



Health Technology Assessment Program

Health Technology Clinical Committee
October 2008 Meeting

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Washington's Health Technology Assessment Program Background

- **Part of Governor's 2006 Five point health strategy for state to lead by example**
 - **Emphasize evidence-based health care**
<http://www.hca.wa.gov/conf/contf/doc/GovGregoireHealthBrief.pdf>

- **Program Purpose: Achieve better health by paying for technologies that work**
 - Better health with better information: investigate what works and maintain a centralized website.
 - Open and transparent process: publish process, criteria, reports, and committee decisions in public meeting.
 - Eliminate Bias: contract for independent evidence report and independent clinical committee.
 - Promote consistency: state agencies rely on a single, scientifically based source.
 - Flexible: review evidence regularly to ensure update information is included.

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Why Now

WA Blue Ribbon Commission

TODAY (2007 Report Findings):

- There are roughly **593,000 Washingtonians without health care** coverage, including 73,000 children.
- The **annual increase in insurance premiums** for small businesses in Washington is **greater than the increase in wages** or gross business income, some years by a factor of five.
- The **state spends an estimated \$4.5 billion** on health care, up from \$2.7 billion in 2000. Share of the state budget going to health care has increased from 22 percent in 2000 to 28 percent today.
- The United States **spends more** on health care than any other country, but **ranks 28th** in life expectancy and 37th in health system performance.
- **Approximately 20 to 30 percent of current health expenditures do not improve or extend life. It is also estimated that adult patients receive the recommended care only 55 percent of the time.**

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Why Health Technology

Health Care Context

- **Part of an overall strategy**
- **Medical technology is a primary driver of cost**
 - The development and diffusion of medical technology are primary factors in explaining the persistent difference between health spending and overall economic growth.
 - Some health experts arguing that new medical technology may account for about one-half or more of real long-term spending growth.
[Kaiser Family Foundation](#), March 2007: [How Changes in Medical Technology Affect Health Care Costs](#)
- **Medical Technology has quality gaps**
 - Medical technology diffusing without evidence of improving quality
Highly correlated with misuses, overutilization, underutilization.
Cathy Schoen, Karen Davis, Sabrina K.H. How, and Stephen C. Schoenbaum, "U.S. Health System Performance: A National Scorecard," *Health Affairs*, Web Exclusive (September 20, 2006): w459

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ConsumerReports.org

10 overused tests and treatments November 2007

1 BACK SURGERY. ... surgery, which can cost \$20,000 plus physician's fees

2 HEARTBURN SURGERY. operation, costs \$14,600 or more

3 PROSTATE TREATMENTS. . . over treated with surgery that costs \$17,000, or by radiation therapy for \$20,700

4 IMPLANTED DEFIBRILLATORS. ... cost some \$90,000 over a lifetime.

5 CORONARY STENTS. Billions are spent each year....

6 CESAREAN SECTIONS. ..cost almost \$7,000, about 55 percent more than natural delivery...

7 WHOLE-BODY SCREENS. CT scans, which can cost \$1,000 ... no proven benefits for healthy people. A few CT scans a year can increase your lifetime risk of cancer.

8 HIGH-TECH ANGIOGRAPHY. Using a CT ... costs an average of \$450...standard angiography is sometimes still needed.

9 HIGH-TECH MAMMOGRAPHY. Using software to flag suspicious breast X-rays would add \$550 million a year to national costs if used for all mammograms. But a 2007 study found that this technique failed to improve the cancer-detection rate significantly, yet resulted in more needless biopsies.

10 VIRTUAL COLONOSCOPY. ... Though less costly than a standard colonoscopy, the virtual test isn't cost-effective because any suspicious finding requires retesting with the real thing.

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- Issue: WA citizens pay high cost for health care and receive poorer outcomes
- Common reaction: “Thin the soup or cut the line”
 - Reduce Eligibility, Rates, or Benefits

Vision: Transform WA state from a passive payer to an active purchaser of higher quality, more efficient health care

- Focus: Variability in care is a sentinel of higher cost and worse outcome.

“Better ingredients in the soup make it go farther”

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Outcome: Pay for What Works

- Coverage decisions:
 - scientifically based
 - use transparent process, and
 - consistent across state health care purchasing agencies

- Formal, systematic process to identify, review, and cover appropriate health care technologies.
 - Is it safe?
 - Is it effective?
 - Does it provide value (improve health outcome)?

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HTA Program – 18 Month Outcomes

- **Identifying Potential Waste:** Ten technologies have been selected because of unsettled issues about the evidence of their safety, effectiveness, and/or value. Of these ten HTA technologies, five identified by Consumer Reports as “Medical Ripoffs”

- **Amass and Rate the data:** For the first seven technologies, out of the hundreds of thousands of articles,
 - 5,422 potentially relevant articles were identified, and
 - 127 were thoroughly and critically appraised
 - The seven comprehensive, unbiased, peer-reviewed technology assessment reports that summarize and rate clinical literature and highlight that many technologies have widespread use despite unreliable, low quality, or absent data on health benefit and value.

- **Purchasing Decisions Aligned with Evidence of Patient Centered Health Benefits:** The committee has concluded that evidence on five technologies do not currently demonstrate net health benefit and therefore should not be covered. Two technologies have evidence that demonstrate net health benefit in some circumstances, and are covered with conditions. This will reduce health care expenditures on unproven, unsafe, or ineffective medical interventions.

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Health Technology Assessment Program

Health Technologies			Evidence			Decision	
Topic	Report	Date	Safe?	Effective?	Cost?	Health Benefit	Coverage
Upright MRI	X	May-07	Equal	Inconclusive	More	N/A	No
Ped Bariatric Surgery <18	X	Aug-07	Inconclusive	More	Inconclusive	No	No
Ped Bariatric Surgery 18-21	X	Aug-07	Less	More	Inconclusive	Yes	Yes/ Conditions
Lumbar Fusion	X	Nov-07	Less	Equal/More	More	Yes	Yes/ Conditions
Discography	X	Feb-08	Inconclusive	Inconclusive	Inconclusive	No	No
Virtual Colonoscopy (CTC)	X	Feb-08	Equal	Equal/More	More	No	No
Intrathecal Pump for	X	Feb-08	Inconclusive	Inconclusive	Equal	No	No
Arthroscopic Knee Surgery	X	Aug-08	Less	Equal	Less	No	No
Artificial Discs		Oct-08					
Computed Tomographic Angiography(cardiac care)		Nov-08					
Cardiac Stent (Off-label Use)		Jan-09					

Measure Health Technology Assessments Completed and in progress
Data Source: Health Technology Assessment Program
Comments: Values for evidence categories are relative to alternative accepted therapies.
EA *



HTA Outcomes: GMAP

- Government Management and Accountability Program (GMAP)
 - Governor led status checks on her government priorities
 - Health Care has four categories: Access, Healthy State, Quality, and Cost
 - Quality includes two measures: evidence based care management and Chronic care management
- Presented October 8th 2008
- **Result expected:** Decisions correlating with evidence on good health outcomes and are we paying for things that work
- **Comments:** Express appreciation for clinicians in this very difficult and important work, “this is cutting edge”



HTA Outcomes: Senate Update

- **WA Senate Health and Long Term Care Committee Meeting 9/4/08**
- 2007 Blue ribbon commission: Emphasize EBM; IOM Bending the Curve
 - Patient Decision Aids, Technology Assessment
- **Result expected:** Using scientific evidence and clinician panel, not state bureaucracy to decide on which treatments work
- **Comments:** Recognition by Chair, Senator Karen Keiser that this is very difficult and important work

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HTA: Other Updates

Presentations

- Maine Governor Health Policy –Sept. briefing
- New York Medicaid – October briefing
- Public Sector Health Care Roundtable - 2008 Conference, Washington DC

Others Reviewing

- Private Health Plans – Washington
- CMS – Medicare Coverage Center and Local Carriers
- Consumers Union

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HTA Program – Ongoing Operations

Pay for What Works: Better Information is Better health

- Coverage Decisions
 - Approximately Eight technologies per year
 - Consider for re-review at least every 18 months
- Evidence Reports
 - Re-procurement of vendors
 - Continue investigating collaborative efforts
- Clinical Committee
 - Re-appointment criteria, training, retreat
- Implementation
 - Metrics, Impact

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Potential 2009 Topics

	<i>Safety</i>	<i>Efficacy</i>	<i>Cost</i>
Glucose Monitoring	Med	High	High
Sleep Apnea Diagnosis and Treatment	Med	High	Med
Calcium Scoring for Cardiac Disease	Med	High	High
Vagal Nerve Stimulation	High	High	High
Elective Cesarean Section	High	High	High
Hip Resurfacing	Med	High	Low
Osteoarticular Transfer System – Cartilage Surgery (OATS procedure)	Med	High	Low
Bone Growth Stimulators	Low	High	Med
Massage Therapy for Chronic Head, Neck and Back Pain	Low	High	Med
Transcutaneous Electrical Neural Stimulation (TENS procedure)	Low	High	Low
Essure Permanent Birth Control Procedure	High	High	Low
Breast Cancer Tumor Screening	Low	High	Low

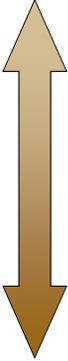
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Artificial Disc Replacement

Process Overview

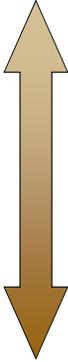
1. HCA Administrator Selects Technology
Nominate, Review, Public Input, Prioritize
↓ *Semi-annual*
2. Vendor Produce Technology Assessment Report
Key Questions and Work Plan, Draft, Comments, Finalize
2-8 Months ↓
3. Clinical Committee makes Coverage Determination
Review report, Public hearing
↓ *Meet Quarterly*
4. Agencies Implement Decision
Implements within current process unless statutory conflict

Hierarchy of Evidence

- 
- Best:** Meta-analysis of large randomized head-to-head trials.
- Large, well-designed head-to-head randomized controlled clinical trials (RCT):
- Long-term studies, real clinical endpoints
 - Well accepted intermediates
 - Poorly accepted intermediates
- Smaller RCTs, or separate, placebo-controlled trials
- Well-designed observational studies, e.g., cohort studies, case-control studies
- Safety data without efficacy studies
- Case series, anecdotes
- Least:** Expert opinion, non-evidence-based expert panel reports, and other documents with no direct clinical evidence

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Evidence in Health Care Decision Making

- 
- **Level 3:** *“What would I recommend to the state or nation?”*
 - **Must be based on rigorous assessment of the scientific evidence.**
 - **Affects hundreds of thousands, even millions of people.**
 - **Level 2:** *“What would I recommend to my patient/client?”*
 - Influenced by prior experience, but the scientific evidence may play a greater role.
 - Affects possibly hundreds of people.
 - **Level 1:** *“Would you have this done for yourself or for someone else in your immediate family?”*
 - Influenced by one’s personal experience with the disease and capacity to deal with risk.
 - Affects few people.

Used with Permission from [Dr. Mark Helfand](#), OHSU

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Different Data Sources

- Efficacy
 - How technology functions in “best environments”
 - Randomized trials-distinguish technology from other variables
 - Meta-analysis
- Effectiveness
 - How technology functions in “real world”
 - Population level analyses
 - Large, multicenter, rigorous observational cohorts (consecutive pts/objective observers)
- Safety
 - Variant of effectiveness
 - Population level analyses
 - Case reports/series, FDA reports
- Cost
 - Direct and modeled analysis
 - Administrative/billing data (charge vs cost)
- Context
 - Mix of historic trend, utilization data, beneficiary status, expert opinion

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Back and Neck Pain

- Back and neck pain are common conditions, with 60% – 80% of U.S. adults afflicted at some time during their life.
- Back pain, and then neck pain, is the most common cause of disability and loss of productivity.
- Approximately 90% of low back pain is of the nonspecific type, and a similar majority of neck pain is non-specific.
- Most patients’ symptoms resolve satisfactorily within a relatively short time span (within six weeks).

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Back and Neck Pain

- Non-surgical treatments include cognitive behavioral therapy, medications, and rehabilitation
 - Rehabilitation includes psychological care, exercise, education, interdisciplinary rehabilitation, and spinal manipulation.
- In 5–10% of patients, pain does not resolve; symptoms can be disabling; physical, social and economic impact is enormous.
- Discovering the cause for continuing nonspecific low back and neck pain symptoms remains challenging.
- For patients with unresolved pain, surgical treatment is considered.

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Artificial Disc Replacement

- The predominant surgical treatment has been fusion. Spinal fusion is used to reduce pain by immobilizing the spinal column vertebrae surrounding the disc that is thought to cause pain.
- Fusion results remain controversial, and one aspect, accelerated adjacent disc degeneration, led to ADR development.
- ADR is the complete removal of the damaged disc and implantation of an artificial disc.
- The intent is to treat the pain and disability believed to be caused by the degenerative disc disease by removing the diseased disc.

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ADR Potential Benefits

- Primary potential benefits
 - Pain relief
 - Functional restoration (quality of life, return to work)
 - Resolves potential fusion surgery issues
 - Preserve normal range of motion
 - Restore disc height

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Potential Drawbacks

- Surgical intervention is controversial and there are high variation in rates, techniques, indications
- Adding instrumentation to resolve a side effect of fusion surgery (ASD)
- Safety Issues
 - Device/ Mechanical complications
 - Surgical Complications
- Permanent implantation implications
 - Non-life threatening condition with unknown resolution
 - Generally middle age candidates
 - Maintenance and revisions required –risks with each surgery;
- Device and added technique costs for unknown benefits

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Agency Prioritization

- **Efficacy concern: High**
 - Unclear that the proposed benefit of adding device to surgery in order to preserve motion is actually achieved and results in better health outcomes
 - The advantages of ADR as better than medical management are not measured at all
 - The advantages of ADR as better than fusion are not measured with current non-inferiority trials
- **Safety concern: Medium-High**
 - Short term – surgical risks, mechanical failure of the implant, re-operation
 - Long term - mechanical failure of the implant; spontaneous fusion
- **Cost Concern: Medium**
 - adding device costs and additional surgical procedures to spinal pain treatment benefits will cost more with no better outcome
 - Long term viability of devices is not currently understood, yet most patients are middle age

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Medicare Coverage and Clinical Guidelines

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
Medicare	2007	Lumbar ADR only, no cervical national coverage decision. CMS will not cover lumbar ADR for patients older than 60. No national coverage determination for under 60 years of age.	Yes	Appraisal scheme for assessing study quality described.
No clinical guidelines related to use of artificial discs				

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Questions?

Agency Utilization and Outcomes Information

Health Technology Clinical Committee
Artificial Disc Replacement

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Key Concerns for Prioritization

- **Efficacy concern: High.**
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Potential Washington Agencies Populations Eligible for ADR

- **State agency annual Fusion utilization:**
 - 1435 surgeries
 - average per surgery cost **\$27,311**
 - Total annual cost **\$38,588,892**

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Potential Washington Agencies Populations Eligible for ADR

LUMBAR FUSION UTILIZATION

Annual Lumbar Fusion Utilization - SFY2006

Agency	Patients	Average cost	Total Cost
L&I	435	\$37,200	\$16,100,000
PEHP	122	\$34,500	\$4,218,718
DSHS	175	\$21,000	\$3,602,080
Lumbar Totals	732	\$32,679	\$23,920,798

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Potential Washington Agencies Populations Eligible for ADR

Annual Cervical Fusion Utilization - SFY2007

Agency	Patients	Average cost	Total Cost
L&I	341	\$20,658	\$7,403,593
PEHP*	122	\$26,254	\$2,601,431
DSHS**	240	\$20,927	\$5,022,175
Cervical Totals	703	\$21,527	\$15,027,199

*Average cost based on primary payer average cost only.

**DSHS utilization from 2006.

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Agency Coverage Determination (Artificial Disc for Lumbar and Cervical)

- **Coverage Policy:** Agencies consider the artificial disc to be experimental and investigational. It is either non-covered or requires a client to be in a registered trial
- **Evidence Review Scope:** The agencies are requesting a review for artificial disc for the patients with FDA indications of the lumbar and cervical spine disease.

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State Agency Coverage Policy

The agencies cover alternatives*

- Medications (Acetaminophen, NSAID, etc.)
- Rehabilitation
 - Physical Therapy
 - Psychological
 - Exercise, education
 - Interdisciplinary Rehabilitation
- Spinal manipulation
- Alternative and Complimentary medicine (massage, acupuncture)
- Surgical: Spine fusion (currently working on a chronic pain program and physical conditioning benefit)

*Coverage varies by agency

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Artificial Disc Replacement (Possible Codes and Billing)

The below table outlines agency administrative codes that could potentially be billed for ADR.

- Facility Fees/Hospital
- Professional Fees
 - General / vascular surgeon (lumbar)
 - Orthopedics / Neurosurgeon (lumbar & cervical)
 - Anesthesia
 - Radiology
- No clear history on second outcomes
(e.g. re-hospitalization and outliers)

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Agency Conclusions

- Consistent with systematic reviews indicate:
 - The benefit and harms are not clear from the research (e.g. clinical expertise needed for ADR placement)
 - Insufficient evidence to address significant issues:
 - Important and more objectively measured health outcomes
 - Return to work, reduced disability, clinically significant metrics; applicability beyond single level
 - Client selection is not clear for who will benefit and who could be harmed
 - Long term ramifications and safety of the products is not clear

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Artificial Disc Replacement

Questions?

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**State Agency Experience
Artificial Disc Replacement
October 17, 2008**

Health Technology Assessment
676 Woodland Square Loop SE
PO Box 42712
Olympia, WA 98504-2712
Phone 360-923-2742.
www.hta.hca.wa.gov

Agency Experience & Background

Disease / condition introduction

Back and neck pain are common conditions, with sixty to eighty percent of U.S. adults afflicted at some time during their life. Back pain, and then neck pain, is the most common cause of disability and loss of productivity. Approximately 90% of low back pain is of the nonspecific type, and a similar majority of neck pain is non-specific. Most patients' symptoms resolve satisfactorily within a relatively short time span (within six weeks). Non-surgical treatments for include cognitive behavioral therapy, medications, and rehabilitation (including psychological care, exercise, education, interdisciplinary rehabilitation, and spinal manipulation).

In 5 – 10% of patients, pain does not satisfactorily resolve and the symptoms can be disabling and the social and economic impact of chronic pain is enormous. Discovering the cause for nonspecific low back and neck pain symptoms remains challenging. Some psychosocial risk factors for the progression to chronicity have been identified, but the origin and neurophysiologic pain sensations are poorly understood. Frequently, persistent pain is attributed to a damaged intervertebral disc. Disc damage, or degeneration, can occur as an ongoing process where ultimately the disc's reparative capacity is overwhelmed. Degenerative disc disease is common in middle age and a universal condition in old age, though not all individuals experience pain. For these patients with unresolved pain, surgical treatment is considered.

Washington agencies current coverage for the disease

The agencies cover many treatments for back and neck pain, including but not limited to (single or in combination):

- Cognitive behavioral therapy
- Medications (anti-depressant, Acetaminophen, NSAID)
- Rehabilitation
- Psychological
- Exercise, education
- Interdisciplinary Rehabilitation
- Spinal Manipulation
- Spinal Fusion

Washington agencies are interested in new technologies that will offer more effective relief and fewer incidence of harm at lower or equivalent cost. However, based on the low evidentiary ratings, all agencies currently consider Artificial Disc Replacement (Lumbar and Cervical) experimental and investigational. Medical consultants reviewed evidence ratings from HAYES and ECRI as well as Medicare coverage policy and other technology assessments.

ADR Technology

The predominant surgical treatment has been fusion. Spinal fusion is used to reduce pain by permanently immobilizing the spinal column vertebrae surrounding the disc(s) that is (are) thought to cause pain. Indications for spinal fusion are variable and not clearly defined. These different opinions

concerning the indications for surgery are reflected in the significant regional variation of rates of surgery, surgical techniques used, technical success, and rate of fusion. The effectiveness of fusion for chronic degenerative disc disease is not well established. Short term relief of pain may occur with the various types of fusion procedures, but long-term results remain controversial, particularly accelerated adjacent degeneration.

In response to fusion concerns, ADR was developed and is the complete removal of the damaged disc and implantation of an artificial disc. The intent is to treat the pain and disability believed to be caused by the degenerative disc disease by removing the diseased disc, with the primary potential benefits of preserving normal range of motion and restoring disc height.

Additionally, concerns remain due to the controversial diagnosis and management of back pain and the uncertainty over the extent of benefit of surgery. Further, unlike fusion where recent trials suggest intensive physical and behavioral therapy produce equivalent outcomes, ADR has not been directly compared to these interventions. Finally, given that the target population requiring discs are aged 30 to 50 years, disc implants need to last up to 40 years to avoid the need for repeat procedures and the intervention itself needs to be assessed for long term health improvement.

HTA Review Request

Given the wide prevalence and burden of chronic neck and back pain, additional evaluations (particularly the Blue Cross Blue Shield Technology Assessment), potential technological advances, continued dissemination pressure, and concerns about cost impact, the state agencies referred ADR to the HTA program for a more thorough evidence review of safety, efficacy, and cost-effectiveness and a consideration.

Key concerns for prioritization:

ADR Agency Concerns

- **Efficacy concern: High.**
 - Unclear that the proposed benefit of adding device to surgery in order to preserve motion is actually achieved and results in better health outcomes.
 - The advantages of ADR as better than medical management are not measured at all.
 - The advantages of ADR as better than fusion are not measured with current non-inferiority trials.
- **Safety concern: Medium-High**
 - Short term – surgical risks, mechanical failure of the implant, re-operation.
 - Long term -- mechanical failure of the implant; spontaneous fusion.
- **Cost Concern: Medium.**
 - Adding device costs and additional surgical procedures to spinal pain treatment benefits will cost more with no better outcome.
 - Long term viability of devices is not currently understood, yet most patients are middle age.

Current State Agency Medical Policy

All agencies analyze procedure codes as a part of an annual review of procedure codes and rates. As noted above, agencies concluded that ADR procedure was investigational. Itemized lists of procedure codes not covered due to investigational status are updated yearly.

The table below contains the medical policy language for each agency when procedures are deemed investigational.

Table: Investigational Procedures Policy

Current State Agency Investigational Procedures Medical Policy
<p>Medicaid: Itemized procedures by CPT code are <u>not</u> a covered service as they were deemed “investigational” by Medicaid medical consultants. According to WAC 388-531-0050 and 388-531-0150, a service is considered “investigational” if it is not generally accepted by medical professionals as effective and appropriate for the condition in question; or is not supported by an overall balance of objective scientific evidence, in which the potential risks and potential benefits are examined, demonstrating the proposed service to be of greater overall benefit to the client in the particular circumstance than another, generally available service. For services deemed experimental, providers can request an exception through Medicaid’s Utilization Review Clinical Committee.</p>
<p>Uniform Medical Plan: Itemized procedures by CPT code are <u>not</u> a covered service as they were deemed “investigational” by UMP medical consultants. According to UMP’s Summary of Benefits, a service or supply is considered experimental or investigational if it is under continued scientific testing and research concerning safety, toxicity, or efficacy and is unsupported by prevailing opinion among medical experts (as expressed in peer-reviewed literature) as safe, effective, and appropriate for use outside the research setting. Providers may request an exception through the UMP medical review staff.</p>
<p>Labor and Industries: Itemized procedures by CPT code are <u>not</u> a covered service as they were deemed “investigational” by Labor and Industries medical consultants. WAC 296-20-01002 outlines that in no case shall services which are inappropriate to the accepted decision or which present hazards in excess of the expected medical benefits be considered proper and necessary. Services that are controversial, obsolete, investigational or experimental are presumed to not be proper and necessary. Providers may request an exception through the medical director.</p>

State Agency Experience

Washington State background information:

- State agency enrollment (PEHP/DSHS FFS/L&I): 773,000

State agency annual Fusion utilization: 1435 surgeries Average Cost \$27,311 Total \$38,588,892

Annual Lumbar Fusion Utilization - SFY2006

Agency	Patients	Average cost	Total Cost
L&I	435	\$37,200	\$16,100,000
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Cervical Totals	703	\$21,527	\$15,027,199

*Average cost based on primary payer average cost only.

**DSHS utilization from 2006. Also, generally DSHS average unit costs are significantly lower due to reimbursement rate differences among the agencies. One unique factor here is that DSHS cases include a high number of lab and radiology charges.

State agencies have very limited experience with ADR. Although considered investigational, in 2006-2007, UMP did approve 3 artificial disc replacements (1 lumbar and 2 cervical), with currently available cost data displayed below.

Lumbar and Cervical Artificial Disc Replacement:

Procedure	Patients	Cost
Cervical ADR	2	\$ 23,710.00
Lumbar ADR	1	\$ 23,082.00
Average ADR Cost		\$ 15,597.33

*Currently available data is incomplete because it includes only the inpatient and professional charges coded with the disc replacement procedure code, and therefore has missing components related to the surgery such as second surgeon, anesthesiologist, etc.



SRI

Artificial Disc Replacement (ADR) in the Lumbar and Cervical Spine

**Health Technology Clinical Committee Meeting
Washington State Health Technology Assessment
Program**

Joseph R. Dettori, Ph.D., M.P.H.
Andrea C. Skelly, Ph.D.
Robin E. Hashimoto, Ph.D.
Erika Ecker, B.A.

Seattle, Washington
Oct 17, 2008



SPECTRUM
RESEARCH

Scope of Report

This report evaluates relevant published research describing use of lumbar and cervical artificial disc replacement (ADR)

ADR refers to mechanical total disc arthroplasties and not nucleus replacements, annular reconstruction techniques or other forms of intradiscal spacers



Background

What would be the ideal disc spacer?

- Alleviates pain and improves function
- Preserves flexibility
- Restores stability
- Has material strength to withstand normal forces
- Limits adjacent level stress transference



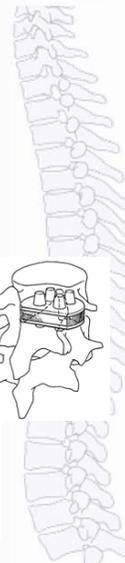
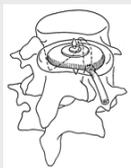
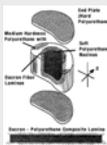
Background

- Nearly 50 years of research into artificial disc replacement
- Early attempts to replace nucleus
 - Methyl-acrylic into disc space (1955-Cleveland)
 - Self-curing silicone (1962-Nachemson)
 - Swedish Ball Bearings (1964- Fernström)
 - Research continues in nucleus replacement



Background

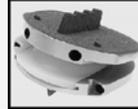
- Early attempts to replace entire disc
 - Numerous design types
 - Hinged
 - Spring loaded
 - Low friction sliding surfaces
 - Constrained fluid filled chambers
 - Elastic disc prostheses



Contemporary L-ADR Designs

- **Lumbar**

- Charité III (DePuy Spine, Raynham, MA)
- ProDisc (Synthes, Paoli, PA)
- Flexicore Disc (Stryker, Allendale, NJ)
- Maverick Disc (Medtronic, Memphis, TN)



Contemporary C-ADR Designs

- **Cervical**

- Prestige ST (Medtronic, Memphis, TN)
- Prodisc-C (Synthes, Paoli, PA)
- Bryan disc (Medtronic, Memphis, TN)



What spine disease is treated by ADR?

Lumbar spine –

- Skeletally mature
- DDD at one level without neurological deficit
- No more than grade 1 spondylolisthesis
- No relief from pain after 6 months of non-surgical care

Cervical spine –

- Skeletally mature
- DDD or HNP at one level resulting in radiculopathy or myelopathy
- No relief from pain after 6 weeks of non-surgical care

ADR – Key Questions

1. What is the evidence of efficacy and effectiveness of ADR compared with comparative therapies?
2. What is the evidence related to the ADR safety profile?
3. What is the evidence of differential efficacy or safety issues amongst special populations?
4. What are the cost implications and cost effectiveness for ADR?

Inclusion Criteria

Study design

- Key Question 1 - Randomized controlled trials (RCTs) and comparative studies with concurrent controls
- Key Questions 2 & 3 - RCTs and comparative studies with concurrent controls (some case-series briefly summarized for context)
- Key Question 4 - formal economic analyses and cost data reported in other systematic reviews or technology assessments

Inclusion Criteria

Publications

- Peer-reviewed full-length publications (no meeting abstracts or supplements)
- English language publications
- FDA reports

L-ADR: Summary of Safety and Effectiveness Data (SSED), In-depth Statistical Review, In-depth Clinical Review

C-ADR: Summary of Safety and Effectiveness Data (SSED), Executive Summary of FDA panel meeting

Literature Search

- We searched 13 electronic databases through May 08
- 120 articles identified for lumbar and 56 for cervical
- **Lumbar KQ1-3:** 2 Index Studies (FDA) included
 - 1 Charité, 1 Prodisc-L
- **Lumbar KQ4:** 2 reports included
- **Cervical KQ1-3:** 2(+) Index Studies (FDA) included
 - 1 Prestige ST, 1 Prodisc-C, 1(-) Bryan
- **Cervical KQ4:** 0 reports included



Literature Search

- All included studies compared ADR with spinal fusion
- No comparative studies were found that directly compared ADR with continued nonoperative care or with surgical treatment other than fusion



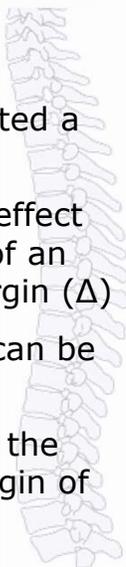
Data Analysis

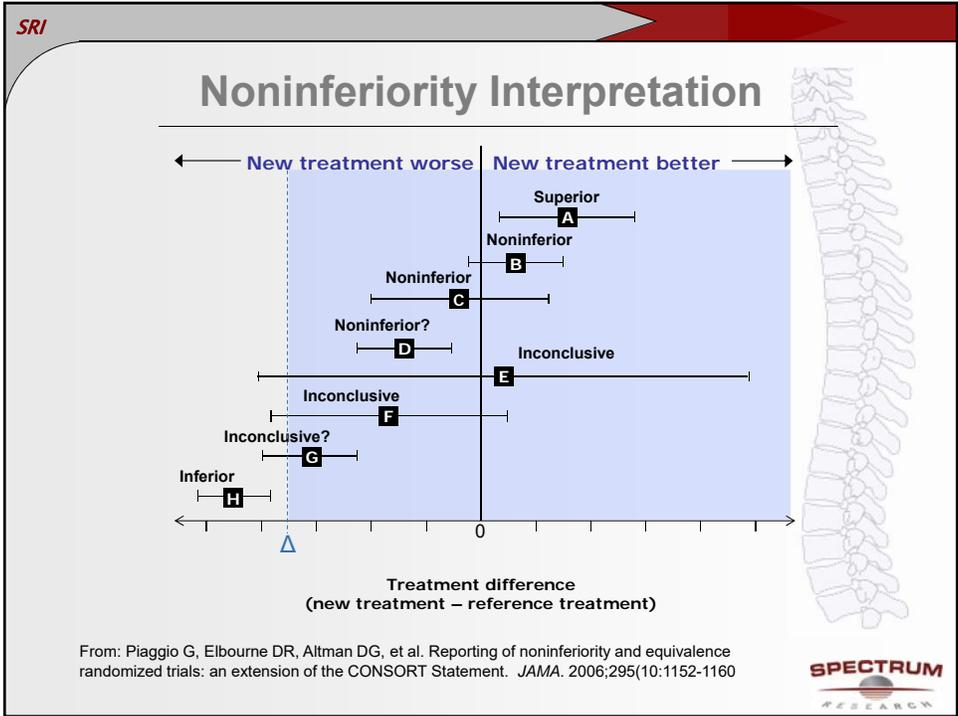
- Meta-analysis when 2 or more RCTs were available and no clinical or statistical heterogeneity
- Risk differences reported for dichotomous data
- Two analyses were performed: intent-to-treat (ITT) and completer-only



Noninferiority Studies

- All FDA trials reported in this report conducted a noninferiority study design
- Noninferiority is intended to show that the effect of a new treatment is not worse than that of an active control by more than a specified margin (Δ)
- However, superiority in this type of design can be demonstrated
- Interpretation depends on where the CI for the treatment effect lies relative to (1) the margin of noninferiority, Δ and (2) the null effect





SRI

RCTs comparing L-ADR with spinal fusion

Study	Demographics	ADR	Fusion	Follow-up
Blumenthal et al. 2005	Mean age: 40 % male: 52	Charité n = 205	ALIF* n = 99	2 years
Zigler et al. 2007	Mean age: 39 % male: 49	Prodisc-L n = 161	Circumferential n = 75	2 years

*anterior lumbar interbody fusion

SPECTRUM
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Internal Validity

- Blumenthal et al.
 - no *a priori* statistical plan
 - low f/u rate using all patients randomized (79% ADR, 68% fusion)
 - no intention to treat analysis
 - treatment groups with potentially important differences at baseline
- Zigler et al.
 - no report on whether random assignment was concealed
 - follow-up rate 88% ADR, 86% fusion
- Neither had blinding of patients or outcome assessors



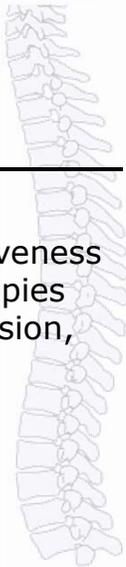
Generalizability

- Both studies included single level DDD after 6 months of failed conservative treatment
- One study included implant levels from L3-4 to L5-S1, the other included L4-5 and L5-S1
- Fusion strategies: one study used ALIF, one circumferential fusion
- Patients: Average age 39-40 years, 49-52% males



Key Question 1 (lumbar)

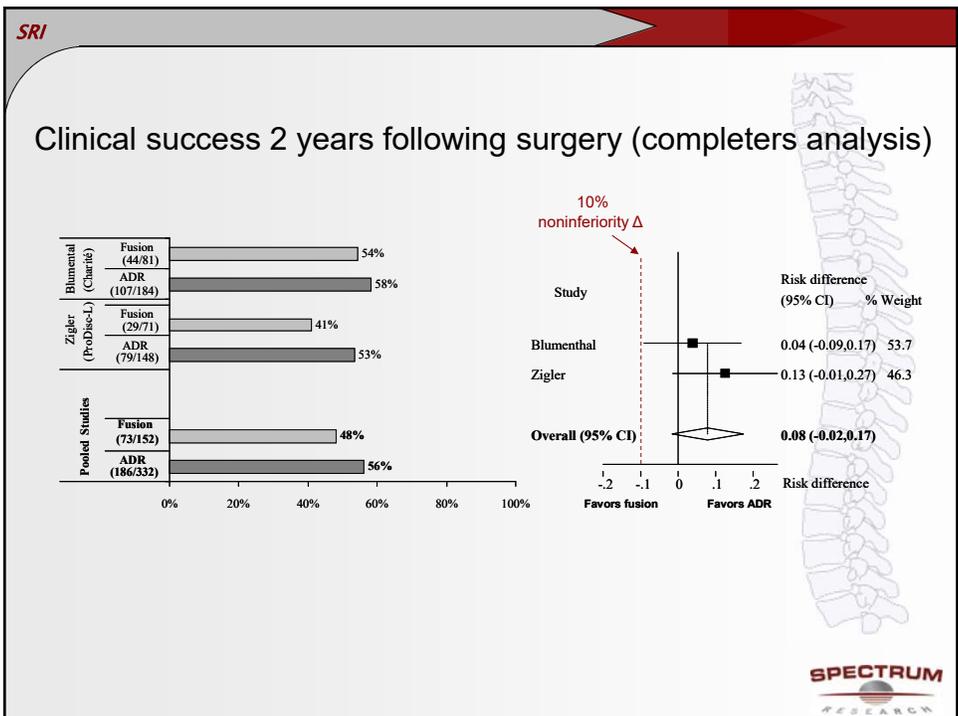
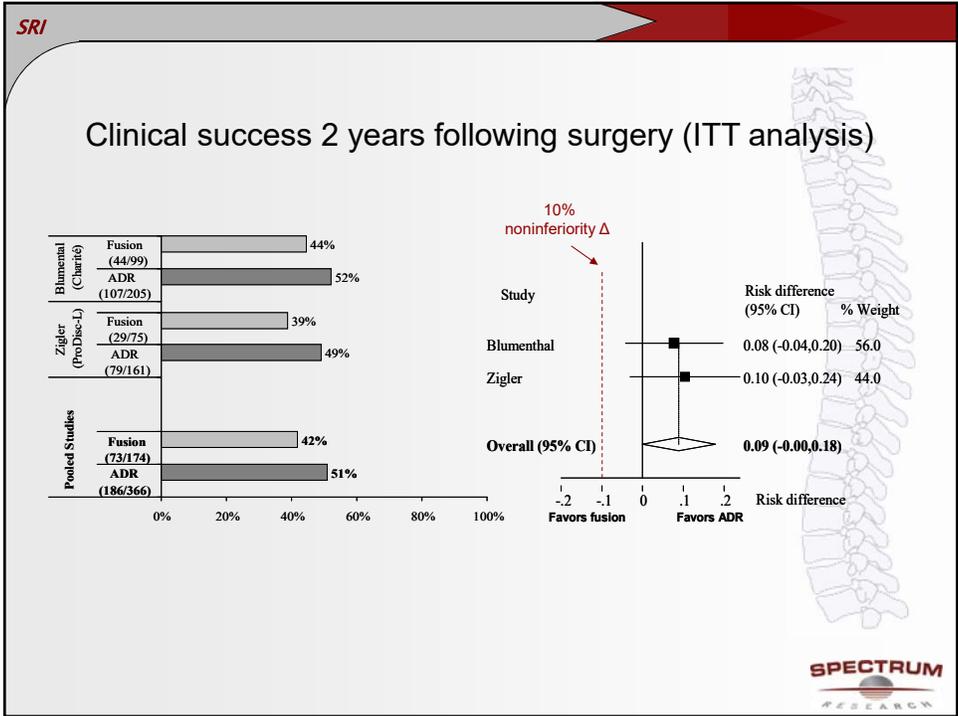
What is the evidence of efficacy and effectiveness of ADR compared with comparative therapies (including nonoperative therapy, spinal fusion, other surgery)?



Outcomes efficacy/effectiveness

1. Overall clinical success (FDA), a composite:
 - ODI improvement (≥ 15 points from baseline)
 - No device failure (revision, reoperation, removal)
 - No neurological deterioration compared with preoperative status
 - Blumenthal et al. added no major complication, Zigler et al added any improvement in SF-36 and radiographic success
2. ODI improvement (≥ 15 points from baseline)
3. Neurological success (no deterioration from baseline)
4. Pain reduction compared with baseline





Results

1. Overall Clinical Success Composite Outcome

Not inferior to fusion

L-ADR (56%) vs. lumbar fusion (48%)

RD = 8%, (CI = -2 to 17%)

2. ODI improvement of ≥ 15 pts over baseline

Not inferior to fusion

L-ADR (65%) vs. lumbar fusion (57%)

RD = 9%, (CI = -0 to 18%)



Results

3. Pain

Not inferior to fusion

Reduction in pain from baseline similar between groups with respect to VAS and narcotic use

4. Neurological success

Not inferior to fusion

L-ADR (91%) vs. lumbar fusion (81-95%) depending on study



Results

5. Patient satisfaction

Tended to be higher with L-ADR vs. fusion

6. Preservation of motion

Post-op as good or better than pre-op segmental motion after 2-3 years - (improved with surgical technical accuracy)

Motion at L4-5 similar to asymptomatic controls >10 year F/U

7. Radiographic (asymptomatic) ASD

2 studies with ≤ 10 years of F/U: 0% and 24% with lumbar ASD

1 study with > 10 years of F/U: 17% with lumbar ASD

Patients with $\geq 5^\circ$ of motion versus $< 5^\circ$: the rate of ASD was 0% in the high motion group and 34% in the low motion group



Efficacy/effectiveness conclusion

- **No evidence comparing L-ADR with continued conservative care or with other surgical treatment other than fusion**
- **Moderate evidence that the efficacy/effectiveness of L-ADR is comparable with anterior lumbar interbody fusion or circumferential fusion up to two years following surgery**



RCTs comparing C-ADR with ACDF

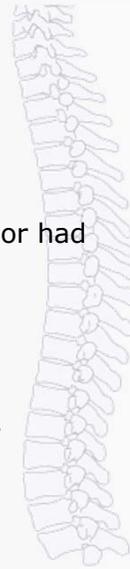
Study	Demographics	ADR	Fusion	Follow-up
Mummaneni et al. 2007 (Prestige ST FDA report)	Mean age: 44 % male: 46	Prestige ST n = 276	ACDF n = 265	2 years
Prodisc-C FDA report 2007	Mean age: 43 % male: 45	Prodisc-C n = 103	ACDF n = 106	2 years
Bryan FDA interim report 2007	Mean age: 45 % male: 48	Bryan n=140/242	ACDF n=160/221	2 years

Internal Validity

- Mummaneni et al.
 - low f/u rate using all patients randomized (80% ADR, 75% fusion)
 - no blinding of patients or outcome assessors
- Prodisc and Bryan FDA reports not critically appraised

Generalizability

- All three studies included patients with single level radiculopathy, myelopathy or both between C3-C7
- Failed conservative treatment for at least 6 weeks or had progression of neurological deficit
- Excluded were patients with advanced or severe spondylosis or cervical instability
- Patients: Average age 43-45 years, 45-48% males



Key Question 1 (cervical)

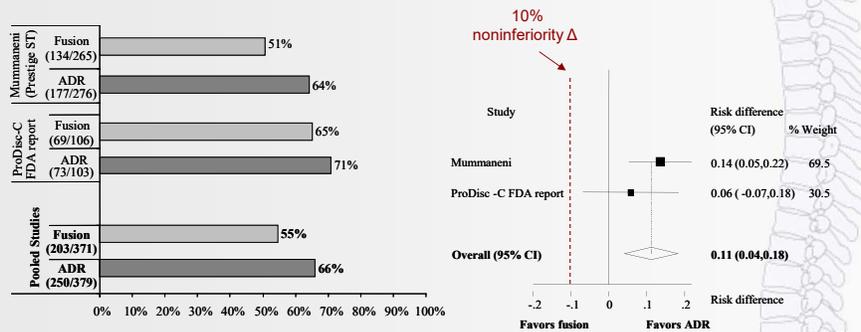
What is the evidence of efficacy and effectiveness of ADR compared with comparative therapies (including nonoperative therapy, spinal fusion, other surgery)?

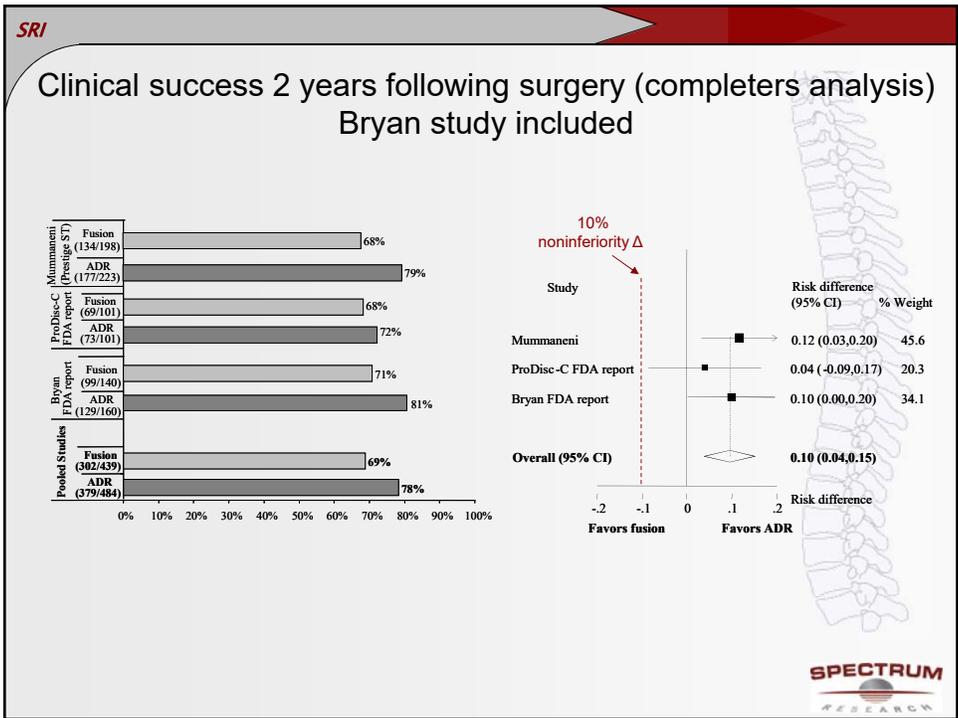
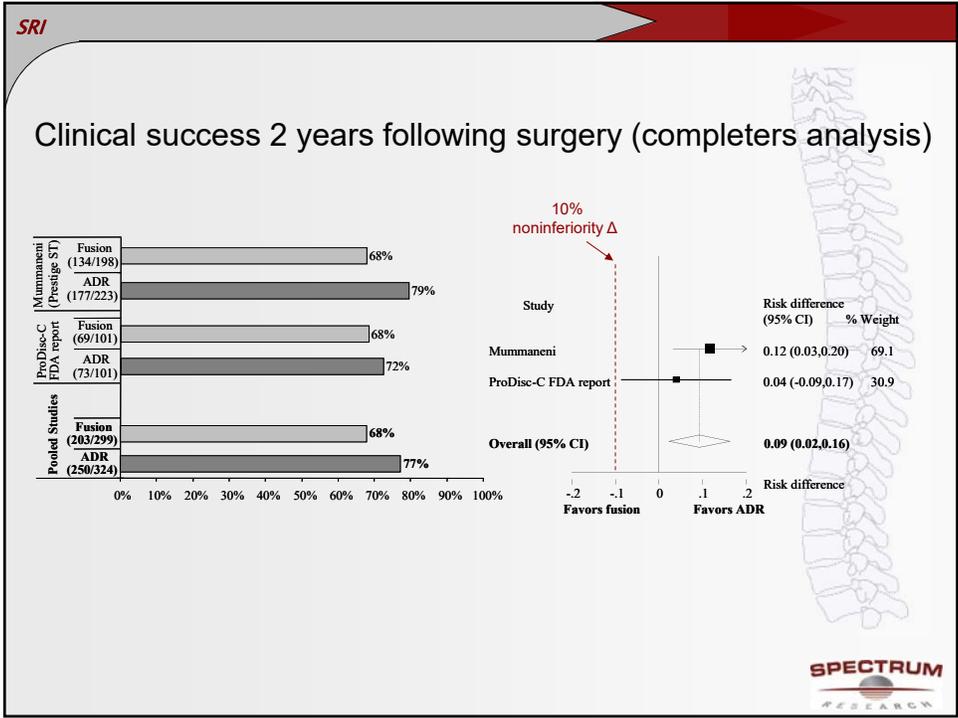


Outcomes efficacy/effectiveness, C-ADR

1. Overall clinical success (FDA), a composite:
 - NDI improvement (≥ 15 points from baseline)
 - Device success (no secondary surgery as a result of device failure)
 - Neurological success (maintenance or improvement in neurological status)
 - No adverse event related to implant of implantation
2. NDI improvement (≥ 15 points from baseline)
3. Neurological success
4. Pain reduction

Clinical success 2 years following surgery (ITT analysis)





Results

1. Overall Clinical Success Composite Outcome

Superior to fusion

C-ADR (77%) vs. cervical fusion (68%) RD = 9%,
(CI = 2 to 16%)

- addition of Bryan study does not change results

2. NDI improvement of ≥ 15 pts over baseline

Not inferior to fusion

C-ADR (82%) vs. cervical fusion (80%) RD = 2%,
(CI = -2 to 9%)

- addition of Bryan study does not change results



Results

3. Neurological success

Superior to fusion

C-ADR (92%) vs. cervical fusion (86%), RD = 7%,
(CI = 1 to 12%)

- addition of Bryan study does not change results

4. Pain

- Pooling data for pain was not possible
- C-ADR or ACDF resulted in significant relief of neck and arm pain
- No statistical differences in the change of the intensity of neck or arm pain comparing the C-ADR with the fusion group at follow-up



Results

5. Patient satisfaction

Tended to be similar between groups in 1 trial
Prodisc-C trial – >80mm on VAS (satisfaction)
- 71% C-ADR
- 68% ACDF

6. Preservation of motion

Post-op similar to pre-op segmental motion after 6-48 months F/U
Motion greater compared with fusion after 6-35 months F/U

7. ASD

Symptomatic ASD requiring surgical intervention ranged from 1 to 7% with varying F/U lengths
Asymptomatic ASD ranged from 0% to 17% at 1 and 2 year F/U

Efficacy/effectiveness Conclusion

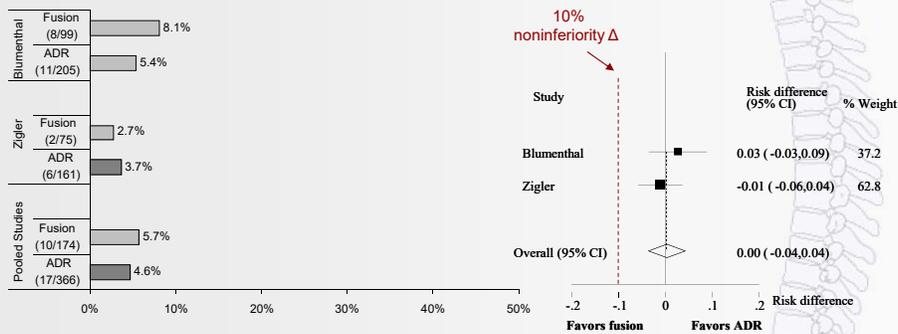
- **No evidence comparing C-ADR with continued conservative care or with other surgical treatment other than fusion**
- **Moderate evidence that the efficacy/effectiveness of C-ADR is superior to ACDF up to two years following surgery**

Key Question 2 (lumbar)

What is the evidence related to the ADR safety profile (including complications, adverse events, device failure, reoperation)?



Device failure L-ADR



Note: Quantity of events, not quality – 1 reoperation for ADR may be more difficult than 1 reoperation for fusion

Morbidity associated with reoperation for ADR is not known

Adverse Events L-ADR

Adverse events/complications	Blumenthal		Zigler	
	ADR (n = 205)	Fusion (n = 99)	ADR (n = 162)	Fusion (n = 80)
All irrespective of relationship to treatment	76%	78%	84%	88%
Device related	7%	4%	18%	20%
Major complications	1%	1%	0%	0%
Severe or life-threatening adverse event	15%	9%	NR	NR
Deaths associated with device or procedure	0%	0%	0%	0%

L-ADR AEs from case series

Complication	No. of studies	No. of patients w/ complication	Range of rates
New or residual pain	13	67	1%-37%
Vein or vessel laceration	7	10	2%-6%
Hematoma	3	17	1%-28%
Retrograde ejaculation	5	5	1%-4%
Heterotopic ossification	8	28	1%-60%
Prosthesis migration	3	15	8%-11%
Subsidence	8	54	2%-52%
Prosthesis malposition	4	8	1%-7%
Secondary fusion	4	37	5%-23%
Disc replacement surgery	1	6	6%

Safety L-ADR Conclusions

L-ADR has a similar safety profile as lumbar anterior or circumferential fusion 2 years following surgery

Strength of evidence: Moderate

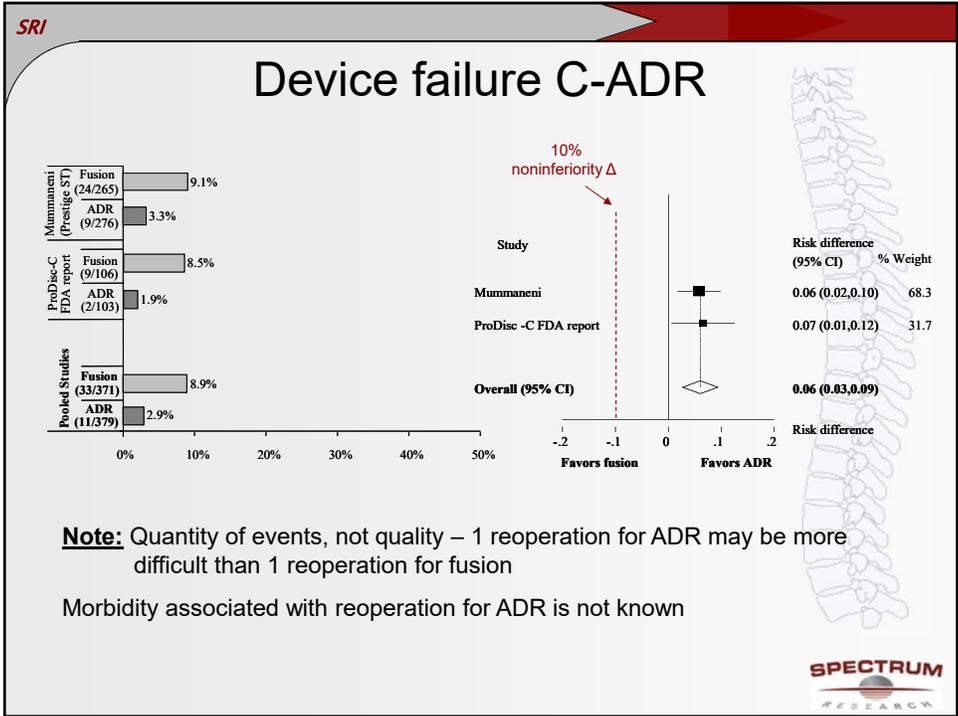
Longer term safety is not yet known



Key Question 2 (cervical)

What is the evidence related to the ADR safety profile (including complications, adverse events, device failure, reoperation)?





SRI

Adverse Events C-ADR

	Mummaneni (Prestige ST FDA)		Prodisc FDA		Bryan FDA	
	C-ADR (n = 276)	Fusion (n = 265)	C-ADR (n = 103)	Fusion (n = 106)	C-ADR (n = 242)	Fusion (n = 221)
All irrespective of relationship to treatment	82%	80%	82%	81%	84%	79%
Device related	3%	10%	13%	22%	3%	5%
Serious adverse event	NR	NR	16%	30%	26%	25%
Deaths associated with device or procedure	0%	0%	0%	0%	0%	0%

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C-ADR AEs from case series

Complication	No. of studies	No. of patients w/ complication	Range of rates
New or residual pain	8	42	1.3%-33.3%
Hematoma	8	9	0%-4.0%
Dysphonia	4	6	0%-13.3%
Dysphagia	3	51	0%-100%
Heterotopic ossification	7	23	0%-17.8% 62.2%*
Migration of the device	8	7	0%-4.1%
Revision decompression	2	3	1.4%-1.6%
Device removal	4	4	1.3%-10.0%
Adjacent level surgery	3	3	1.3%-6.7%

*Proportion based on number of segments with signs of ossification

Safety C-ADR

C-ADR tends to be safer than ACDF as measured by the risk of device failure or device/surgical procedure related adverse events or complications up to two years following surgery

Strength of evidence: Moderate

Longer term safety is not yet known

Safety issues

- 1. Morbidity associated with reoperation for ADR is not known**
- 2. Longer follow-up is needed, preferably from cohort studies**
- 3. To better characterize the safety profile, FDA requires the sponsors of ADR to perform:**
 - Post approval studies for 7 years**
 - Enhanced surveillance studies for 5 years**
- 4. However, RCTs contribute less information on safety than on efficacy**

Key Question 3 ADR

What is the evidence of differential efficacy or safety issues amongst special populations (including but not limited to the elderly and workers compensation populations)?

- There is insufficient evidence to draw conclusion regarding the safety and efficacy of L-ADR in the few special populations studied (elderly, smokers, athletes)**
- No reports were found evaluating C-ADR in subpopulations**

Key Question 4

- What are the cost implications and cost effectiveness for ADR?



In the peer-reviewed literature

- No complete formal economic analyses were found for either L-ADR or C-ADR
- Two incomplete economic analyses compared costs between L-ADR and fusion using hospital and/or payer perspectives
- Both suggest that mean L-ADR costs may be lower or at least similar to those for fusion - overall strength of evidence is very low and any effect size estimates are uncertain for L-ADR
- No evidence for C-ADR



In HTAs

- Ontario and Australia (MCAS) HTAs suggest that L-ADR may be more expensive than fusion
- MSAC HTA suggests that C-ADR costs more than cervical fusion

However, these analyses are limited because:

- ✓ Of differences in health care systems, practice patterns and reimbursement strategies
- ✓ Assumptions were not evidence-based and/or taken from low-quality studies; some assumptions may tend to bias toward ADR (MCAS)
- ✓ Limited data from a small number of cases were used for analyses (Ontario)
- ✓ The impact of rehabilitation following surgery is not included
- ✓ Assumptions regarding cost of longer-term complications (eg, ASD) are speculative

Summary

1. There are no direct comparisons of either L- or C-ADR with continued conservative nonoperative care or other surgical treatment other than fusion
2. There is moderate evidence that the efficacy/effectiveness of L-ADR as measured by the composite measure of overall clinical success, ODI improvement, pain improvement, neurological success, SF-36 improvement, and patient satisfaction is comparable with anterior lumbar interbody fusion or circumferential fusion up to two years following surgery

Summary

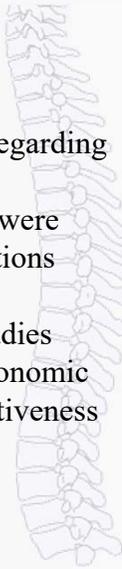
3. There is moderate evidence that C-ADR is superior to ACDF with respect to overall clinical success (77% versus 68%) and neurological success (92% versus 86%), and is comparable with ACDF with respect to NDI and pain up to two years following surgery
4. There is evidence that segmental motion is maintained or improved up to 3 years in the L-ADR and up to 4 years in C-ADR patients compared with preoperative motion – however, it is unclear if preserving segmental motion by using ADR instead of fusion influences rates of ASD or whether ASD is a continuation of a disease process or a result of fusion

Summary

5. There is moderate evidence that L-ADR is as safe as lumbar anterior or circumferential fusion, and that C-ADR is safer than ACDF as measured by the risk of device failure or device/surgical procedure related adverse events or complications up to two years following surgery
6. There is insufficient data at this time to determine the longer term safety of both L-ADR and C-ADR

Summary

7. There is insufficient evidence to draw conclusions regarding the safety and efficacy of L-ADR in the few special populations studied, and no studies or sub-analyses were found on the use of C-ADR in special or subpopulations
8. There are inadequate data from partial economic studies reflecting short time horizons for L-ADR and no economic studies for C-ADR to assess the potential cost-effectiveness of ADR technology



Questions?



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>

³ The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

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 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
Mortality	
Morbidity - Device related	
Morbidity - Surgical complications - Magnitude	
Morbidity - Long term adverse events - re-operation	
Efficacy/Effectiveness Outcomes	Efficacy/Effectiveness Evidence
Pain Relief: Short/Long term Magnitude of relief Direct or surrogate measure(s)	
Improves Function Short/Long term Magnitude of relief Direct or surrogate measure(s)	
Return to Work	
Preserves Flexibility Direct or surrogate outcome?	
Restores stability Direct or surrogate outcome?	
Relieves adjacent level stress Direct or surrogate outcome?	
Cost Outcomes	Cost Evidence
Other Factors	Evidence
Durability of device and outcomes Single Level vs. multiple level	

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

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

Safety Outcomes	Safety Evidence
Mortality	
Morbidity - Device related	
Morbidity - Surgical complications - Magnitude	
Morbidity - Long term adverse events - re-operation	
Efficacy/Effectiveness Outcomes	Efficacy/Effectiveness Evidence
Pain Relief: Short/Long term Magnitude of relief Direct or surrogate measure(s)	
Improves Function (Disability Index) Short/Long term Magnitude of relief Direct or surrogate measure(s)	
Neurological improvement	
Quality of life / return to work -Direct or surrogate outcome?	
Flexibility/ Stability Direct or surrogate outcome?	
Relieves adjacent level stress Direct or surrogate outcome?	
Cost Outcomes	Cost Evidence
Other Factors	Evidence
Durability of device and outcomes Single Level vs. multiple level	

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
Medicare	2007	Lumbar ADR only, no cervical national coverage decision. CMS will not cover lumbar ADR for patients older than 60. No national coverage determination for under 60 years of age.	Yes	Appraisal scheme for assessing study quality described.
No clinical guidelines related to use of artificial discs				

Report searched the National Guidelines Clearinghouse. Additionally, report authors chose to contact professional organizations who confirmed that no evidence based, transparently developed clinical guidelines are yet formulated.

Report includes two tables of other Health Technology Assessments that have been completed. This information, while not a required consideration may be informative for the clinical committee.

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 discussion.

- 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 meeting.

- 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.

Clinical Committee Evidence Votes

IF NEEDED IN CASE CERVICAL AND LUMBAR ADR OR SEPARATELY VOTED ON

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 discussion.

- 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 meeting.

- 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 that use of the technology results in more beneficial, important health outcomes? Consider:
 - Direct outcome or surrogate measure
 - Short term or long term effect
 - Magnitude of effect
 - Impact on pain, functional restoration, quality of life
 - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, 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 use of the test change treatment choices

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?