
**Health Technology Clinical Committee
Findings and Coverage Decision**

Topic: Implantable Drug Delivery System
Meeting Date: August 15, 2008
Final Adoption:

***D*R*A*F*T**

Number and Coverage Topic

20080815A – Implantable Drug Delivery System for Chronic non-cancer pain.

HTCC Coverage Determination

Implantable drug delivery systems (Infusion Pump or IDDS) for treatment of chronic non-cancer pain is **not a covered benefit**. This decision does not apply to the use of IDDS for other purposes.

HTCC Reimbursement Determination

- ❖ **Limitations of Coverage**
Not Applicable
- ❖ **Non-Covered Indications**
Chronic Non-cancer pain
- ❖ **Agency Contact Information**

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plans	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

The infusion pump topic was selected by the HCA Administrator and published in August 2007 to undergo an evidence review process per RCW 70.14.100(1)(a). Infusion pumps are surgically implanted devices used to deliver drugs to a specific site in the body, rather than relying on systemic levels of medication(s) that are administered orally or by other route. The Infusion pump topic was reviewed for the indication of chronic non-cancer pain (CNCP) where an infusion pump is permanently implanted for opioid administration.

The HCA Administrator contracted with an independent technology assessment center for a systematic evidence based technology assessment report of the technology's safety, efficacy, and cost-effectiveness consistent with RCW 70.14.100(4). On June 27, 2008, the HTA posted a draft report, invited public comment, and posted a final report on July 18, 2008. The contractor reviewed publicly submitted information, and searched,

Draft version not officially adopted yet

summarized, and evaluated trials, articles, and other evidence about the topic. This comprehensive, public and peer reviewed, report is approximately 190 pages, identified 549 potentially relevant articles, a Medicare coverage decision and 3 expert treatment guidelines. Based on pre-established criteria and clinical research methodology, the technology assessment center included the most relevant and best available evidence on the safety, effectiveness, and cost effectiveness of the infusion pump for treatment of CNCP. The result is a critical appraisal of 13 case series and 4 cost analyses. Using a formal, objective method of evaluating evidence, the evidence based technology assessment report concluded that the case series rated as low overall internal validity for all key questions.

On August 15th, 2008, the HTCC, an independent group of eleven clinicians met at an open public meeting, to decide on whether state agencies should pay for the infusion pump for treatment of CNCP. The HTCC reviewed the TA report, including peer and public review comments; and invited and heard public comments at the meeting. Meeting minutes detailing the discussion are available through the HTA program or online at <http://www.hta.hca.wa.gov> in the committee section.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee finds the following health outcomes, and evidence related to those health outcomes, are key factors:

1. Evidence availability and technology features

The committee finds the following key factors relevant to the coverage decision:

- 1.1. The evidence based technology assessment report indicates that chronic pain is burdensome and costly; an important and common medical concern. There are many conservative treatments for chronic pain and medical treatment also includes treatment of the underlying disorder, when possible. The permanent implantation of infusion pumps is an invasive alternative for medication delivery and requires ongoing maintenance and successive surgeries to replace the infusion pump approximately every five years
- 1.2. The evidence based technology assessment report search of peer reviewed medical literature, submitted comments and other sources and did not identify any relevant randomized controlled trials or other controlled trials.
- 1.3. The thirteen case series identified in the evidence based technology assessment report included 413 patients overall (11 to 30 per study) averaging in age from mid-forties to mid-fifties. Internal validity rating of the case series for all outcomes was low; with factors limiting validity including high attrition, failure to compare characteristics of completers and non-completers, use of ancillary treatments, and funding from a source with a financial interest in the outcome.
- 1.4. The evidence based technology assessment report identified three expert treatment guidelines and included the Medicare national coverage decision
- 1.5. Medicare national coverage decision covers implantable pumps for epidural or intrathecal administration of opioid drugs for chronic non-cancer pain. Decision rendered in 1994 and updated in 2004. However, the update addressed coverage of insulin pumps and no update to the infusion pump for CNCP was completed.

- 1.6. Two expert treatment guidelines identified through the National Guidelines clearinghouse search did not support use of infusion pumps for chronic pain or morphine use
- 1.7. One expert treatment guideline supported use of implantable intrathecal infusion systems for long term management of chronic pain.

2. Is the technology safe?

The committee found that adverse events were the most significant safety outcome measure. The report identified the following evidence:

- 2.1. Case series reported 8% discontinuation rate due to adverse events;
- 2.2. Case series reported 9% to 42% re-operation rate for major and minor complications;
- 2.3. Case series reported 8% rate of discontinuation of device due to inadequate pain control
- 2.4. FDA reports of 9 deaths reported in 2006 within 3 days of pump implantation
- 2.5. FDA database of adverse events. Of over 9,000 filed for infusion pumps, the evidence based technology assessment report identified 975 directly relevant events, including 53 deaths
- 2.6. FDA database's highest number of serious reports included infection (128), inflammatory masses (83), and paralysis (20).

3. Is the technology effective?

The committee found that there were four key health outcomes were most significant in assessing the technology's effectiveness. The report identified the following evidence:

3.1. Pain Control

- 3.1.1. Pain is a subjective sensation and was measured in the studies by the visual analogue scale (VAS).
- 3.1.2. The committee focused on the evidence based technology assessment report's analysis of seven case series that measured at least 50% pain reduction which included 150 patients. The studies were assessed as low quality internal validity, limited by high attrition, failure to compare characteristics of completers and non-completers, use of ancillary treatments, and funding from a source with financial interest in outcome.
- 3.1.3. Evidence based technology assessment report meta-analyzed results of the seven case series and concluded that there was weak evidence that 41% of patients treated indicated that they experienced more than 50% pain relief, and 59% of patients indicated that they had not. The percentage varied widely among studies, from 11% to 100% attaining relief, and due to unexplained differences and inconsistency among studies, the statistic is unstable.
- 3.1.4. The Evidence based technology assessment report concluded overall that there is weak evidence of clinically significant pain relief, but the percent of patients that would experience relief and the amount of pain relief could not be calculated due to the low evidence quality.

4. Functional Status

- 4.1. The evidence based technology assessment report indicated only one low quality study addressed functional status, and thus there was insufficient quantity of evidence to form evidence based conclusion.

5. Return to Work



- 5.1. Four low quality studies identified in the evidence based technology assessment report, included 115 patients, found that the results were too imprecise to permit an evidence based conclusion (the variation supported two inconsistent conclusions- either employment reduces slightly after pump implantation or increases greatly).
 - 5.2. Washington State's small worker's compensation experience, not peer reviewed and similar to case series data (11 claimants) shows no claimant receiving pump has returned to work
6. **Quality of Life:**
- 6.1. The evidence based technology assessment report indicated that two studies, ranked low quality of internal validity, had inconsistent findings (one low quality study found no observed change while another low quality study observed a dramatic improvement).

7. Is the technology cost-effective?

The committee found that there was key information about cost and value:

- 7.1. The evidence based technology assessment report identified a number of costs related to the infusion pump including: screening; initial purchase; pump implantation; medication refills; consultations; complications; adjunctive medications; pump replacement or removal.
- 7.2. The evidence based technology assessment report identified four peer-reviewed articles addressing cost analysis that indicated mixed results, several with equivalent costs with wide confidence intervals
- 7.3. The higher up front and maintenance of the pump costs may be offset by longer term medication and other medical services reduction
- 7.4. One analysis in the report was a five year cost model that concluded: non-pump cost of \$83,000; and pump costs ranging from a best case of \$53,000, average of \$83,000, and worst case of \$125,000

Committee Conclusions

Having made findings as to the most significant and relevant evidence regarding health outcomes and factors and identified evidence related to those factors primarily based on the evidence based technology assessment report, the committee concludes:

8. Evidence availability and technology features

The committee concludes that the best available evidence on infusion pumps had been collected and summarized, however the overall quality of this evidence is low, methodologically challenged and not robust as follows:

- 8.1. Efficacy is best proven via randomized or well designed controlled trials, with adequate participants, assessment of all patient centered health outcomes, and for sufficient duration. Despite growing use for several decades, the entire body of literature on infusion pumps for CNCP (all studied outcomes) includes only 13 case-review articles on 413 patients. As a result, the quality of evidence for outcomes was at best rated as weak. On the other hand, complications and

Draft version not officially adopted yet

adverse events can be identified by case-review studies and other sources such as the FDA database.

- 8.2. Chronic pain is burdensome and significantly impacts patients, but is not life threatening. Many non-invasive alternatives are available and currently covered by the agencies.

9. Is it safe?

The committee concludes that the comprehensive evidence reviewed does not show that the technology has been proven safe, indicating that the infusion pumps were either less safe or unproven to be as safe or safer. Key factors to the committee's conclusion included:

- 9.1. Safety data identifies a substantial risk to patients and procedure is performed where there is a serious, though not life threatening underlying condition
- 9.2. FDA reporting is a voluntary database, which most likely under reports the total number of actual adverse events.
- 9.3. The 9 reported deaths in 2006 within 3 days of implantation confirm that this invasive treatment, especially when use in real practice settings carries significant risk. The overall rate remains unknown due to the fact that reporting is voluntary and the denominator or total number of implantations is not required to be released. Until such information is made available, the significant adverse events cannot be ignored.
- 9.4. Even in the case series trial setting which presents a best case scenario for selection, experience, and monitoring; significant adverse events occurred and the variation among trials was large: reoperation rate due to complications ranged from 9% to 42%; and overall discontinuation for adverse events was high at 8%.

10. Is it effective?

The committee concludes that the comprehensive evidence reviewed does not show that the technology has been proven effective.

- 10.1. Of the four identified key health outcomes impacting effectiveness, only one outcome had a sufficient quality of evidence to draw even weak proof of effect from use of implanted infusion pumps in the treatment of CNCP.
- 10.2. Pain control was a primary studied outcome and is an important benefit to patients. The totality of the low quality evidence showed that there is a pain control benefit for some patients, though the proportion of those benefiting to those who did not was not capable of being determined. This was a weak evidence conclusion based on combining, or meta-analyzing the case series. Committee members placed low confidence in the individual studies and in combining the low internal validity studies to produce a combined effect because, methodologically it is problematic to meta-analyze poor quality case series data, as also noted by the methodology peer reviewer. In this case, the following factors weighed heavily: pain is a subjective sensation so difficult to measure reliably, the report and the case series did not provide sufficient information to confirm that all other alternatives had been exhausted; the assumption of little placebo affect from this intervention in pain relief was challenged; a primary measurement tool, the VAS, has unclear usefulness to measure pain and other available tools may be more reliable and accurate; 150 patients in small case series is a very small evidence

base and represented only a subset of the 413 total patients included in the analyzed studies; the benefit over time is not well measured even though this is proposed as a permanent treatment; most patients continued oral pain medications; and the pain control benefit is highly inconsistent.

- 10.3. Even with low quality evidence of some pain relief, it is not possible to identify which patients might benefit and which do not.
- 10.4. Functional status, employment status, and quality of life are important health outcomes that combined would demonstrate overall effect of the treatment, but no reliable data demonstrates improvement in these outcomes.

11. Is it cost-effective?

The Committee concludes that the comprehensive evidence review does not show that the technology is more cost effective. Although cost-effectiveness was not a major decision factor, the committee concluded that it is likely of equivalent cost.

- 11.1. Four peer-reviewed articles addressing cost analysis indicated mixed results and indicated equivalent costs with wide confidence intervals
- 11.2. Because the committee could not find high quality evidence demonstrating effectiveness, a determination of cost-effectiveness, which requires a positive benefit, cannot yet be established.

12. Medicare Decision and Expert Treatment Guidelines

The committee deliberations included a discussion of National Medicare Decisions and expert treatment guidelines, and an understanding that the committee must find substantial evidence to support a decision that is contrary. RCW 70.14.110. Based on the following, the Committee concludes that a decision consistent with two expert treatment guidelines and contrary to the National Medicare Coverage Decision and one treatment guideline is justified:

- 12.1. The independent evidence vendor identified four relevant policies, two supporting the infusion pump and two that did not support use. The committee decision is consistent with two expert treatment guidelines and inconsistent with an expert treatment guideline and Medicare national coverage decision. For those policies that are inconsistent, the committee was persuaded by the evidence cited above from the evidence based technology assessment report, and less persuaded by the older policies that, while citing some evidence, were not supported by an independent assessment and grading of the evidence. In particular,
 - 12.1.1. Committee found that it had the most complete and current evidence available
 - 12.1.2. Committee found that this substantial evidence reviewed does not currently demonstrate that the technology is equally safe or safer, equally or more effective, or more cost effective
 - 12.1.3. Medicare Coverage Decision on infusion pumps for CNCP was from 1994 and did not include a review of the many recent studies noted in the evidence report, and most importantly any safety data
 - 12.1.4. The critical safety data from the FDA, including the 9 deaths occurring in 2006 was not available nor reviewed by Medicare nor identified in the treatment guideline

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that evidence on infusion pumps did not demonstrate net health benefit because weak or unproven evidence of some effectiveness for certain patients was undermined by significant evidence of serious harms and adverse events associated with the implantation of infusion pumps. The committee found that infusion pumps were not proven to be equally or more safe or effective, and the cost, while not a significant factor for this decision was likely equivalent. Based on these evidentiary findings, the committee voted 8 to 2 for non-coverage.

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open meeting. The Washington State [Health Technology Clinical Committee \(HTCC\)](#), determines how selected health technologies are covered by several state agencies. RCW 70.14.080-140. These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Infusion Pump Draft Decision - public comment summary

Proposed Coverage Determination (Public comment period - August 29, 2008 to September 12, 2008)

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft decision for no coverage on Implantable Infusion Pumps for chronic non-cancer pain. This is a total count, where some duplication has occurred because some commenter's submitted duplicative comments through various channels or had multiple family or staff members submit comments.

Commenter	w/i time	post deadline	Cited Evidence
	Aug 29-Sep 12	Sep. 13- Oct 10	
Patient, relative, and citizen	552	101	1
Legislator and public official	2	3	0
Physician and health care professional	40	7	0
Industry and Manufacturer	1		1
Professional Society and Advocacy Organization	9		5
	All Total	715	

Comments without Evidence

590 of the 715 comments opposed the decision and were generated from a public comment template; a pre-stamped postcard. The postcards were pre-filled with the following message.

"I oppose the HTA decision to deny access to pain pumps for non-cancer pain. There should be continued statewide coverage for drug pumps for those with non-cancer chronic related pain – similar to coverage provided by Medicare."

Some individuals wrote additional notes on the postcard and came from both individuals and providers.

117 of the 715 comments without evidence opposed the decision or expressed concern with decision and were received by E-mail, telephone, voicemail and letters. These comments opposing the decision and indicated that the Infusion pump is an important treatment, has provided relief and improved quality of life, is covered by Medicare and other payers and should be covered. A representative comment:

I'm writing in response to the Washington State Health Technology Assessment Clinical committee's vote to Deny Coverage for FDA approved Medicare covered pain pumps for the treatment of non-cancer pain. I oppose this decision. My friend has a pain pump to treat the pain from her disintegrating spine. Before her

pump she was in a hospital bed in the living room, with debilitating pain. After her pump, she is in far less pain. She is up walking, doing a bit of gardening; she has a life and is finally enjoying it. To deny her a pain pump is to condemn her to a life of intolerable pain. I believe that there should be continued statewide coverage for drug pumps for those with non-cancer chronic pain

1 of 715 comments supported the decision. A telephone commenter supported the decision because her husband had a pump that gave relief when it worked, but he died of an overdose, so she thinks further study is needed because there are problems with the pump that could result in death.

Comments with Evidence

7 of the 715 comments included citations to evidence.

Citizen, patient, and relatives

One individual opposed the decision based on his personal experience with pain relief using the IDDS. He also cited a November 2000 report by Saadat Kamran MD and Ballard Wright MD indicating “*IDDS are effective and safe devices for pain management. The complications associated with implants are mostly pharmacological and transient. Careful attention to the implant technique is required to minimize the complications.*”

Professional Society and Organization Comments

The National Pain Foundation opposed the draft decision citing the statutory criteria for determinations to be consistent with medicare decisions and expert treatment guidelines and including a new expert treatment guideline; the state’s inappropriately addressing issues reserved for the FDA; moral and ethical grounds that widely accepted safe and effective treatments should not be excluded and non-cancer pain patients should not be treated differently.

Reden&Anders, a company that conducted an economic analysis for MedTronic commented that it believes parts of the ECRI report and presentation regarding its analysis were inaccurate, particularly that the non-pump cost projection was not based on a single month, but on all the months prior to the implant.

A combined comment from the National Physician Professional Pain Societies, which includes: the American Academy of Pain Medicine (AAPM); American Society of Interventional Pain Physicians (ASIPP); International Spine Intervention Society (ISIS); and the North American Neuromodulation Society (NANS) indicated that these organizations are opposed to the draft decision and IDDS should be covered for well selected patients, noting that multiple expert specialty societies conclude the therapy is efficacious, safe and cost effective and that the committee did not meet its statutory

burden of proof to have substantial evidence to override Medicare's coverage when the committee essentially determined that the IDDS evidence was inconclusive.

The American Association of Neurological Surgeons and Congress of Neurological Surgeons oppose the draft decision, indicating that they do not believe that the committee has a substantial evidence burden of proof that was not met to overcome Medicare's long standing coverage. Further, deficiency in level of evidence research is inherent in studying a subjective disease. They urge the committee to focus on the prospective analysis (Anderson 1999; Deer 2004; and Kumar 2001) that show a clear benefit of IDD. They believe there is a natural bias against "invasive procedures" such as surgical pump implantation, but they cite a Europe study indicating only a .7% infection and annual complication rate requiring surgical intervention of 10.5% over 12 year follow up (Fluckiger, et al 2008), and that the pump continues to evolve. Lastly, they feel the committee incorrectly concluded that the therapy was not cost-effective, citing the multiple cost analysis included in the report.

The Washington-Alaska Pain Initiative opposes the draft decision indicating that they do not believe that the committee has met statutory criteria that require substantial evidence for decisions contrary to Medicare and expert treatment guidelines and the decision unfairly discriminates against vulnerable individuals in chronic pain. The new expert guideline is cited.

Industry and Manufacturer

Medtronic Inc. opposes the draft decision citing the statutory criteria for determinations to be consistent with medicare decisions and expert treatment guidelines, referencing a new expert treatment guideline and a chart citing approximately 25-26 treatment guidelines that support IDDS coverage, and 1-2 that do not; with of those, treatment guidelines that are endorsed by medical specialty and patient advocacy groups, at least 10 support coverage and 1 does not. Because the committee voted that there is inconclusive evidence on safety, efficacy, and cost effectiveness, and most treatment guidelines and the Medicare decision support coverage, the decision is contrary to the statute.

Medtronic believes that it was inappropriate for HTA staff to highlight only four sources and not include other treatment guideline information. MedTronic cites three new and recently updated treatment guidelines from Institute for Clinical Systems Improvement (ICSI); Intracorp; and American College of Occupational and Environmental Medicine (ACOEM) that support selected use of the pump.



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. Craig 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.



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 public meeting.



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

12-11-2008: Draft version not officially adopted yet



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.
 - 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.
 - 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.
 - 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
 - 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.
 - 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.
 - Context: Unanimous recommendation for approval from FDA Advisory Panel.
 - 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.
 - Complications – What hasn't happened: Not seen / reported on device retro-expulsions, traumatic subluxations / dislocations, or catastrophic failure.
 - 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.
 - 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.
 - 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.



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.
 - 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.

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 public 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.