



Health Technology Clinical Committee
Date: November 16, 2007
Time: 8:00 am – 4:30 pm
Location: Marriott Hotel – 3201 South 176th Street, Seattle, WA 98188
Teleconference Bridge: 360-923-2996 Access Code: 360-946-1464
Adopted Date: 02/15/2008
HTCC MINUTES

Members Present: Brian Budenholzer; C. Craig Blackmore; Michael Myint; Carson Odegard; Daniel Abrahamson; Richard Phillips; Michelle Simon, Michael Souter, Louise Kaplan, and Jay Klarnet.

HTCC Formal Action

- ✓ **Call to Order:** Dr. Budenholzer, Chair, called the meeting to order at 8:03 a.m. Sufficient members were present to constitute a quorum.
- ✓ **August 24, 2007 Minutes:** Dr. Budenholzer referred members to the draft minutes and called for discussion or objection, and received none.
 - *Outcome:* The committee unanimously approved the August 24, 2007 minutes.
- ✓ **Lumbar Fusion Determination:** The HTCC reviewed and considered the Lumbar Fusion and Discography technology assessment report, information provided by the Administrator, agency comments, ECRI Institute's presentation; and invited public testimony. The committee considered all the evidence and has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Lumbar fusion for patients with chronic low back pain and lumbar degenerative disc disease is a **covered benefit** only under the criteria identified in the reimbursement determination. This decision does not apply to patients with the following conditions:

- Radiculopathy
- Functional neurologic deficits (motor weakness or EMG findings of radiculopathy)
- Spondylolisthesis (>Grade 1)
- Isthmic spondylolysis
- Primary neurogenic claudication associated with stenosis
- Fracture, tumor, infection, inflammatory disease
- Degenerative disease associated with significant deformity

❖ Limitations of Coverage

Covered under certain conditions: when there is a failure or inability to access a structured, intensive, multi-disciplinary program.

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HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

Agenda Item: Welcome & Introductions

Brian Budenholzer, Committee Chair, and Leah Hole-Curry, HTA Program Director, opened the meeting with an overview of the agenda, meeting purpose and introductions.

- ✓ The Health Technology Clinical Committee (HTCC) met on November 16, 2007, to discuss the evidence of the safety, efficacy and cost-effectiveness of Lumbar Fusion and Discography for patients with chronic, uncomplicated low back pain ; hear ECRI Institute's report presentation and public comment; approve the August 24, 2007 public meeting minutes; and make a coverage determination on the health technology based on the evidence.

Agenda Item: HTA Program Update

Leah Hole-Curry, HTA Program Director, presented an HTA program update

- ✓ HTA Goal: Achieve better health by paying for technologies that work.
 - Maintain an open and transparent process; eliminate bias; promote consistency; and remain flexible by reviewing evidence regularly to ensure updated information is included.
 - The purpose of the committee is to make coverage determinations for the participating agencies (Health Care Authority; Department of Social and Health Services; and Labor and Industries) based on a health technology assessment that reviews the scientific evidence of the relative safety, efficacy, and cost; information from any special advisory groups; and their professional knowledge and expertise.
 - Medical technologies identified as a primary driver of increased costs
 - Variation in care studies demonstrate significant variation in rate of treatment resulting in higher cost, higher utilization in certain areas that do not have corresponding better health
 - Consumer reports – new report on over utilized services including back surgery
 - Key focus questions: Is it safe? Is it effective? Does it provide value?
- ✓ Program Progress: Current technologies under review
 - 3 topics selected in January 2007
 - Upright MRI: Clinical committee decision of no coverage in May 2007. Agencies have implemented coverage change (July 2007).
 - Pediatric Bariatric Surgery: The committee unanimously voted that Pediatric Bariatric surgery for patients under 18 is not a covered benefit due to insufficient evidence to conclude that it is safe, efficacious, and cost-effective. The committee decided by a majority vote that Pediatric Bariatric surgery for patients aged 18 – 20 years is a covered benefit only under certain criteria. Bariatric surgical procedure of Laparoscopic adjustable gastric banding only.
 - Lumbar Fusion and discography: committee decision pending today.
 - New selected technologies are published to the website and public comment period is completed. Work plans and key questions are being drafted.

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- Cardiac Stent
 - Artificial Discs
 - Arthroscopic Surgery of the Knee
 - Computed Tomographic Angiography (CTA for cardiac care)
 - Virtual Colonoscopy (CTC)
 - Intrathecal Pump (Chronic non-cancer pain management)
 - ✓ Coverage Determination Process:
 - As defined in the WAC when making a coverage determination, committee members shall review and consider the health technology assessment. The committee may also consider other information it deems relevant, including other information provided by the administrator, reports and/or testimony from an advisory group, and submission or comments from the public.
 - HCA Administrator selects technology → Vendor produce Technology Assessment Report → Clinical committee makes coverage determination → Agencies implement decision (unless statutory conflict).
 - The committee shall give the greatest weight to the evidence determined, based on objective factors, to be the most valid and reliable, considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The committee may also consider additional evidentiary valuation factors such as recency (date of information); relevance (the applicability of the information to the key questions presented or participating agency programs and clients); and bias (presence of conflict of interest or political considerations).

Agenda Item: Topic Introduction, Agency Utilization, Medicare and Other Guidelines

Dr. Dave Flum, HTA Clinical Consultant, introduced the Lumbar Fusion topic; Leah Hole-Curry, HTA program director provided agency, medicare, and guideline information; and Dr. Gary Franklin, L&I Medical Officer provided outcomes information on L&I clients.

- ✓ No consensus that uncomplicated, chronic low back pain (discogenic) is indication for spinal fusion. (Other indications related to trauma, neurological issues, etc. not under consideration)
 - Discography as a test to confirm or select patients for surgery is also based on theory that disc causing pain, no clear case definition of degenerative disc disease; no correlation between positive test results and surgical benefits
- ✓ Efficacy concerns: Surgery is based on theory that immobilizing a degenerated disc relieves pain - some individuals respond to surgery, others do not, rarely completely resolves pain; patients with equivalent disc degeneration can have no pain; L&I experience, over 60% remain disabled
- ✓ Safety concerns: high surgical complication rates and re operation rates makes some patients worse off
- ✓ High variation in nation in back surgery and in WA – up to a three fold difference based on geographic location
- ✓ Centers for Medicare and Medicaid Services (CMS) has no national Medicare coverage policy on spinal fusion or discography.

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- CMS Medicare Coverage Advisory Committee considered lumbar fusion for treatment of DDD in Medicare enrollees over 65 on Nov 2006 based on a systematic review that found no clinically meaningful difference between lumbar fusion and non-surgical alternatives but no coverage decision issued.
 - ✓ Four entities published Spinal fusion guidelines: American Association of Neurological Surgeons (2005); Work loss Data Institute (2006); American College of Occupational Health and Environmental Medicine (2004); Washington State Department of Labor & Industries (2002)
 - Evidence relied upon for guideline not explicit/variable
 - No consensus that uncomplicated, chronic low back pain is indication for spinal fusion
 - ✓ Five entities published guidelines including discography: American Society of Interventional Pain Physicians (2007); Work loss Data Institute (2006); American Association of Neurological Surgeons (2005); American College of Occupational Health and Environmental Medicine (2004); Washington State Department of Labor & Industries (2002)
 - Evidence relied upon for guideline not explicit/variable
 - No guideline recommends discography as stand along pre-operative diagnostic test; MRI recommended as diagnostic test of choice
 - Three guidelines indicate reserve for patients with equivocal or inconclusive MRI; two do not recommend use; one recommends against surgery if positive discogram but normal MRI
 - ✓ Medicaid and UMP currently cover Lumbar Fusion and Discography (no indication restrictions). L&I covers, with certain restrictions
 - 2006 – total of 732 beneficiaries received surgery, cost of 23.9 million; average surgical cost \$30,900. 148 discographies prior to surgery, cost of \$323,600; approx. \$2000 each
 - ✓ Labor & Industries covers Lumbar Fusion under certain criteria based on the Industrial Medical Advisory Committee guideline (2001). Requires prior authorization for fusion; approval for fusion only if either 1) measurable instability present, and/or 2) objective evidence of neurological impairment associated with DDD / bony deformity. Considers relative contra-indications to fusion (smoking, multi-level DDD, significant psyche factors, no improvement from prior spine surgery).
 - ✓ Washington State Agency outcome experience from a Labor and Industries 2006 study (Spine 31: 2715-23) of 1950 cases reported on scope, disability status, and safety profile for both post operative complications and Re-operations; included all surgeries from 1994-2001.
 - 63.9% disability at 2 years (214 cases or 11.3% total disability)
 - 22% re-operation rate; with instrumentation doubling re-operation risk
 - 11.8% (218 cases) serious postoperative complications
 - ✓ The agencies cover fusion surgery alternatives, including but limited to (single or in combination): cognitive behavioral therapy; medications (anti-depressant, Acetaminophen, NSAID); and rehabilitations (psychological, exercise & education, interdisciplinary rehabilitation, and spinal manipulation).
 - ✓ Eight multi-disciplinary pain clinics with cognitive behavioral therapy (CBT) available including Tacoma, Seattle, Redmond, Spokane, Portland, OR and Boise, ID. All must be accredited by



CARF - Commission on Accreditation of Rehabilitation Facilities. All intensive, six to eight hours/daily, up to eighteen consecutive days (plus, five follow-up days over three months post-discharge and ten more days if needed). Approximately one thousand workers each year are evaluated and treated with an approximate average of \$7,000 per case = about \$7 million per year.

Agenda Item: Technology Assessment Presentation

James Reston, Ph.D., M.P.H., and Jonathan Treadwell, Ph.D., from ECRI Institute presented a summary of the technology assessment report.

- ✓ ECRI Institute's technology report evaluates relevant published research describing use of lumbar fusion and discography in patients with chronic low back pain and uncomplicated degenerative disc disease (DDD).
- ✓ The word "uncomplicated" is intended to exclude patients who had fusion for the following conditions: Radiculopathy; functional neurologic deficits (motor weakness or EMG findings of radiculopathy); spondylolisthesis; isthmic spondylolysis; primary neurogenic claudication associated with stenosis; fracture, tumor, infection, inflammatory disease; and degenerative disease associated with significant deformity.
- ✓ *Epidemiology of low back pain*: most common cause of disability in patients under age 45. Causes greater loss of productivity than any other medical condition. 1.2 million patients in the U.S. disabled by chronic low back pain. Degenerative disc disease and low back pain: DDD can be identified by a plain radiography, CT, or MRI. DDD can occur at any level, but is not always associated with pain. No clear case definition for "discogenic back pain".
- ✓ *Non-operative therapies*: back education; medications; weight reduction; exercise; physical therapy; cognitive behavioral therapy; chiropractic manipulation; acupuncture; and therapeutic massage.
- ✓ DDD in association with chronic low back pain that has not responded to conservative therapy is considered by some surgeons as an indication for spinal fusion. Goal is to permanently immobilize the spinal column vertebrae surrounding the disc(s) that is/are diagnosed as the cause of chronic low back pain.
- ✓ Inclusion criteria: peer-reviewed full-length publications (no meeting abstracts or supplements). English language publications. Patients had chronic (3+ months) lumbar pain. At least 80 percent did not have excluded conditions. At least 80 percent of patients must have contributed follow-up data to a given time point. At least 80 percent of patients enrolled for fusion must have received fusion.
- ✓ Literature search: Medical librarians searched 15 databases. 482 articles identified; 243 retrieved; 30 included (27 unique studies). 4 studies were identified for Key Question 1; 27 studies identified for Key Question 2; and 1 study identified for Key Question 3.

Evidence-Based Summary and Conclusions

- ✓ Assessment of Overall Strength of Evidence
 - Key Question #1: Strength of evidence was insufficient to conclude that lumbar fusion surgery is more effective to a clinically meaningful degree than nonsurgical treatments for any of the following patient populations, comparisons and outcomes:

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- Fusion versus Intensive exercise/rehabilitation plus cognitive behavioral therapy (CBT) in patients without prior back surgery: 2 moderate-quality RCTs (n = 413 patients) revealed no clinically meaningful difference between fusion and intensive exercise-rehabilitation plus cognitive behavioral therapy in patients without prior back surgery. Strength of evidence: Weak.
- Fusion versus intensive exercise/rehabilitation plus cognitive behavioral therapy in patients with prior back surgery: the evidence from one moderate-quality RCT (n = 60 patients) was insufficient to determine the relative benefits of lumbar fusion compared to intensive exercise/rehabilitation in patients with prior back surgery.
- Fusion versus non-intensive physical therapy in patients without prior back surgery: the evidence from one moderate-quality RCT (n = 294 patients) was insufficient to determine the relative benefits of lumbar fusion compared to conventional physical therapy in patients with or without prior back surgery.
- Key Question #2: Strength of evidence assessments were not performed because of variability in the reporting of adverse events across different studies.
 - None of the four RCTs comparing fusion to non-intensive physical therapy or intensive exercise/rehabilitation plus CBT reported any adverse events occurring in patients who only received non-operative care.
 - Categories of adverse events most frequently reported in fusion studies include reoperation (18/27 studies); infection (14/27 studies); various device-related complications (13/27 studies); neurologic complications (12/27 studies); thrombosis (11/27 studies); bleeding/vascular complications (10/27 studies); and dural injury (10/27 studies).
- Key Question #3: The evidence from one moderate-quality RCT (n = 294 patients) was insufficient to conclude what patient characteristics are associated with differences in the benefits and adverse events of lumbar fusion surgery.
- Key Question #4: The evidence was insufficient to permit any conclusions about the reliability of discography for patients with chronic low back pain and uncomplicated lumbar degenerative disc disease.
- Key Question #5: The evidence was insufficient to permit any conclusions about the use of discography to predict fusion outcomes in patients with chronic low back pain and uncomplicated lumbar degenerative disc disease due to the low quality and heterogeneous results from three studies (n = 330 patients).
- Key Question #6: No evidence of reasonable quality was available; thus, the evidence was insufficient to permit any conclusions about the influence of discography on fusion outcomes in patients with chronic low back pain and uncomplicated lumbar degenerative disc disease.

Agenda Item: Public Comments

- ✓ Four scheduled public comments: 1) Dr. Paul McCormick, American Association of Neurological Surgeons and The Congress of Neurological Surgeons; 2) Dr. Jens Chapman; 3) Dr. Charles Fisher for AdvaMed; and Dr. Richard Wohms (substituted) and 4) Dr. Sohail Mirza.
- ✓ Three individuals provided public testimony: Anthony Petroff; Theodore Wagner; and Steven Vanstone.



Agenda Item: HTCC Decision Tool

Brian Budenholzer, Chair, and the committee used the decision worksheet in evaluating the evidence of the technologies’ safety, efficacy, and cost effectiveness. The tool was a combination of efforts based on staff, committee input and Dr. Budenholzer’s research, it was refined after the first and second committee meeting based on input of the committee. Committee members use the worksheet to assist them in their discussion and evaluation of the technology.

Agenda Item: HTCC Lumbar Fusion Technology Decision

Brian Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost effectiveness of lumbar fusion surgery. The related discussion on discography as a diagnostic tool to identify patients for lumbar surgery was tabled for future discussion due to time constraints.

Effectiveness: The committee found that there was sufficient scientific evidence to draw conclusions about effectiveness based on a total of four randomized controlled trials of moderate quality. Committee members separated the evaluation of effectiveness of lumbar fusion into a comparison with usual care and cognitive behavioral therapy with intensive rehabilitation. Three outcomes were important in this evaluation: pain relief, disability improvement, and return to work.

- ❖ A majority of the committee found that the scientific evidence confirms that, as compared with usual care/no additional treatment, lumbar fusion provides greater benefit in terms of pain relief and disability improvement. However, a majority were not confident in the evidence (e.g. while evidence is sufficient, further evidence could change results). A majority of the committee found that the evidence is inconclusive on whether lumbar fusion resulted in an equivalent or improved number of patients returning to work.
- ❖ A majority of the committee found that the scientific evidence confirms that, as compared with cognitive behavioral therapy and intensive rehabilitation, lumbar fusion provides an equivalent benefit in terms of pain relief and disability improvement. However, a majority were not confident in the evidence (e.g. while evidence is sufficient, further evidence could change results). A majority of the committee found that the evidence is inconclusive on whether lumbar fusion resulted in an equivalent or improved number of patients returning to work.

EFFECTIVENESS				
Spinal fusion versus intensive rehabilitation therapy				
	Health Outcome			
	Greater Benefit	Equivalent Benefit	Less Benefit	Inconclusive
Pain Relief	0	8 (N=6;C=2)	0	3
Disability Improvement	1 (N=1;C=0)	7 (N=4;C=3)	0	3
Return to work	0	1 (N=0;C=1)	0	10
EFFECTIVENESS				
Spinal fusion versus usual care				
	Health Outcome			
	Greater	Equivalent	Less	Inconclusive

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	Benefit	Benefit	Benefit	
Pain Relief	7 (N=4;C=3)	3 (N=3;C=0)	0	1
Disability Improvement	6 (N=1;C=5)	1 (N=1;C=0)	0	4
Functional Restoration	N/A	N/A	N/A	N/A
Return to work	3 (N=2;C=1)	0	0	8

N and C designation are as defined in the decision tool and apply throughout vote record

N= Not Confident	C= Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

Safety: The committee members that there was sufficient scientific evidence to make conclusions about the safety of spinal fusion. Committee members were confident that the scientific evidence confirmed that spinal fusion resulted in a small increase in mortality; and more morbidity related to surgical complications (including infection, device complication, neurological complications, thrombosis, bleeding, vascular complication, and dural injuries) than any non-surgical alternative treatment. Compelling considerations included the reported adverse events from the randomized trials and the high disability rate and complications rate reported by the Labor and Industries study.

SAFETY				
Spinal fusion versus non operative care				
	Adverse Outcome			
	Fewer Outcomes	Equivalent Outcomes	More Outcomes	Inconclusive
Mortality	0	0	Small: 7 (N=0;C=7) Large: 4 (N=0;C=4)	0
Morbid complications of surgery (infection, device complication, thrombosis, bleeding/vascular complication; dural injury)	0	0	11 (N=1;C=10)	0

Cost: The committee members found that there was no independent cost analysis, though data from agencies, a follow up of one of the cited studies, and the technology assessment report were available. The technology assessment report cited average billed cost for a commercial carrier for an inpatient spinal fusion surgery cost \$62,982. The cost to state agencies for lumbar fusion (including the facility and professional fees) ranged between \$21,000 and \$37,200. This estimate does not include any pre-surgery care, post surgical complications or outliers. Committee members found that there was

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sufficient evidence to conclude that the short term costs associated with lumbar fusion are greater than alternatives, but that there was insufficient evidence regarding long term costs.

COST							
Spinal fusion to non operative approach (including intensive rehabilitation therapy)							
Short Term Cost (1 st yr of care)				Long Term Costs (beyond the first year)			
Greater	Equivalent	Lower	Incon- clusive	Greater	Equivalent	Lower	Incon- clusive
10	0	0	1	3	0	0	8

Benefit Evaluation: A majority of the committee members found that spinal fusion resulted in a net benefit when compared with usual care, and an equivalent benefit when compared with intensive therapy and cognitive behavioral therapy; and that use of the technology is likely to increase costs. Given the increased cost and additional harms caused by the surgery, the committee discussed conditions for coverage, focused on ensuring that spinal fusion is a last resort option. Compelling considerations included the chronic nature of the condition, alternatives that were not effective for all patients or provided no greater benefit; harms of spinal fusion apply in many surgical interventions, the inability to determine which patients benefit, and the potential to reduce utilization to only those that have tried non-invasive alternatives first.

BENEFIT EVALUATION				
Spinal Fusion compared to Usual Care				
Net	Equivalent	Less	Net Harm	Inconclusive
6	0	2	0	3
Spinal Fusion compared to intensive treatment				
Net	Equivalent	Less	Net Harm	Inconclusive
1	6	0	0	4
Based on the technology's cost impact...				
Increase Cost	Equivalent Cost	Lower Cost	Inconclusive	
8	0	0	3	

* Usual care = Net Benefit / Increased Cost

* Intensive treatment = Equivalent Benefit / Increased Cost