Health Technology Clinical Committee

Findings and Coverage Decision
Date: **11/16/07**
Topic: **Lumbar Fusion – Updated 02/15/08**

Number and Coverage Topic

2001101 – Lumbar Fusion

HTCC Coverage Determination

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

HTCC Reimbursement Determination

- **Limitations of Coverage**

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

- **Non-Covered Indicators**

  - Not applicable.

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plans	1-866-214-3724
Health and Recovery Services Administration	1-800-562-3022

***Due to time constraints, the committee did not discuss or make a coverage determination on discography. This technology, as it relates to diagnosing patients with chronic low back pain appropriate for lumbar fusion, will be reviewed at the next HTCC meeting conducted. Until that time, current agency policy remains in place.**

Health Technology Background

Low back pain is the most common cause of disability and loss of productivity in patients under age 45. Disabling, chronic low back pain impacts 1.2 million patients in the United States.

Spinal fusion is one treatment alternative that is used to reduce back pain by permanently immobilizing the spinal column vertebrae surrounding the disc(s) that is (are) thought to cause discogenic low back pain. Immobilizing the vertebrae is believed to reduce pain by limiting movement of degenerated discs. There are five surgical approaches that are used for spinal fusion in patients with discogenic low back pain that is attributed to degenerative disc disease. They are: posterolateral fusion, posterior lumbar interbody lumbar fusion, transforaminal lumbar interbody fusion, anterior lumbar interbody fusion, and circumferential fusion. The surgeries use various forms of instrumentation such as pedicle and facet screws, rods, and cages. The potential advantage of spinal fusion surgery is that surgery can more effectively immobilize disc movement, and thus reduce pain and disability caused by chronic back pain.

Harms caused by fusion surgery, regardless of surgical approach, include: the need for reoperation, infection, various device-related complications, neurologic complications, thrombosis, bleeding/vascular complications, and dural injury. These harms do not occur with non-surgical treatments. Non-surgical treatments for chronic low back pain include cognitive behavioral therapy, medications (NSAID, Acetaminophen, anti-depressant) and rehabilitation (including psychological care, exercise, education, interdisplinary rehabilitation, and spinal manipulation). The potential impact on the health system is unknown. Potential benefits include reduction in back pain and disability, thus reducing utilization and cost of therapies to treat pain. The potential burden includes the initial intensity of the surgical intervention on health care resources and patient, cost of surgery and pre and post operative care; costs and burden of complication caused by surgery; and long term maintenance for implanted devices.

Committee Findings

The HTCC reviewed and considered the evidence on lumbar fusion as a treatment for uncomplicated, chronic low back pain (discogenic), including the technology assessment report, cited studies, information provided by the Administrator, and public and agency comments.

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.

Safety: The committee members found 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.

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 from $21,000 to $37,200. This estimate does not include any pre-surgery care, post surgical complications or outliers. Committee members found that there was 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.

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 also apply in other 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.

Committee Authority

Participating state agencies are required by law to comply with the decisions of the Washington State Health Technology Clinical Committee (HTCC), an independent committee of eleven health practitioners. RCW 70.14.090 The HTCC makes coverage determinations for selected health technologies. A health technology may include medical and surgical devices and procedures, medical equipment, and diagnostic tests. The HTCC will also decide under what specific clinical situations the health technology is covered. RCW 70.14.110 HTCC decisions are based on evidence that the committee finds most valid that demonstrates the technology's safety, efficacy and cost effectiveness. Evidence includes a report concerning the technology, provided by a

company specializing in objective reviews of the scientific literature, information submitted by the agencies, and public comments. The HCA Administrator considers technologies for re-review within 18 months or if new evidence becomes available. RCW 70.14.100