Washington State Health Care Authority

Health Technology Clinical Committee
Date: October 17, 2008
Time: 8:00 am – 5:00 pm
Location: Marriott Hotel – 3201 South 176th Street, Seattle, WA 98188
Teleconference Bridge: 1-360-923-2996 Access Code: 1-360-946-1464

D*R*A*F*T

HTCC MINUTES

Members Present: Brian Budenholzer; Michael Myint; Carson Odegard; Daniel Abrahamson; Richard Phillips; Michelle Simon, Lydia Bartholomew, and Jay Klarnet.

Telephonic: Louise Kaplan

Members Absent: C. Craige Blackmore and Michael Souter

HTCC FORMAL ACTION

1. **Call to Order**: Dr. Budenholzer, Chair, called the meeting to order at 8:00 a.m. Sufficient members were present to constitute a quorum.
2. **Executive Session**: Dr. Budenholzer called the meeting into Executive Session at 8:08 a.m. Executive Session lasted until 9:30 a.m.
3. **August 15, 2008 Minutes:** Dr. Budenholzer referred members to the draft minutes and called for further discussion or objection, and received none.
   - *Action:* The committee unanimously approved the August 15, 2008 minutes.
4. **Knee Arthroscopy Findings and Decision:** Dr. Budenholzer referred members to the draft findings and decision and called for further discussion or objection. Committee included one amendment.
   - *Action:* The committee unanimously approved the amended Knee Arthroscopy findings and decision document.
5. **Artificial Disc Replacement Determination:** The HTCC reviewed and considered the Artificial Disc Replacement (ADR) in the Lumbar and Cervical Spine technology assessment report, information provided by the Administrator, state agencies, and public members; and heard comments from the evidence reviewer, HTA program, agency medical directors, a multi-society advocacy workgroup, and several public members. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

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HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Artificial Disc Replacement: Lumbar	2	0	6
Artificial Disc Replacement: Cervical	0	0	8

- *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Artificial Disc Replacement reflective of the majority vote for final approval at the next pubic meeting.

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SUMMARY OF HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

Agenda Item: Welcome & Introductions

- ✓ The Health Technology Clinical Committee (HTCC) met on October 17, 2008.

Agenda Item: HTCC Executive Session

Chair, Dr. Brian Budenholzer, after advice from the Assistant Attorney General called for an executive session and requested the committee members remain present. The Assistant Attorney General; all present committee members; the HTA Director, HCA Legal Director, and the HCA Assistant Administrator participated in an executive session for the Assistant Attorney General to advise on the statute and regulations governing committee decisions and potential litigation. The executive session was closed at 9:30. The Chair called for a short break and then resumed the public meeting.

Agenda Item: Meeting Open and HTA Program Update

Dr. Brian Budenholzer, HTCC Chair opened the public meeting and deferred his chair remarks due to time constraints. Leah Hole-Curry, HTA Program Director, provided an overview of the agenda, meeting guide and purpose, room logistics, and introductions.

Leah Hole-Curry, HTA Program Director, provided an update on HTA program activities and outcomes.

- ✓ Eighteen Month outcomes
  - Ten topics chosen because of concerns - Five of ten first set of topics correlate with a later produced Consumer Reports – Top Ten Medical Rip Offs
  - For the first seven technologies – 5,422 potentially relevant articles reviewed; 127 thoroughly and critically appraised; resulted in seven comprehensive and peer reviewed technology assessments
  - Committee conclusion that five do not yet demonstrate net health benefit; two have evidence of health benefit in some circumstances.
- ✓ Committee and program is receiving attention and feedback from WA Governor and Legislature for its good work
  - WA Senate Health and Long Term Care Committee meeting – expected result is to use scientific evidence and clinician panel to decide which treatments work. Recognition by Chair, Senator Karen Keiser to committee that this is very difficult and important work
  - Governor's Government Management and Accountability Program (GMAP) – status check on priorities – health care quality – a primary measure is evidence based care management. Expected result that decisions correlating with evidence on good health outcomes and we are paying for things that work. Recognition and appreciation for clinicians – this is cutting edge
- ✓ Other states and plans are interested: Presentations to Maine & New York State, Public Sector Health Care Roundtable; private health plans in Washington; and CMS local carriers group
- ✓ 2009 - Potential Topics are being referred to the Administrator for his consideration, and will be posted to the website today, including: Glucose Monitoring, Sleep Apnea Diagnosis and

treatment, Calcium Scoring for cardiac disease, Vagal Nerve Stimulation, Elective Cesarean Section, Hip Resurfacing, Osteoarticular Transfer System – Cartilage Surgery (OATS procedure), Bone Growth Stimulators, Massage Therapy for Chronic Head, Neck and Back pain, Transcutaneous Electrical Neural Stimulation (TENS procedure), Essure Permanent Birth Control procedure, and Breast Cancer Tumor Screening.

- ✓ A committee member provided notification to the Chair and HTA staff of his resignation. Daniel Abrahamson has served as a valued committee member, providing thoughtful input and thorough review of the health technologies since committee inception. He is resigning to pursue additional academic interests and will be missed greatly. Daniel was recognized and thanked for his service.

Agenda Item: Previous Meeting Business

Overview of the draft minutes from the August 2008 by Leah Hole-Curry, HTA Program Director - the minutes were drafted by HTA staff, posted to the web and circulated to committee members for comments. Draft minutes were updated based on the comments received from both Dr. Budenholzer and Dr. Kaplan. Dr. Brian Budenholzer, HTCC Chair, referred members to the August minutes, and called for further discussion, or a motion to approve.

- ✓ No further discussion, minutes were approved.

Overview of the draft findings and decision for Knee Arthroscopy from the August 2008 by Leah Hole-Curry, HTA Program Director - the document was drafted by HTA staff, posted to the web and circulated to committee members for comments. Document was updated. Dr. Brian Budenholzer, HTCC Chair, referred members to the draft findings and decision, and called for further discussion, or a motion to approve.

- ✓ No further discussion, draft findings and decision was approved.

Agenda Item: Artificial Disc Replacement Topic Review

Dr. Dave Flum, HTA Clinical Consultant, introduced the primary technology topic to discuss were:

- ✓ *Artificial Disc Replacement in the Lumbar and Cervical Spine:* review of the evidence of the safety, efficacy and cost-effectiveness of Artificial Disc Replacement.

Artificial Disc Replacement

- ✓ ADR is the complete removal of a damaged disc and implantation of an artificial disc.
  - o The intent is to treat the pain and disability believed to be caused by a diseased disc by removing it.
- ✓ Surgery is generally indicated when non-operative conservative treatments fail to relieve symptoms attributed to lumbar degenerative disc disease (DDD) or relieve signs of neurological compression or prevent progression of nerve damage in the case of cervical DDD.
  - o The current surgical standard of care for lumbar DDD is lumbar fusion. The goal of this surgery is to remove the disc and fuse the vertebrae, thereby limiting the motion at the painful segment.
  - o For cervical DDD resulting in radiculopathy or myelopathy, the current surgical standard is anterior cervical discectomy and spinal fusion. The goal of this procedure is nerve decompression and restoration of spinal alignment and stability.

- ✓ ADR Potential Benefits: pain relief, functional restoration (quality of life, return to work), and resolves potential fusion surgery issues (preserve normal range of motion, restore disc height).
- ✓ ADR Potential Drawbacks: surgical intervention is controversial and there are high variation in rates, techniques and indications. Safety issues include: device/ mechanical complications and surgical complications.
- ✓ CMS Decisions and Expert Treatment Guidelines
    - o Centers for Medicare and Medicaid Services (CMS): a national coverage decision only on Lumbar ADR. No cervical national coverage decision. CMS will not cover lumbar ADR for patients older than 60 years of age. No national coverage determination for less than 60 years of age.
    - o National Guideline Clearinghouse: No clinical guidelines related to the use of artificial discs were found when the AHRQ, NGC database were searched.

Agenda Item: Public Comments

- ✓ Scheduled Public Comments: A total of twenty minutes was provided for scheduled presentations from a Multi-society Spine Work Group, representing: American Association of Neurological Surgeons, Cervical Spine Research Society, Congress of Neurological Surgeons, North American Spine Society, Scoliosis Research Society, and the Spine Arthroplasty Society. Presenters included: Dr. Jens Chapman, Dr. Praveen Mummaneni, and Dr. John Devine.
    - o Context: Unanimous recommendation for approval from FDA Advisory Panel.
    - o PRESTIGE IDE results summary: largest prospective, randomized study in the cervical spine; clinical results favor PRESTIGE cervical disc due to statistically fewer revision surgeries at 24 months; while motion varied, on average PRESTIGE Cervical Disc maintained 7.59 degree motion at 24 months; PRESTIGE group returned to work earlier (median value); and PRESTIGE cervical disc superior to ACDF in both overall and neurological success.
    - o Complications – What hasn't happened: Not seen / reported on device retro-expulsions, traumatic subluxations / dislocations, or catastrophic failure.
    - o Estimated procedures globally: Excess of 20,000 C-ADR; excess of 20,000 L-ADR (> 3,000 in US).
- ✓ Open Public Comments: seven individuals provided comments during the open portion: one spine surgeon and six patients.
    - o Dr. Reginald Knight, Spine Surgeon, shared how Artificial Disc Replacement has significantly improved his patient's pain and quality of life, and believes these devices work.
    - o All patients that provided open public comments shared separately how Artificial Disc Replacement has significantly improved their pain and that they have a better quality of life and urged the committee to cover the devices, those patients were: William Carpenter; Stading Frank Jr., Travis Haugen; Anthony Brock; Gill Bolden and Leslie Coelho.

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Agenda Item: Artificial Disc Replacement Topic – Agency Data

Dr. Nancy Fisher, HCA Agency Medical Director, presented to the committee the agency utilization and outcomes for Artificial Disc Replacement.

- ✓ 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; and spinal fusion.
    - o 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. Current State Agency Investigational Procedures Medical Policy:
        - **Medicaid:** Itemized procedures by CPT code are not 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.
        - **Uniform Medical Plan**: Itemized procedures by CPT code are not 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.
        - **Labor and Industries:** Itemized procedures by CPT code are not 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.
- ✓ Washington State background information:
    - ➢ State agency enrollment (PEHP/DSHS FFS/L&I) = 773,000
    - ➢ State agency annual fusion utilization: 1,435 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
PEHP	122	$34,500	$4,218,718
DSHS	175	$21,000	$3,602,080
Lumbar Totals	**732**	**$32,679**	**$23,920,798**

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. 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.*

- ✓ Efficacy Concerns: 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 advantage of ADR as better than medical management are not measured at all; and the advantages of ADR as better than fusion are not measured with current non-inferiority trials.
- ✓ Safety Concerns: Short terms – surgical risks, mechanical failure of the implant, re-operation. Long term – mechanical failure of the implant; spontaneous fusion.
- ✓ Agency Conclusions: consistent with systematic review, which indicates: the benefit and harms are not clear from the research (e.g. clinical expertise needed for ADR placement); insufficient evidence to address significant issues; client selection is not clear for who will benefit and who could be harmed; and long term ramifications and safety of the products is not clear.

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Agenda Item: Evidence Review Presentation

Spectrum Research, Inc presented an overview of their evidence report.

- ✓ Key Questions for Artificial Disc Replacement were on efficacy, safety, and cost:
  - What is the evidence of efficacy and effectiveness of ADR compared with comparative therapies?
  - What is the evidence related to the ADR safety profile?
  - What is the evidence of differential efficacy or safety issues amongst special populations?
  - What are the cost implications and cost effectiveness for ADR?
- ✓ Inclusion Criteria:
  - Key Question 1: Randomized controlled trials (RCTs) and comparative studies with concurrent controls.
  - Key Question 2 & 3: RCTs and comparative studies with concurrent controls (some case-series briefly summarized for context).
  - Key question 4: formal economic analysis and cost data reported in other systematic reviews or technology assessments.
- ✓ Evidence Base: 13 electronic databases searched through May 2008. 120 articles identified for lumbar and 56 for cervical.
  - All included studies compared ADR with spinal fusion.
  - No comparative studies were found that directly compared ADR with continued non-operative care or with surgical treatment other than fusion.
  - Data Analysis: meta-analysis when two or more RCTs were available and no clinical or statistical heterogeneity.
- ✓ Non-inferiority Studies: All FDA trials reported in the report conducted a non-inferiority study design.
  - Non-inferiority 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. Interpretation depends on where the CI for the treatment effect lies relative to (1) the margin of non-inferiority, and (2) the null effect.
- ✓ Effectiveness evidence: 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.
  - Overall clinical success composite outcome: Not inferior to fusion. L-ADR (56%) vs. lumbar fusion (48%)
  - ODI Improvement of ≥ 15 points over baseline: Not inferior to fusion. L-ADR (65%) vs. lumbar fusion (57%)
  - Pain: Not inferior to fusion. Reduction in pain from baseline similar between groups with respect to VAS and narcotic use.

- Neurological Success: Not inferior to fusion. L-ADR (91%) vs. lumbar fusion (81 – 95%) depending on study.
- Patient Satisfaction: Tended to be higher with L-ADR vs. fusion.
- Preservation of Motion: Post-op as good as or better than pre-op segmental motion after 2-3 years (improved with surgical technical accuracy).
- Radiographic (Asymptomatic) ASD: 2 studies with ≤ 10 years of follow-up: 0% to 24% with lumbar ASD. 1 study with > 10 years of follow-up" 17% with lumbar ASD.

✓ Efficacy Outcomes for C-ADR: No evidence compared 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.

- Overall clinical success composite outcome: Superior to fusion. C-ADR (77%) vs. lumbar fusion (68%).
- ODI Improvement of ≥ 15 points over baseline: Not inferior to fusion. C-ADR (82%) vs. lumbar fusion (80%).
- Neurological Success: Superior to fusion. C-ADR (92%) vs. lumbar fusion (86%).
- Pain: Pooling data for pain was not possible. 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.
- Patient Satisfaction: Tended to be similar between groups in 1 trial.
- Preservation of Motion: Post-op to pre-op segmental motion after 6 – 48 months follow-up. Motion greater compared with fusion after 6 – 35 months follow-up.
- ASD: Symptomatic ASD requiring surgical intervention ranged from 1% to 7 % with varying follow-up lengths. Asymptomatic ASD ranged from 0% to 17% at 1 and 2 year follow-up.

✓ Safety L-ADR Conclusions: L-ADR has similar safety profile as lumbar anterior or circumferential fusion two years following surgery. Strength of evidence: Moderate. Longer term safety is yet known.

✓ Safety C-ADR Conclusions: 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 yet known.

- Safety issues: morbidity associated with reoperation for ADR is not known; longer follow-up is needed, preferably from cohort studies; to better characterize the safety profile, FDA requires the sponsors of ADR to perform (1) post approval studies for seven years and (2) enhanced surveillance studies for five years; yet, RCTs contribute less information on safety than on efficacy.

✓ Costs: No formal economic analyses were found for either L-ADR or C-ADR. Two incomplete analysis 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.

- ✓ Conclusions: There are no direct comparisons of either L-ADR or C-ADR with continued conservative non-operative care or other surgical treatment other than fusion.
  - ➢ Efficacy: 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.
  - ➢ Safety: 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. There is insufficient data at this time to determine the longer term safety of both L-ADR and C-ADR.
    - ▪ 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-analysis were found on the use of C-ADR in special or subpopulations.
  - ➢ Costs: 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.

Agenda Item: HTCC Artificial Disc Replacement Discussion

Brian Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost effectiveness of Artificial Disc Replacement beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors. For issues and evidence on efficacy and safety, lumbar and cervical disc replacement were separately addressed.

Key Factors and Health Outcomes Considered

Evidence overall: The committee noted that the evidence based was more robust than some of the other technologies, including randomized controlled trials. However, the RCT's had several overall limitations:

- Five primary studies form evidence base and compare ADR to fusion/surgery; and do not include an optimal medical treatment comparison. Fusion comparator is not a gold standard (reference previous evidence report and committee decision) so comparing to a treatment that is not good does not yield reliable information.
- the RCTs were primarily conducted for FDA approval and were designed to prove that the new treatment is no worse than the comparator (non-inferiority design). Studies were not blinded, though this remains a difficulty of most surgical trials.
- FDA trial "success" is defined based on specified clinical outcomes that must be within a margin to be not worse than the alternative. FDA specified success focus on clinical or surgical success (e.g. devise operation (technical performance, no device failure, no deterioration) and an ODI improvement of 25%
- Committee discussion, debate, and dialogue with evidence vendor about the appropriateness of concluding superiority or equivalency from a study designed to prove non-inferiority, reference and review of report at page 48-50.

Lumbar ADR Safety: The committee discussed multiple outcomes related to safety. The committee relied primarily on the independent evidence vendor's report.

- Mortality – No case related deaths.
- Device Related failure – failure that required reoperation, revision, or removal not statistically different (fusion 2.7 and 8.1% vs. ADR 5.4 and 3.7%) reported in trials. (p81). Committee agreed comparable for short term but no long term data available and could potentially be important given average age of patient.
- Morbidity (Short-term data) – complication rates varied greatly from 1% to 60%; heterotopic ossification, hematoma, subsidence, and new or residual pain, secondary fusion had high ranges. No statistical differences in major adverse events/complications from trials. Committee concluded ADR not-inferior to lumbar fusion for short-term safety.
- Morbidity (Long-term data) – Studies did not report adequate data; therefore, the committee determined long-term data to be inconclusive due to a lack of data.

Lumbar ADR Efficacy: The committee identified multiple key health outcomes that were important for consideration in their overall decision on whether the technology was effective. Summary of committee consideration, discussion, comments are listed below.

- Pain Relief - An important outcome to the committee. Evidence report conclusion was that L-ADR appears to provide as good or greater pain relief for single level disease than fusion (pages 66-68). VAS pain score reductions over 2 years were statistically significant. The committee considered it as non-inferior to anterior lumbar interbody fusion or circumferential fusion up to two years following surgery. Inconclusive long term data available.
- Improves Function -- An important outcome to the committee. Evidence report included analysis on SF-36, clinical success and ODI. SF-36 a common health survey, scores that demonstrated higher improvement on physical and mental component with L-ADR over fusion at 12 months 81% versus 77%). The clinical success (FDA measures) including ODI improvement, pooled at 57% improvement for fusion and 65% for L-ADR. The committee considered it no worse than lumbar fusion up to two years following surgery. Inconclusive long term data available.
- Return to Work – While an important outcome, studies did not report adequate data; therefore, this key factor was inconclusive.
- Preserves flexibility – not comparative (fusion designed to limit motion; ADR designed to preserve flexibility). Adequate evidence (FDA clinical success) that device maintains flexibility. Committee questioned whether this was an important outcome if it doesn't provide health benefit (e.g. assumption that motion prevents ASD – see next).
- Relieves adjacent level stress/ adjacent segment disease (ASD) - this is proposed as the key health benefit of ADR over fusion – not measured in RCT; non-randomized trial reported ASD in 0% to 34% (page 70). Committee found that L-ADR reduction in ASD is not demonstrated.
- Outcome Patient Satisfaction – this is very subjective and no standard/blinded measures. Don't have data on as many as 25%; but more reported patient satisfaction. When the questions are asked is important in looking for long term results. Overall, committee considered it likely as non-inferior to lumbar fusion.

Cervical ADR Safety: The committee discussed multiple outcomes related to safety.

- No case related deaths reported – likely equivalent to fusion.
- Morbidity (Device Related) – Two studies reported fewer device complications with ADR (2.9%) versus fusion (8.9%) that were statistically significant.

- Morbidity (Short-term data) – Evidence report concluded that trials showed similar adverse events where the differences were not statistically significant (e.g. 26.4% vs 24.9% serious adverse events). Rates of complications from case series varied broadly (dysphagia 0% to 100%; new or residual pain 1% to 33%). No denominator information for Maude safety events. Committee determined C-ADR non-inferior to lumbar fusion for short-term safety.
- Morbidity (Long-term data) – Studies did not report adequate data on long term outcomes; RCT's not best source for this data. Committee indicated no compelling data that one is better or worse than other – inconclusive.

Cervical ADR Efficacy: The committee identified multiple key health outcomes that were important for consideration in their overall decision on whether the technology was effective. Summary of committee consideration, discussion, comments are listed below.

- Pain Relief - An important outcome to the committee. Both C-ADR and fusion patients reported significant relief in neck and arm pain (no non-surgical control). There were no statistical differences in pain relief between C-ADR and fusion (page 77). The committee considered C-ADR non-inferior to fusion up to two years following surgery. Concern about longer term data – this is being requested by FDA - inconclusive long term data available.
- Improves Function -- An important outcome to the committee, primary measure used was neck disability index (NDI). NDI improvement in score of at least 15 points reached in 80% fusion and 82% C-ADR – not statistically significant (page 74). The committee considered C-ADR as non-inferior to fusion surgery in the short term.
- Neurological 'Success" – defined in trial as maintain or improve. Committee discussed whether this was appropriate clinical significance if surgical intervention only results in maintaining same level. 78% C-ADR patients and 67% fusion achieved bar. The majority of the committee found this to be non-inferior to fusion; however, some committee members were persuaded that it was superior to lumbar fusion.
- Quality of life/Return to Work – While an important outcome, no study information available.
- Flexibility/stability – pre and post operative motion generally maintained; C-ADR had greater motion preservation than fusion.
- Relieves adjacent level stress/ adjacent segment disease. ASD reported at 1% in C-ADR vs 3% in fusion in RCT; other studies reported ASD rates of 1% to 7%. Committee considered data inconclusive.
- Overall Clinical Success defined by FDA standard – 66% C-ADR success vs. 55% fusion success. Surgical success considered by committee considered to be superior to fusion.
- No studies looked at subgroups or subpopulation evaluation. Committee discussed applicability in older population – could expect more negative outcomes; prudent not to extend beyond FDA limits.

ADR Cost: The committee discussed cost and cost-effectiveness as a whole. This topic generated the least discussion because of the inadequate data. Two HTA's did include economic analysis comparing fusion and L-ADR(Ontario and Australia) resulted in mixed findings that may suggest L-ADR has similar costs to fusion, but finding was not supported in Ontario analysis and could be dependent on fusion procedure used. (page 92). One Australian HTA concluded that C-ADR and fusion surgical costs were the same, but C-ADR would be more because of additional device related cost.

- Analysis include assumptions related to health care system; practice patterns, and reimbursement mechanisms not present in US

- Economic studies reflecting short time horizons to assess the potential cost-effectiveness of ADR technology and need appropriate comparator.
- Approximate cost for L-ADR in WA based on 50% of hospital costs: $20,113 and C-ADR at $14,344; no manufacturer provided any cost data.
- Committee determined cost data insufficient and inconclusive.

Overall ADR Evidence Evaluation and conclusions: The committee discussed multiple key health outcomes and relied primarily on the independent evidence vendor's report.

- Fusion as comparator is troubling because fusion is not proven highly successful/ gold standard.
- RCTs point to conclusion that not worse; treatments/study confidence is not high due to methodological issues, young population, good short term outcomes
- Pain relief experienced with ADR is not worse than fusion.
- ADR good evidence that it does what it is designed to do – preserve motion at segment. However clinical significance unclear - no proven health benefit (e.g. adjacent level stress).
- Appears equivalent to fusion for efficacy and safety; but no long term information. Or efficacy shown to be no worse than fusion, which is a currently paid alternative
- Safety equivalence – relatively confident in short term but long term unknown, given device durability question this could be a large issue.
- L-ADR may be more effective in some situations, more flexibility in joint and patient satisfaction data shows higher satisfaction and is important consideration, although subjective.
- C-ADR greater effectiveness shown in neurological improvement and overall clinical success for short term; long term unclear.

Medicare Decision and Expert guidelines related to ADR

Committee reviewed and discussed the Medicare coverage decision and expert guidelines as identified and reported in the technology assessment report. Medicare's guidelines state that they cover Lumbar ADR only. No cervical national coverage decision. CMS will not cover lumbar ADR for patients older than 60 years of age. No national coverage determination for less than 60 years of age. No clinical guidelines related to use of artificial discs.

Agenda Item: Artificial Disc Replacement Vote

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

Lumbar Artificial Disc Replacement Votes:

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

	Inconclusive (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective	**2**	**4**	0	**2**
Safe	**2**	**6**	0	0
Cost-effective	**8**	0	0	0

Cervical Artificial Disc Replacement Votes:

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

	Inconclusive (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective	**1**	**1**	0	**6**
Safe	**3**	**4**	0	**1**
Cost-effective	**8**	0	0	0

Committee Discussion related to ad hoc group. Committee discussed whether an ad hoc group was needed to provide more information to the committee:

- Review of literature is well done; information is present to make decision. Ad hoc committee would provide more opinion, but not additional evidence.

HTCC Artificial Disc Replacement Decision

The HTCC reviewed and considered a comprehensive 2008 HTA Evidence Report on Artificial Disc Replacement that included and analyzed the relevant and highest quality studies. The committee also reviewed information provided by the Administrator, state agencies, and public members; and heard comments from the evidence reviewer, HTA program, agency medical director, a multi-society workgroup, and several public members.

Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

HTCC COMMITTEE COVERAGE DETERMINATION			
	Not covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Lumbar Artificial Disc Replacement	**2**	**0**	**6**
Cervical Artificial Disc Replacement	**0**	**0**	**8**

Committee Discussion related to Expert Treatment Guidelines and Medicare Decision: There are no clinical guidelines related to the use of artificial discs for lumbar or cervical. Medicare does not cover lumbar artificial disc replacement for patients older than 60; there is no national coverage decision for cervical artificial disc replacement.

- Majority of the committee felt that moderate evidence was presented to show that ADR is equivalent or more effective than lumbar or cervical fusion.

- Majority of committee felt that moderate evidence was presented to show that L-ADR is as safe as lumbar fusion. Majority of committee felt that moderate evidence was presented to show 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. There is insufficient data at this time to determine the longer term safety of both L-ADR and C-ADR.
- Committee unanimously agreed that insufficient data is present on cost; therefore, the committee determined it as Inconclusive.
- Committee decision is based on all evidence, including the vendor, public, agency medical directors and report.

Committee Discussion related to Conditions:
Committee vote for coverage was with conditions, discussion ensued about the type of conditions and whether the committee or a subgroup should identify.

- Primary concern is that the moderate evidence from the current clinical studies is specific to the population studied and committee is not comfortable generalizing to a broader population.
- There are no clinical guidelines related to the use of artificial discs for lumbar or cervical, and other coverage policies are limited.
- Related back surgery decision (lumbar fusion) required individuals to go through a structured multi-disciplinary program first because surgical options provide benefit to some individuals, but also have severe risks, and equivalent results were found over longer time period.
- Need for a patient registry that would provide more complete information on health outcomes, especially key longer term issues. Can this be a condition for payment? Patient data registry estimated by stakeholder to cost $280.00 per patient. Should coverage be allowed if committee feels need for more data
- Center of excellence or certification requirements – limit harm by requiring expertise. Trials often have expert providers/ centers; however, may limit access, administrative feasibility and cost a concern.
- No evidence in elderly – shouldn't extend beyond approved ages and consistency with medicare
- FDA indications and contra-indications reflect many of the study population characteristics: failure of medical management, one level only.

➢ Action: The committee chair directed HTA staff to prepare a Findings and Decision document on Artificial Disc Replacement reflective of the majority vote for coverage with conditions for final approval at the next pubic meeting. Conditions shall include: FDA inclusion / exclusion criteria; Medicare age restriction; consistency with lumbar fusion decision requirement.

- The committee noted that current process of posting the Findings and Decision for public comment and then presenting it at the next public meeting should be used.
- The committee feels strongly that a well designed registry would provide important information about health outcomes and overall benefit and risks. The chair directed HTA staff to investigate the feasibility of the HTCC imposing a registry requirement and reporting back to the committee.