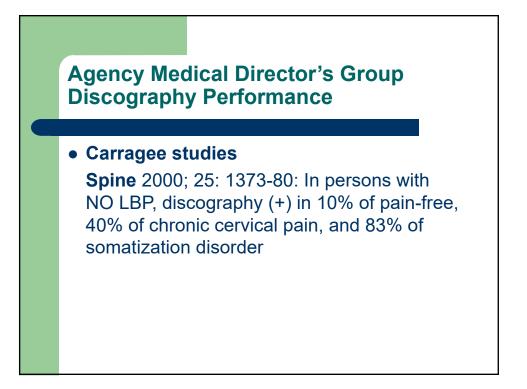








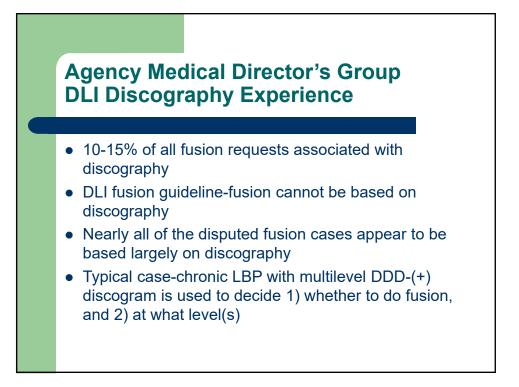
- Injection of dye under pressure at multiple disc levels
- Follow up CT to look at anatomic abnormalities consistent with DDD-most can be seen on MRI
- Subjective response to injection-1) How much does it hurt (1-10)?, and 2) Does it reproduce your usual pain (concordant pain)?



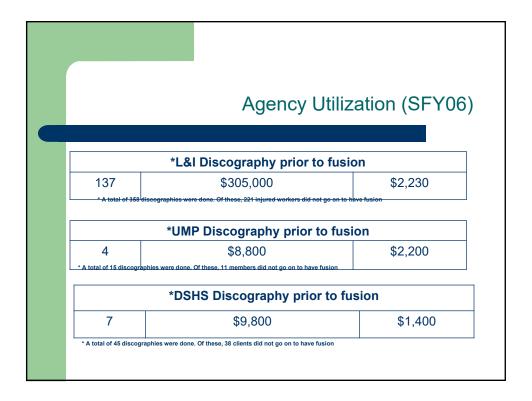
Agency Medical Director's Group Discography Performance

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

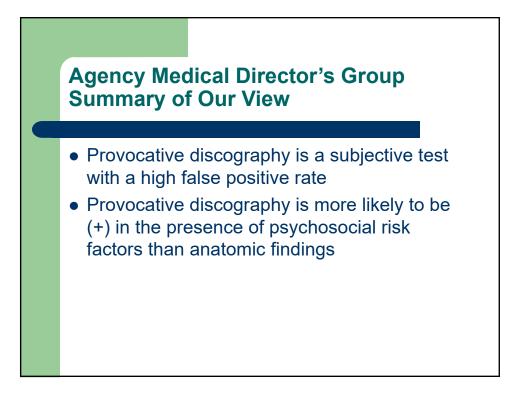






Agency Medical Director's Group UW Discography Research

- 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)

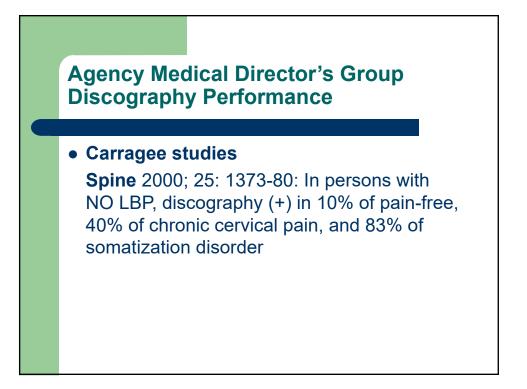


Agency Medical Director's Group Summary of Our View

- Provocative discography is 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



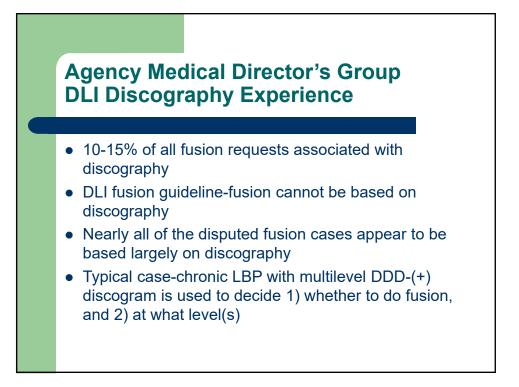
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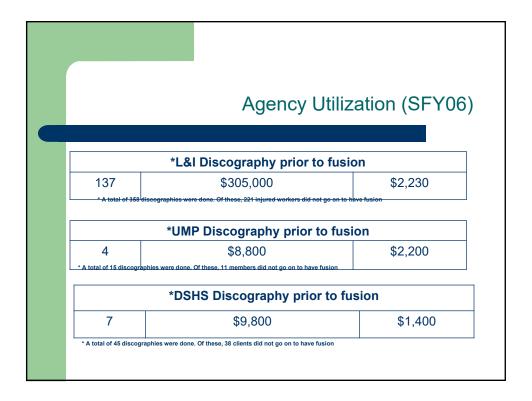
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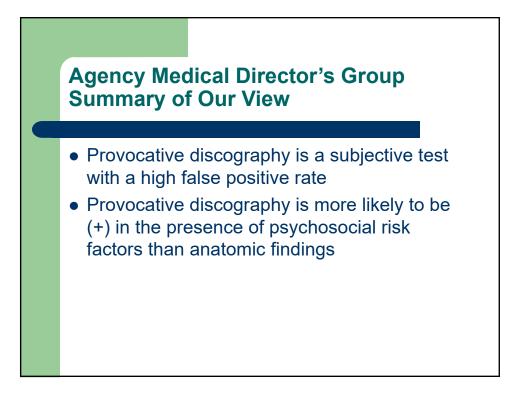






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HTCC Coverage and Reimbursement Determination Analytic Tool

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-effective¹ 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 evidence⁴ 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	Very certain of evidentiary support.
information is needed or further	Further information is unlikely to change
information is likely to change confidence.	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: <u>http://www.gradeworkinggroup.org/FAQ/index.htm</u>

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 costeffective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and costeffective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and costeffective 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
 - $\circ \quad \text{Short term or long term effect} \\$
 - Magnitude of effect
 - o Impact on pain, functional restoration, quality of life
 - Disease management

<u>Safety</u>

- 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 lifethreatening, 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?

<u>Overall</u>

- 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?