

## Health Technology Clinical Committee Findings and Coverage Decision

Topic: Artificial Disc Replacement

Meeting Date: October 17, 2008

Final Adoption: March 20, 2009

### Number and Coverage Topic

10172008 - Artificial Disc Replacement

### HTCC Coverage Determination

Cervical and Lumbar Artificial Disc Replacement is a **covered benefit** only under criteria identified in the reimbursement determination.

### HTCC Reimbursement Determination

#### ❖ **Limitations of Coverage:**

##### **Lumbar ADR**

- 1) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
- 2) Patients must be 60 years or under;
- 3) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
  - Failure of at least six months of conservative treatment
  - Skeletally mature patient
  - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Artificial Disc Replacement FDA general contra-indications:

- Active systemic infection or infection localized to site of implantation
- Allergy or sensitivity to implant materials
- Certain bone and spine diseases (e.g. osteoporosis, spondylosis)

##### **Cervical ADR**

- 1) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
  - Skeletally mature patient

- Reconstruction of a disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

Artificial Disc Replacement FDA general contra-indications:

- Active systemic infection or infection localized to site of implantation
- Allergy or sensitivity to implant materials
- Certain bone and spine diseases (e.g. severe spondylosis or marked cervical instability)

❖ **Non-Covered Indications**

Non-FDA approved uses

❖ **Agency Contact Information**

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Uniform Medical Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

**A. Health Technology Background**

The Artificial Disc Replacement (ADR) topic was selected and published in August 2007 to undergo an evidence review process per RCW 70.14.100(1)(a). ADR is the complete removal of the damaged disc and implantation of an artificial disc. The intent is to treat the pain and disability believed to be caused by a degenerated disc by removing the diseased. Both L-ADR and C-ADR are intended to preserve motion at the involved spinal level and therefore decrease stresses on adjacent segment structures and the risk of adjacent segment disease.

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 August 27, 2008, the HTA posted a draft report, invited public comment, and posted a final report on September 19, 2008. The contractor reviewed publicly submitted information, and searched, summarized, and evaluated trials, articles, and other evidence about the topic. This comprehensive, public and peer reviewed, report is 230 pages, identified 176 potentially relevant articles, and a Medicare coverage decision. 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 artificial disc replacement. The result is a critical appraisal of: 2 moderate quality randomized controlled trials, 25 low quality case series, and 2 economic analysis for lumbar ADR; and 3 moderate quality randomized controlled trials, 22 low quality case series, and 1 economic analysis for cervical ADR. Using a formal, objective method of

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evaluating evidence, the evidence based technology assessment report concluded that there was: no evidence comparing ADR to non surgical alternatives; moderate evidence of equivalent or superior short term efficacy of ADR compared to fusion; no evidence for broad safety conclusions, and moderate evidence of comparable short term safety profiles between ADR and fusion, and no evidence on cost effectiveness.

On October 17<sup>th</sup>, 2008, the HTCC, an independent group of eleven clinicians, met at an open public meeting to decide on whether state agencies should pay for artificial disc replacement in the lumbar and cervical spine based on whether the evidence report and other presented information proves it is safe, effective and has value. The HTCC reviewed the 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.

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## **B. Committee Findings**

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

### **B.1. Evidence availability and technology features**

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

- 1.1. Five (two lumbar and three cervical) randomized controlled studies form primary evidence base comparing ADR to fusion surgery. Efficacy of comparator treatment, fusion remains uncertain and given evidence uses only this comparator, it limits the ability to fully answer efficacy/effectiveness question.
- 1.2. No evidence compares ADR to optimal medical treatment.
- 1.3. 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.
- 1.4. 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. device operation [technical performance, no device failure, no deterioration] and an ODI improvement of 25%).

### **B.2. Is the technology safe?**

The committee separately discussed lumbar and cervical ADR safety outcomes. The committee found the following key evidence on safety from the evidence report:

- 2.1. No case related deaths were reported for either lumbar or cervical ADR.
- 2.2. No data on long term safety and complication rates was available for either lumbar or cervical ADR.
- 2.3. FDA database (MAUDE) listed about 500 safety events, but does not include denominator information.
- 2.4. L-ADR device related failure that required reoperation, revision, or removal as reported in trials was not statistically different (fusion 2.7 and 8.1% vs. ADR 5.4 and 3.7%)
- 2.5. L-ADR short term complications from trials and case series varied greatly from 1% to 60% - heterotopic ossification, hematoma, subsidence, and new or residual pain, secondary fusion especially had high ranges. No statistical differences in major adverse events/complications from trials between fusion and L-ADR.
- 2.6. C-ADR device related complications and failures (2.9%) occurred statistically significantly less than with fusion (8.9%).
- 2.7. C-ADR short-term complications from 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.

### **B.3. Is the technology effective?**

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

- 3.1. Neither lumbar nor cervical ADR had evidence on the long term durability of the device and efficacy of the intervention.
- 3.2. No studies looked at subgroups or performed subpopulation evaluation to determine those most or least likely to benefit. Applicability in older population and generalizability outside trial population unclear.
- 3.3. Return to Work and quality of life measures were not adequately reported on in either lumbar or cervical studies.
- 3.4. Preservation of flexibility measure was reviewed. This is generally not a comparative measure with fusion because fusion is designed to limit motion. Trials demonstrate pre operative motion generally maintained with ADR; both C-ADR and L-ADR had greater motion preservation than fusion.
- 3.5. A key proposed health benefit of ADR over fusion is that preservation of motion will relieve adjacent level stress/ adjacent segment disease (ASD). This outcome was not measured in the randomized controlled trials. For L-ADR, non-randomized studies reported ASD in 0% to 34%. For C-ADR, ASD was reported at 1% in C-ADR vs 3% in fusion in RCT; other studies reported ASD rates of 1% to 7%.
- 3.6. Pain Relief. The evidence report concluded that ADR appears to provide as good or greater pain relief for single level disease than fusion. VAS pain score reductions for patients receiving L-ADR, over 2 years, were statistically significant. For C-ADR, both surgical groups reported clinically significant pain relief. There were no statistical differences in pain relief between C-ADR and fusion as measured out to two years.
- 3.7. Functional improvement. The evidence report included analysis on SF-36, clinical success and ODI for L-ADR. SF-36 a common health survey, scores 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. For C-ADR, the primary measure used was neck disability index (NDI). NDI improvement in score of at least 15 points reached in both groups - 80% fusion and 82% C-ADR. The difference was not statistically significant.
- 3.8. Neurological success for C-ADR was defined in the trials to include both maintain and improve neurological function. 78% of C-ADR and 67% of fusion patients achieved bar – a statistically significant difference.
- 3.9. A composite measure of overall clinical (surgical) success defined by FDA standard – 66% C-ADR success vs. 55% fusion success.
- 3.10. Patient Satisfaction measured in two lumbar ADR trials and one cervical trial was reported higher for ADR than for fusion and more ADR patients than fusion patients would choose their treatment again. Not reported when the patients were asked questions; variable tools used.

#### **B.4. Is the technology cost-effective?**

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

- 4.1. The evidence report summarized two technology assessments that did include economic analysis comparing fusion and L-ADR (Ontario and Australia). These 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. One Australian HTA concluded that C-ADR and fusion costs were the same. Analysis includes assumptions related to health care system; practice patterns, and reimbursement mechanisms not present in US.

- 4.2. Economic studies reflected short time horizons to assess the potential cost-effectiveness of ADR technology and need appropriate comparator.
- 4.3. Approximate cost for ADR in WA based on 50% of hospital costs: L-ADR at \$20,113 and C-ADR at \$14,344.
- 4.4. No manufacturer provided any cost data.

### **C. Committee Conclusions**

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

#### **C.1. Evidence availability and technology features**

The committee concludes that the best available evidence on artificial disc replacement has been collected and summarized.

- 1.1. There is moderate evidence from 5 randomized controlled trials and about 40 uncontrolled studies about several important health outcomes for artificial disc replacement. The randomized trials have shared limitations: some methodological flaws, fusion as only comparator, non-inferiority design, lack of long term data, and measure/definition of success.
- 1.2. The controlled studies compare surgical options only. Fusion surgery as a treatment for spine pain is still not established a clearly superior option, so the lack of inclusion of optimized medical management severely limits the results.
- 1.3. As compared to fusion, a currently approved alternative, the overall evidence is moderate and demonstrates at least equivalence of ADR in short term safety and efficacy.
- 1.4. Longer follow up data, especially around safety events and reoperation rates is needed (often this evidence comes from non RCT data such as registries). Also, the post approval FDA studies requiring up to seven year follow up should be monitored.

#### **C.2. Is it safe?**

The committee concludes that the comprehensive evidence reviewed shows that the technology has been proven at least equally safe as a currently offered alternative, fusion. Key factors to the committee's conclusion include:

- 2.1. Moderate evidence demonstrated that L-ADR has a similar safety profile as lumbar anterior or circumferential fusion two years following surgery. Longer term safety on L-ADR is not known.
- 2.2. Moderate evidence demonstrated that C-ADR tends to be safer than fusion as measured by the risk of device failure and surgical complications up to two years following surgery. Longer term safety on C-ADR is not known.

**C.3. Is it effective?**

The committee concludes that the comprehensive evidence reviewed shows that the technology has been proven equally or more effective as a currently offered alternative, fusion. Key factors to the committee's conclusion include:

- 3.1. While there is no evidence comparing ADR with non-operative care, there are five moderate quality, controlled studies comparing ADR with a currently performed alternative, fusion. Based on the limited comparator and other evidence limitations, the evidence of efficacy should not be generalized beyond carefully selected patients that match trial and FDA indications.
- 3.2. Moderate evidence demonstrated that the efficacy/effectiveness of L-ADR is comparable with fusion up to two years following surgery based on a composite measure for FDA approval of overall clinical success, pain improvement, an ODI and SF-36 improvement..
- 3.3. Moderate evidence demonstrated that the efficacy/effectiveness of C-ADR is equal to fusion for pain and function and potentially superior to fusion for neurological and overall success up to two years following surgery.
- 3.4. There is insufficient evidence to draw conclusions regarding the safety and efficacy of ADR in special populations or populations outside those studied for FDA approval. Thus, coverage should be limited to studied indications.

**C.4. 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 cost-effectiveness is unproven because of insufficient evidence.

- 4.1. The cost analyses were limited by short time horizons, comparators chosen, and differences with US health system, and provided mixed answers. For L-ADR, one assessment showed an increase in cost based on the device cost and another showed similar or possibly reduced cost based primarily on shorter hospital stays for L-ADR. For C-ADR, one cost analysis showed similar surgical costs, but higher total cost with C-ADR due to device cost.

**C.5. 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. The independent evidence report identified a national medicare coverage decision on lumbar fusion and no expert treatment guidelines. The committee's conditional coverage is consistent with the national medicare decision to not cover lumbar ADR for patients older than 60 years of age.

**D. Committee Decision**

Based on the deliberations of key health outcomes, the committee decided that evidence on Artificial Disc Replacement demonstrates net health benefit because of moderate level evidence based on randomized controlled trials of effectiveness and short term safety.

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The committee found that artificial disc replacement, as compared to fusion, was proven to be equally or more safe and effective, and the cost was not a significant factor for this decision based on inconclusive data. Based on these evidentiary findings, the committee voted for conditional coverage as follows:

- Lumbar-ADR: 6 cover with conditions and 2 no coverage
- Cervical-ADR: 8 cover with conditions

### **E. 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 public 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.

FDA Approved Devices: Use Indications and Contra-Indications

ProDisc C: <http://www.fda.gov/cdrh/pdf7/p070001b.pdf>

Prestige: <http://www.fda.gov/cdrh/pdf6/p060018b.pdf>

Charite: <http://www.fda.gov/cdrh/PDF4/p040006b.pdf>

ProDisc L : <http://www.fda.gov/cdrh/pdf5/p050010b.pdf>