

# Washington State Health Care Authority

## Agency Medical Director Comments

### Lumbar Fusion (Re-Review)

*November 20, 2015*

**Gary Franklin, MD, MPH**

Medical Director, Department of Labor and Industries  
Research Professor, University of Washington

Lumbar Fusion - Re-Review

## 2007 HTCC Coverage Decision on Lumbar Fusion

- Lumbar fusion for patients with chronic low back pain and DDD 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
- Patients must first meet the conditions of a structured, intensive multidisciplinary program as established by the agency (if covered)

2

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## Agency Medical Directors' Concerns

- **Safety = High**
- **Efficacy = High**
- **Cost = High**

3

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Lumbar Fusion - Re-Review

## Background

- Degenerative Disc Disease (DDD) arises from natural degeneration of intervertebral discs and adjacent structures
- Theory is that DDD is associated with low back pain in many individuals
- Some patients with chronic low back pain get better with no treatment while others experience temporary or sustained pain reduction or relief from:
  - Physical rehabilitation/care (graded exercise, rehabilitation, chiropractic)
  - Behavioral health care (education, cognitive behavioral therapy)

4

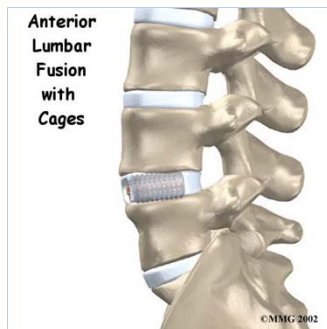
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## Background

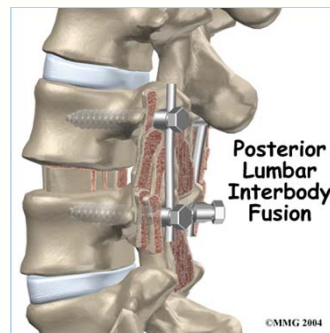
- Lumbar fusion may have a clear role for treating traumatic injuries, patients with significant and measurable instability, congenital defects, or central canal stenosis with neurological impairment
- Significant proportion of the fusion procedures are done in patients with chronic low back pain and uncomplicated DDD. The surgical premise for fusion is that disc degeneration causes pain that can be reduced/eliminated by immobilizing disc(s)
- Substantial evidence shows that lumbar fusion is no better than intensive, structured multidisciplinary treatment for chronic low back pain with DDD, but with much worse safety profile and greater cost
- Re-operation and surgical complication rates are very high
- Multilevel fusions and circumferential approaches are often performed without strong evidence of corresponding improvement in pain and physical functioning

5

## Lumbar Fusion Procedures

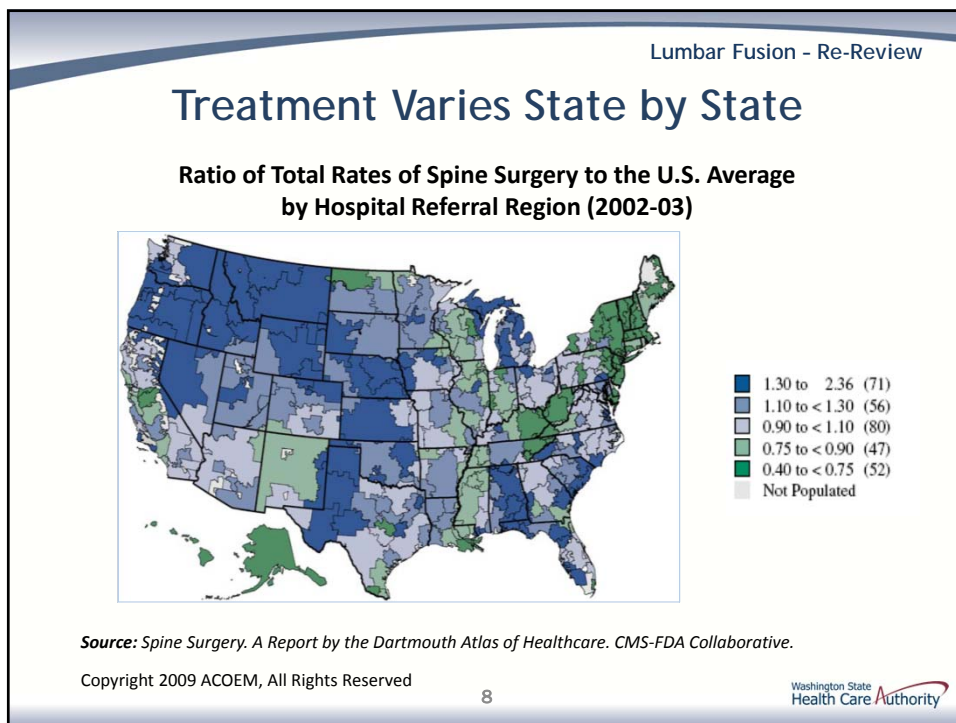
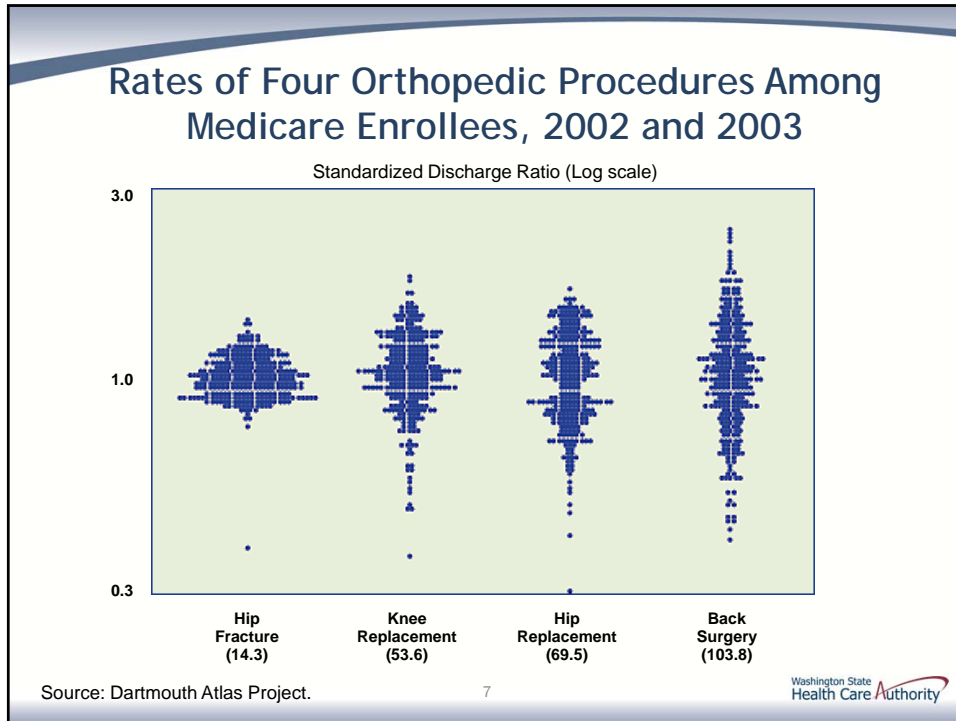


Anterior



Posterior

6



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## Current State Agency Policy

Description	Medicaid	UMP	DOC	LNI
Lumbar Fusion for Chronic Back Pain & DDD	PA	PA	PA	PA

**C:** Covered  
**NC:** Not covered  
**PA:** Prior authorization required

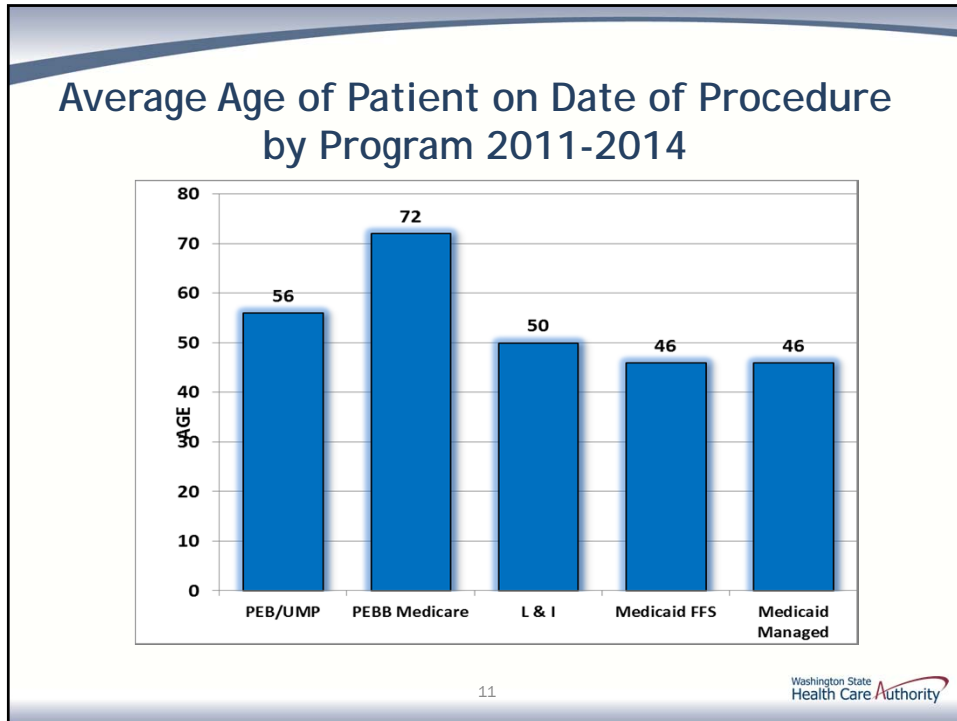
9

## Utilization & Cost of Lumbar Fusion, 2012-2014 - Dollars in millions -

	2012	2013	2014	3-Yr Total
<b>L&amp;I</b>				
Patient Count	401	404	343	1148
Paid (rounded)	<b>\$18.6</b>	<b>\$15.9</b>	<b>\$15.4</b>	<b>\$49.91</b>
<b>Medicaid FFS</b>				
Patient Count	241	281	391	913
Procedure Count	241	281	391	913
Paid (rounded)	<b>\$5.5</b>	<b>\$6.6</b>	<b>\$10.2</b>	<b>\$22.3</b>
<b>PEB/UMP<sup>§</sup></b>				
Patient Count	116	136	154	406
Procedure Count	117	137	157	411
Paid (rounded)	<b>\$6.8</b>	<b>\$7.1</b>	<b>\$8.7</b>	<b>\$22.61</b>

<sup>§</sup> Does not include Medicare

10



### Lumbar Fusion - Re-Review

## L&I Fusion Guideline

- Last Updated 2009 -

- Mandatory prior authorization
- Approval for fusion only if:
  - a) Measurable instability present; and/or
  - b) Objective evidence of neurological impairment associated with DDD/bony deformity; and/or
  - c) DDD and failed structured, intensive multidisciplinary program (SIMP) (since Dec 2009)

12

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### L&I Lumbar Fusion and SIMPs

Year	Procedure Count	Avg. Number of Years*	Number of SIMPs
2000	407	3.9	
2001	419	3.9	
2002	447	3.3	
2003	418	3.7	
2004	412	3.5	
2005	366	3	190
2006	382	3.5	230
2007	341	3.1	269
2008	345	3.3	277
2009	415	3.3	365
2010	412	3.7	549
2011	403	3.5	632
2012			528

\* Average number of years from claim established to lumbar fusion date.

13



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### Effectiveness\*: Lumbar fusion is no better than intensive rehabilitation - ICER

- **Fusion vs. Intensive Rehabilitation**  
 No benefit (3 RCTs - good quality)
- **Fusion vs. PT or Exercise Alone**  
 Small & short term benefits (2 RCTs – fair quality)<sup>§</sup>

\* Pain (VAS), function (ODI) and return to work

<sup>§</sup> In one small RCT (Ohtori et al), the control group was only minimally treated with 30 minutes of physician-supervised daily exercises and stretching.

14



## Compensation Status Relates to Poor Outcomes From Lumbar Fusion

- Lumbar fusion: 19 studies; odds ratio of worse outcome for fusion among compensation patients: 4.33 (95% CI: 2.81-6.62)\*
- Spine SCOAP-WA fusion outcomes-much worse outcomes in smokers and workers compensation

\*Harris I, et al. 2005; JAMA 293: 1644-52. A meta-analysis.

15

## Washington State WC Outcomes

- N= 388 from 1986-87
- 68% TTD at 2 years; 23% more surgery by 2 years
- Instrumentation doubled risk of reoperation
- Surgical experience didn't matter
- Key-WC fusion outcomes far worse than previously reported from surgical case series

Franklin et al, 1994; Spine 20: 1897-903

16



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## Washington State WC Outcomes

- 1,950 fusion subjects from 1994-2000  
85% received cages and/or instrumentation
- 64% disabled at 2 yrs
- 22% reoperated by 2 yrs + 12% other complications
- Cage/instrumentation use increased complications without improving disability or reoperation rate

Juratli et al, 2006; Spine 31:2715-23.

17

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## Safety Issues of Lumbar Fusion

**-ICER-**

- Perioperative Mortality: 0.2-0.3%
- Overall Complications\*: 9-20%
- Serious Complications: 1-3%
- Reoperation Rates: 12.5% over mean of 5 years of f/u. (range 4-32%)
- Reoperation rates in WA WC: 22% within 2 years of fusion<sup>§</sup>

\* The most common complications are cerebrospinal fluid leak, bleeding requiring transfusion, nerve root injury and surgical site infections.

<sup>§</sup> Juratli et al, 2006; Spine 31:2715-23

18

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## Mortality (WC) After Lumbar Fusion Surgery

- N = 2378 fusions between 1994-2001
- Death records - 103 deceased by 1994
- 90 day perioperative mortality 0.29% - Associated with repeat fusion
- Age and gender adjusted all cause mortality 3.1 deaths/1000 worker yrs
- Opioid-related deaths 21% of deaths and 31.4% of potential life lost
- Risk > with instrumentation/cages and DDD

Juratli et al, 2009. Spine 34: 740-47

19

## Failed Back Surgery Syndrome

- Incidence 10-40% (Chan and Peng, Pain Med 2011; 12: 577-606)
- Extremely disabling, often with severe neuropathic pain leading to further invasive procedures (more surgery, more opioids, spinal stimulators)

20

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## Lumbar Fusion Costs

- About \$50,000 PAID/case in PEBB and L&I
- Add costs for high rate of repeat surgery, failed back surgery syndrome

21

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## ICER Integrated Evidence Rating

- Lumbar fusion vs. interdisciplinary rehabilitation
  - Clinical Effectiveness: Inferior
  - Comparative Value: Low value
- Lumbar fusion vs. less intensive conservative management
  - Clinical Effectiveness: Comparable
  - Comparative Value: Low value

22

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## Private Payers' Policies

- Examples of private payers who don't cover lumbar fusion for low back pain due to DDD
  - Aetna
  - Anthem
  - the Regence Group
  - BCBS North Carolina

23

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## Blue Cross Blue Shield North Carolina May 2015

When lumbar spine fusion surgery is not covered:

- If not meet an included condition (eg, fracture, stenosis with neuro compromise)
- Not medically necessary if sole condition is any one or more of the following:
  - Disc herniation
  - Degenerative disc disease
  - Initial diskectomy/laminectomy for neural structure decompression
  - Facet syndrome

24

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## WA - Bree Collaborative Lumbar Fusion Warranty - Sept, 2014

- This model does not endorse the use of lumbar fusion to treat back pain associated with degenerative joint disease in the absence of structural instability.
- Even in the presence of spinal instability, a structured, conservative, non-surgical approach is preferred for patients without neurologic symptoms or signs. Failure of other therapies is likewise not a clear indication for lumbar fusion

25

## State Agency Recommendation

- Lumbar spinal fusion **not covered** for chronic low back pain and uncomplicated degenerative disk disease

26

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# Questions?

**More Information:**

Gary Franklin, MD, MPH

[fral235@lni.wa.gov](mailto:fral235@lni.wa.gov)

27

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**Order of Scheduled Presentations:**

***Lumbar Fusion for Patients with Degenerative Disc Disease – Re-Review***

Name	
	Jens R. Chapman, MD
	Rod J. Oskouian, MD
	Charles Nussbaum, MD
<b>1</b>	Matthew Fewel, MD
<hr/>	
<b>2</b>	Trent Tredway, MD
<hr/>	

**WA - Health Technology Assessment**

**Disclosure**

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	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of \$10,000.		X
2.	Equity interests such as stocks, stock options or other ownership interests.	X	
3.	Status or position as an officer, board member, trustee, owner.	X	
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.	X	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

- 3) AO North America
- 2) Renovis
- 6) AO Spine International

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X \_\_\_\_\_  
 Signature Date

Jens Chapman  
 Print Name

So we may contact you regarding your presentation, please provide the following:

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3.	Status or position as an officer, board member, trustee, owner.		<input checked="" type="checkbox"/>
4.	Loan or intellectual property rights.		<input checked="" type="checkbox"/>
5.	Research funding.		<input checked="" type="checkbox"/>
6.	Any other relationship, including travel arrangements.		<input checked="" type="checkbox"/>

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Washington State Neurosurgical Assoc. —  
No travel or honoraria

	Potential Conflict Type	Yes	No
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If yes to #7, provide name and funding sources: N/A

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X [Signature] 10/23/11 Charles Nussbaum  
Signature Date Print Name

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**WASHINGTON  
HEALTH TECHNOLOGY  
ASSESSMENT PROGRAM**

**November 20, 2015**

Jens R. Chapman, M.D.  
Charles Nussbaum, M.D.  
Matthew Fewel, M.D.  
Rod J. Oskouian, M.D.

WASHINGTON STATE ASSOCIATION OF NEUROLOGICAL SURGEONS

American Association of Neurological Surgeons

SSFS SEATTLE SCIENCE FOUNDATION

Congress of Neurological Surgeons  
The Special Society in Neurosurgical Education

## Re-review of Topic is unwarranted

- The discussion proposes re-review of current policy regarding lumbar fusions for the degenerative disc disease (DDD) population with chronic lumbar back pain (CLBP).
- Concerns:
  - Data limitations of prior literature:
    - The prior literature had multiple significant methodological limitations which prevented significant conclusions from being derived.<sup>1-4</sup>
    - The previously reviewed data was produced from 3 European studies which were not only unrelated to our population but demonstrated inferior results to those seen in North America.
  - Data limitations of newer literature:
    - The ICER report does not present data that justifies the change to the policy drafted in 2008.<sup>1-4</sup>

<sup>1</sup> Fritzell P et al, Spine 2001  
<sup>2</sup> Brox JJ et al Spine 2003  
<sup>3</sup> Brox JJ et al Pain 2006  
<sup>4</sup> Fairbank J et al BMJ 2005

## Lack of Specificity of ICER SR filters

- Heterogeneity of degenerative lumbar disease
- What is '*uncomplicated lumbar disc disease*'?\*

  - Grade 1 spondylolisthesis, spondylolysis
  - Spinal stenosis (central, foraminal)
  - Degenerative scoliosis
  - Modic changes
  - Number of levels
  - Previous lumbar spine surgery (same levels / adjacent)
  - Arthritis / inflammatory disease burden
  - Patient psychosocial and physical variables

\*The available literature does not address these conditions

## Key Points

### *Non-operative Care*

- Limited scrutiny has been placed on the efficacy of non-operative care in the DDD population despite literature failing to demonstrate improved outcomes.
- Excessive duration of ineffective nonoperative CLBP care leads to persistently inferior outcomes<sup>1,2</sup>
- There is no structured systems approach towards CLBP care in Washington state for at risk patients, such as L&I patients.
- Cognitive behavioral therapy (CBT) has been suggested as an alternative – in fact this is a vague therapy concept<sup>3,4</sup>
- Question we should be asking:
  - *What non-operative care should be considered for the DDD patient population with LBP, and how effective is it?*

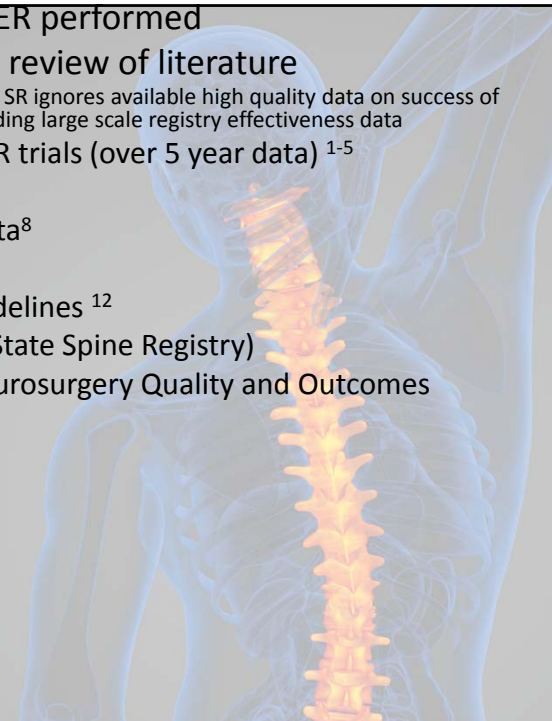
<sup>1</sup> Radcliff KE et al, Spine 36, 2011

<sup>2</sup> Rohan MX et al, Spine J 9, 2009

<sup>3</sup> Hanscom and Brox, Global Spine J (in print) 2015

<sup>4</sup> Williams, Cochrane 2012





**ICER performed selective review of literature**

- Narrow methodological scope of SR ignores available high quality data on success of surgical treatment of CLBP, including large scale registry effectiveness data
  - Control groups of ADR trials (over 5 year data) <sup>1-5</sup>
  - SPORT trials<sup>6-7</sup>
  - Cost effectiveness data<sup>8</sup>
  - PRCT's <sup>9-10</sup>
  - Specialty Society Guidelines <sup>12</sup>
  - SCOAP (Washington State Spine Registry)
  - N2QOD (National Neurosurgery Quality and Outcomes Database)

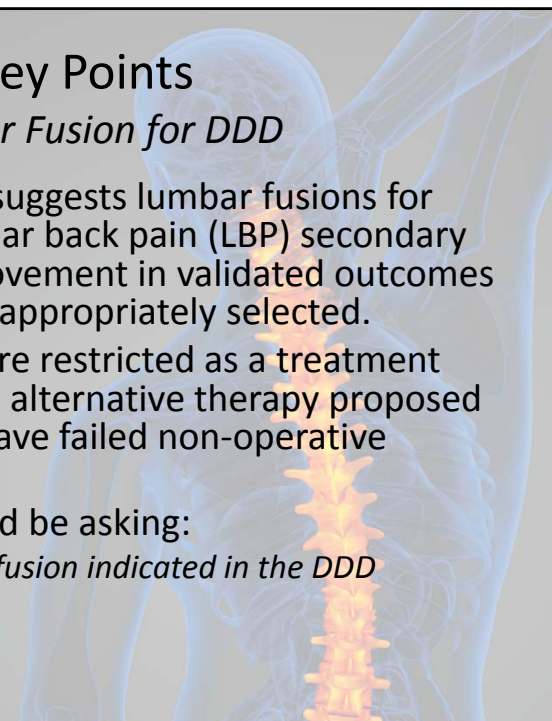
<sup>1</sup>Blumenthal S et al: Spine 30, 2005  
<sup>2</sup>Zigler J, et al: Spine 32, 2007  
<sup>3</sup>Delamarer R et al: JBJS 93, 2011  
<sup>4</sup>Zigler J and Delamarer R: J NS Spine 17, 2012  
<sup>5</sup>Aghayev E et al, ESJ 23, 2014

<sup>6</sup>Weinstein JN et al, NEJM 356, 2007  
<sup>7</sup>Weinstein JN et al, JBJS 91, 2009

<sup>8</sup>Ghogawala Z et al: J NS, 21, 2014

<sup>9</sup>Burkus JK, et al Spine 27, 2002  
<sup>10</sup>Sasso RC, et al Spine 29, 2004  
<sup>11</sup>Mirza et al The Spine Journal 13/2013

<sup>12</sup>Eck JC et al, JNS Spine 21, 2014



**Key Points**  
*Lumbar Fusion for DDD*

- Current literature suggests lumbar fusions for patients with lumbar back pain (LBP) secondary to DDD have improvement in validated outcomes when patients are appropriately selected.
- If lumbar fusions are restricted as a treatment option, what is the alternative therapy proposed for patients who have failed non-operative management?
- Question we should be asking:
  - *When is a lumbar fusion indicated in the DDD population?*

## Considerations

- Proposal challenges current policy based on inadequate data with flawed analysis.
- Bundling the DDD patient population with LBP into generic grouping restricts patient access to appropriate and best care practices.

## Burden of CLBP

- CLBP poses a major health and resource burden to the affected patient and society
- There is no single simple answer for CLBP<sup>1</sup>
- Question of nonoperative *versus* surgical care is fundamentally flawed
- Legislating away surgical care options for CLBP will not solve problem
- <sup>1</sup> Fritz JM et al, JAMA 314, 2015



## Solutions

- Denying access to surgical care for patients with failed nonoperative care is not supported by scientific literature
- *Integrated approach*: Evidence based nonoperative AND surgical care for selected patients who have failed appropriate nonoperative care offers highest likelihood for success

## Prospective Results Tracking

- Increased use of prospective high quality registries (SCOAP, N2QOD et al) offers more realistic and real-life insights into outcomes and patient safety for surgical care of CLBP than iterative SR's

## Conclusion

- In the appropriately selected patient population, lumbar fusions are safe and effective surgical treatments for patients who have failed a sufficient time frame of non-operative treatment, and who meet the criteria on physical exam and on imaging.

## **Lumbar Fusion – Re-Review**

**Clinical Expert**

**Neal Shonnard, MD**

Orthopedic Surgeon, Rainier Orthopedic Institute

Associate Director, The Spine SCOAP Registry  
(Surgical Care Outcome Assessment Program)

### WA - Health Technology Assessment

#### Disclosure

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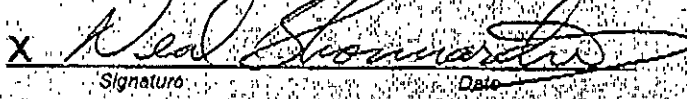
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10/27/15

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# CURRICULUM VITAE

## **NEAL HERMAN SHONNARD, M.D.**

3801 – 5th Street S.E., Suite 110  
Puyallup, WA 98374

Birth date: 01-27-1955 Birthplace: Detroit, Michigan  
Citizenship: USA

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### **EDUCATION**

1979 B.Sc. University of Nevada. Reno, Nevada.  
1980 – 1984 M.D. University of Nevada Medical School. Reno, Nevada

### **POSTGRADUATE TRAINING**

1984 – 1985 Internship:  
Department of General Surgery  
University of California, San Francisco  
San Francisco, CA

1985 – 1989 Residency:  
Department of Orthopedic Surgery  
University of California, San Francisco  
San Francisco, CA

07-85 – 12-85 University of California Hospitals, San Francisco  
01-86 – 06-86 Merritt Hospital, Oakland  
07-86 – 12-86 San Francisco General Hospital, San Francisco  
01-87 – 06-87 Pacific Presbyterian Hospital, San Francisco  
07-87 – 12-87 Oakland Kaiser Hospital, Oakland  
01-88 – 06-88 Mt. Zion Hospital, San Francisco  
07-88 – 12-88 Shriner's Hospital, San Francisco  
01-89 – 06-89 San Francisco General Hospital, San Francisco (Chief Resident)

1989 – 1990 Fellowship: Spine Surgery  
Pennsylvania Hospital, Thomas Jefferson University, Philadelphia,  
PA

07-15-1994 Board Certification (AAOS)  
01-01-2005 Board Recertification (AAOS)

### **LICENSURE**

Washington License #: 027457  
California License#: G56328  
Pennsylvania License# 42629E

## HONORS AND AWARDS

1982 Meritorious Research, American Federation of Clinical Research  
2000 American Academy of Orthopaedic Surgeons – Fellow

## RESEARCH ASSISTANTSHIPS

Mast, J.W., Teipner, W.A. A Reproducible Approach to Internal Fixation of Adult Ankle Fractures. OCNA 11(3) 661-679. 1980.

Teipner, W.A., Mast, J.W. Internal Fixation of Forearm Diaphyseal Fractures. OCNA 11(3) 381-391. 1980.

## PUBLICATIONS

Wakefield, C. Shonnard, N. Observations of HRP Labeling Following Injection Through a Chronically Implanted Cannula. Brain Res. 168:221-226. 1979.

Shonnard, N., Wakefield, C. Observations of Regeneration and Connective Tissue Response in Reconstructed Dorsal Nerve Roots: A Scanning and Transmission Electron Microscope Study in the Cat. Amer. Fed. Clin. Res. (Abstract) 1981 Meeting.

Wakefield, C., Shonnard, N. Regeneration of Cauda Equina Dorsal Nerve Roots after Cross Anastomosis in the Cat. Exp. Neurol. 72:662-671. 1981.

Wakefield, C., Shonnard, N. Scanning Electron Microscopy of Regenerated Cauda Equina Nerve Roots after Cross Anastomosis. In Proceedings Am. Assoc. Anat. (Abstract) 1981 Meeting.

Shonnard, N., Wakefield, C. Physiological and Morphological Observations of Crossed Ventral Nerve Roots in the Sacral Spine of the Cat. In Proceedings Soc. Neurosci. (Abstract) 1982 Meeting.

Shonnard, N., Wakefield, C. Reinnervation of the Gastrocnemius Muscle by the Contralateral S1 Nerve Root. Exp. Neurol. 80:418-426. May 1983.

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Teipner, W.A., Mast, J.W., Shonnard, N. The Acute Management of Fractures Dislocations of the Cervical Spine: A Correlative Approach. Techniques in Orthopaedics: Topics in Orthopaedic Trauma, University Park Press, Baltimore. 1983.

Shonnard, N.H., Rothman, R.H. Clinical Syndromes and Physical Examination of the Cervical Spine, Confirmatory Diagnostic Studies in the Cervical Spine., in The Aging Spine. W.B. Saunders, 1991.

Shonnard, N.H., Anderson, P.A., Low Lumbar (L3-L5) Spinal Fractures, Seminars in Spine Surgery, June 1994.

Taylor, M.V., Shonnard, N.H., et al. Patient-Oriented Outcomes From Low Back Surgery: A Community-Based Study, SPINE 25(19) 2445-2452. 2000.

## **TEXTS**

The Aging Spine, Ch 3 and 4, eds. Boden, S.D., Wiesel, S.W., Laws, E.R., Rothman, R.H. W.B. Saunders, 1991.

## **ACTIVE RESEARCH**

Director, Spine SCOAP Collaborative, Ast. Dir. Spine SCOAP Foundation Health Care Quality, Seattle, Wa.

Researcher SCOAP CERTN Spine Fusion Study, Univ. Washington 2010-present

## **PRESENTATIONS**

ADVAMED National Meeting, Madison, Wi. July, 2010 Spine SCOAP Registry Initiative

Wa. State Association Neurosurgical Society, Seattle, Wa. Aug, 2011 Spine SCOAP Collaborative

Univ. Washington Spine Summit/Spine SCOAP Forum, Sept, 2011 Spine SCOAP Collaborative, Wa. State

Wa. State Orthopedic Assn. Seattle, Wa. Oct, 2011 Spine SCOAP Collaborative





## Lumbar Fusion

### An Assessment of Comparative Clinical Effectiveness & Comparative Value (Re-review)

Presented to the Washington State Health Care Authority by  
Daniel A. Ollendorf, PhD  
November 20, 2015



## Agenda

- Background
  - Low back pain, degenerative disc disease, lumbar fusion
- Topic in Context
- PICO's and Literature Search
- Results
  - Quality and Type of Evidence
  - Key Questions (1-5)
- ICER Evidence Ratings

2



## Background

- Low back pain (LBP)
  - Lifetime prevalence ranges as high as 60-70% in industrialized countries\*
  - Often presents as a temporary condition with an estimated 25-58% of cases spontaneously resolving\*\*
  - Conservative therapy used as a first-line treatment approach
  - Condition becomes chronic when LBP pain continues >3 months
  - The economic impact of LBP is also substantial, in large part due to its detrimental impact on productivity

3 \*World Health Organization *Priority diseases: low back pain*. Jul 2013.  
\*\*Hestbaek *Eur Spine J*. 2003;12(2):149-165.



## Background

- Degenerative disc disease (DDD)
  - Condition in which one or more damaged vertebral discs can cause pain in the lumbar spine
    - Can also occur in the thoracic or cervical spine
  - “Disease” is a misnomer as disc degeneration (dehydration and shrinkage) is a natural consequence of aging
  - Many individuals never develop overt symptoms of DDD
  - Often co-occurs with other spinal diseases or disorders
  - *The presence of DDD correlates poorly with the presence and severity of LBP, making it difficult to attribute symptoms to DDD*

4



## Background

- Lumbar fusion
  - The spine is stabilized by fusing two or more vertebrae together, using bone grafts or instrumentation
  - Designed to eliminate motion in that fused segment of the spine, thereby decreasing or eliminating the back pain created by the motion
  - Used to treat a number of indications, including spinal deformities (e.g., scoliosis) or fractures (e.g., isthmic spondylolisthesis)
  - Use for DDD without clear indication of spinal instability or other symptoms (e.g., radiculopathy) more controversial

5



## Topic in Context

- The number of lumbar fusion surgeries being performed is on the rise in the U.S.
  - There has been >2-fold increase between 2000 and 2009\*
  - But without corresponding increases in prevalence or severity of low back pain
- WA State commissioned ICER to update a previous HTA (2007)
  - Original review focused primarily on 4 RCTs
  - Update includes an additional RCT, new observational studies, and longer-term f/u studies

6 \*Yoshihara *Spine Journal*. 2015;15(2):265-271.



## Key Questions

1. What is the comparative clinical effectiveness of lumbar fusion surgery for patients with chronic low back pain and uncomplicated DDD relative to that of conservative management, minimally-invasive treatments, and other nonsurgical approaches?
2. What are the rates of “treatment success” or “successful clinical outcome” of lumbar fusion as defined by measures of clinically-meaningful improvement in pain, function, quality of life, patient satisfaction, and/or work status?
3. What are the rates of adverse events and other potential harms (perioperative, long-term adverse events, and reoperations) associated with lumbar fusion surgery compared to alternative treatment approaches?

7



## Key Questions

4. What is the differential effectiveness and safety of lumbar fusion according to factors such as age, sex, race or ethnicity, pre-existing conditions (e.g., smoking history), intensity of conservative management (e.g., interdisciplinary rehabilitation vs. physical and/or behavioral therapy alone) technical approach to fusion (e.g., posterolateral vs. interbody, minimally-invasive vs. open procedures), initial vs. repeat surgery, insurance status (e.g., worker’s compensation vs. other), and treatment setting (e.g., inpatient vs. ambulatory surgery)?
5. What are the costs and potential cost-effectiveness of lumbar fusion relative to alternative treatment approaches?

8



## PICO

### Population:

- Adults (age >17 years) with chronic ( $\geq 3$  months) low back pain and uncomplicated degenerative disc disease
- Uncomplicated DDD, defined as “patients without confounding spinal conditions such as radiculopathy, spondylolisthesis (> Grade 1) or severe spinal stenosis, as well as those with acute trauma or systemic disease affecting the lumbar spine”
- Mixed patient populations included ONLY if:
  - Outcomes are reported separately for individuals with chronic low back pain and otherwise uncomplicated DDD, or
  - $\geq 75\%$  of patients carried such a diagnosis

9



## PICO

### Intervention:

- All major technical approaches to lumbar fusion surgery, regardless of surgical technique (e.g., anatomic approach, laparoscopic vs. open) or type of hardware utilized

### Comparators:

- Conservative management approaches
  - Physical therapy, intensive exercise/rehabilitation, cognitive behavioral therapy, and medication management, each alone or in combination
- Other minimally-invasive treatments (e.g., radiofrequency ablation, electrothermal therapy) or nonsurgical modalities

10



## PICO

### Outcomes:

1. Measures of pain, function, and disability
2. Measures of “treatment success” or “successful clinical outcome”
3. Opioid medication use
4. Return to work and/or resumption of normal activities
5. Mortality (both peri-operative and longer-term)
6. Other complications and adverse events
7. Requirements for repeat surgery or other retreatment according to type of initial surgery
8. Costs and cost-effectiveness

11



## Literature Search

- Published studies January 2000 – October 2015
- Randomized controlled trials (RCTs) and comparative studies included without restriction
- Case series limited based on:
  - ≥2 years follow-up
  - ≥100 patients
  - ≥80% retention
  - ≥75% with uncomplicated DDD or findings stratified by indication for fusion

12



## Quality & Type of Evidence

- 19 publications total
  - 5 RCTs, 2 secondary analyses, 6 longer-term f/u studies (all were good/fair)
  - 2 prospective cohort studies (one good, one poor), and one poor-quality retrospective study
  - 3 case series
  - No studies comparing fusion to minimally-invasive treatments
  - Most patients had significant duration of chronic pain (7-11 yrs)
- Quality concerns observed
  - High cross-over rates
  - Patient heterogeneity / treatment group imbalances
  - Variably defined interventions

13



## KQ1: Comparative Effectiveness

Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
<b>KQ1: Effectiveness of Lumbar Fusion Surgery vs. Conservative Management</b>								
Fusion N=473 RCT=3	Intensive or Interdisciplinary Rehabilitation	Medium	Consistent	Direct	Precise	+++ Moderate	Comparable No differences in pain, function, RTW	High crossover rates in some studies
Fusion N=335 RCT=2	Physical Therapy or Exercise alone	Medium	Consistent	Direct	Precise	+++ Moderate	Comparable Small benefits seen over 1-2 years of f/u (e.g., faster RTW); differences diminish over time	High crossover rates in some studies
Fusion	Other non- or minimally- invasive comparators	<b>NO STUDIES</b>						

14



## KQ1: Comparative Effectiveness

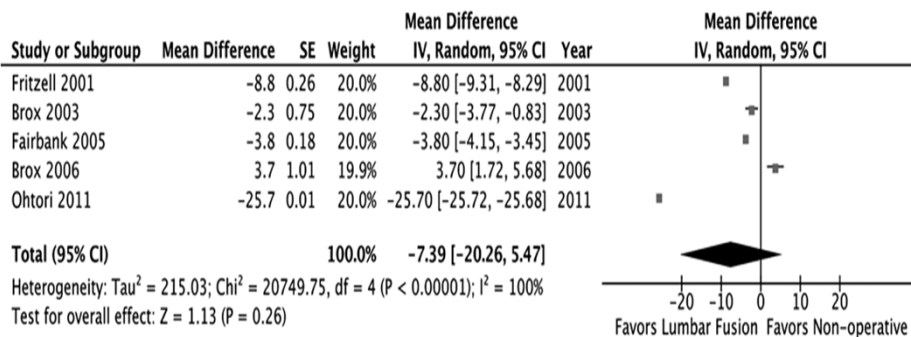
Study (Country of Origin)	Sample Size	Patient Characteristics	Control Group Description	Follow-up Duration	Significant differences in pain/function
Brox 2003 (Norway)	64	Age: 43 Pain duration: 10.8 years % male: 39 % prior surgery: 0	Cognitive intervention and individual exercises with increasing intensity	1 year	No
Brox 2006 (Norway)	60	Age: 43 Pain duration: 8.0 years % male: 52 % prior discectomy: 100	Cognitive intervention and individual exercises with increasing intensity	1 year	No, but nominally in favor of control
Fritzell 2001 (Sweden)	294	Age: 43 Pain duration: 8.0 years % male: 49 % prior discectomy: 18.8	Non-intensive physical therapy + information and education aimed at pain relief	2 years	Yes, in favor of surgery, but pain increased significantly b/w 1-2 yrs of f/u for fusion
Fairbank 2005 (UK)	349	Age: means reported by age groups Pain duration: 8.0 years % male: 49 % prior surgery: NR	75 hours of IRP, including daily muscle strengthening and exercise, CBT, and hydrotherapy	2 years	Yes, in favor of fusion but marginally so
Ohtori 2011 (Japan)	41	Age: 34 Pain duration: 7.3 years % male: 59 % prior surgery: 0	Exercise treatment, including 30 minutes of daily walking and muscle strengthening	2 years	Yes, in favor of fusion

15



## KQ1: Comparative Effectiveness

Forest plot showing final improvement in ODI across studies.\*



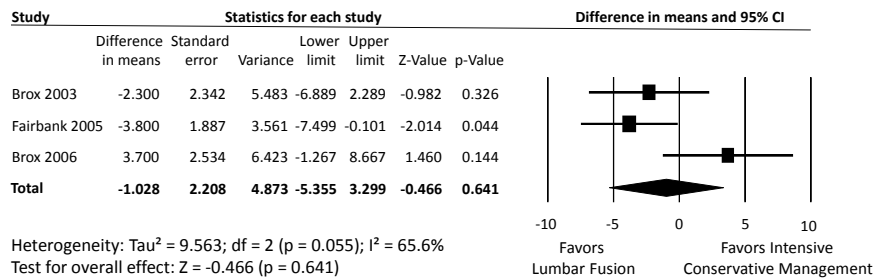
16 \*Bydon J Spinal Disord Tech. 2014;27(5):297-304.





## KQ1: Comparative Effectiveness

Forest plot showing final improvement in ODI across three RCTs with an intensive conservative treatment group



17

## KQ1: Comparative Effectiveness

- Follow-up data were available for 4 of the 5 RCTs, all rated good/fair
  - Between 4-13 years of follow-up available
- No long-term studies found any significant differences between groups in measures of pain or function
- Good-quality prospective cohort study (Mirza 2013)
  - Functional outcomes favored surgery at 1 year of f/u (mean change: -8.8 vs. -1.8 on RDI,  $p < 0.001$ )
  - Authors noted that the conservative group was “minimally-treated” and the treatment group received surgery at physician’s discretion (21% did not receive fusion)

18

## KQ1: Comparative Effectiveness

- Return to Work – 7 studies
  - Brox studies: % of employed individuals who returned to work was numerically-higher in *conservative group* but was:
    - not statistically different (2003), or numbers were too small to be tested (2006)
  - Pooled 4-year (Brox 2010) and 11-year (Mannion 2013) f/u continued to be non-significant
  - Fritzell: statistically-significant in favor of the fusion group
    - Secondary analysis: shorter duration of sick leave prior to treatment was significantly associated with better work status at follow-up in both groups
    - No significant differences between groups after ~13 years

19



## KQ1: Comparative Effectiveness

- Other Outcomes
  - Quality of Life – 4 studies
    - No significant differences between groups in 3 of 4 studies
  - Patient Satisfaction – 8 studies
    - Variable definitions
    - No significant differences between groups in 7 of 8 studies
    - Original Fritzell study found that significantly more patients would undergo surgery again; however, results were numerically in favor of the *conservative group* after ~13 years of f/u (Hedlund 2015)

20



## KQ1: Comparative Effectiveness

- Other Outcomes (cont'd)
  - Mental Health (depression) – 5 studies
    - 2 RCTs (Fairbank, Fritzell) did not find any statistically-significant differences between groups
    - Secondary analysis of Fritzell (Hagg 2003) reported that more depressive symptoms at baseline were predictive of improvement for patients in the conservative group, but not in fusion patients
    - Long-term f/u of Fritzell (Hedlund 2015) did not find any significant differences between groups in the intent-to-treat analysis
    - Only one study (Mirza 2013) reported findings significantly in favor of fusion

21



## KQ2: Treatment Success

Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
<i>KQ2: Rates of Treatment Success or Clinically-Important Differences</i>								
Fusion N=124 RCT=2	Intensive or Interdisciplinary Rehabilitation	Medium	Consistent	Direct	Imprecise	+++ Moderate	Comparable No differences in patient- or observer-rated success rates	
Fusion N=294 RCT=1	Physical Therapy	Medium	Consistent	Direct	Imprecise	++ Low	Incremental Higher rates of success or clinical improvement vs. lower-intensity care	Treatment success in 1 RCT, clinically- significant improvement in 1 obs. study

22



## KQ2: “Treatment success” or MCID

- 2 of the 5 RCTs did not include any measurement of “successful” outcome
  - Patient- or observer-reported measures of success/improvement used in other 3 RCTs: results favored surgery in the Fritzell RCT vs. PT of varying intensity but no differences observed in the Brox RCTs vs. multidisciplinary rehab
  - Studies predated use of published and validated measures of minimum clinically-important differences (e.g., 10-20 point difference on the ODI or VAS)
- Only two studies focused on MCID as a key outcome (30% improvement on the Roland-Morris Disability Questionnaire)
  - Prospective cohort (Mirza 2013): favored surgery
  - Case series (Anderson 2006): did not find any factors that predicted surgical success

23



## KQ3: Harms

Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
<b>KQ3: Potential Harms of Lumbar Spinal Fusion</b>								
Perioperative Mortality	Harms reported in 14 studies comprising 1,420,986 patients	High	Inconsistent	Indirect	Imprecise	++ Low	Rates of 0.2-0.3% by procedure type	Evidence limited to retrospective databases; most do not isolate DDD
Overall Complications		High	Inconsistent	Indirect	Imprecise	++ Low	Range 9-18% overall Range 1-3% serious	Inconsistent reporting and categorization across studies
Subsequent Treatment	Reoperation or Surgical Revision	High	Inconsistent	Indirect	Imprecise	++ Low	Mean of 12.5% over mean of 5 years of f/u Range 4-32%	Hardware repair, repeat fusion, alternative surgery

24



## KQ3: Adverse Events and other Harms

- Literature challenged by:
  - Rating of complication severity done inconsistently or not at all
  - Harms inconsistently reported in many studies
  - Studies were underpowered to detect differences in even relatively common complications
  - Only subsequent treatment assessed over the long-term (>2 years)
- Rate of harms:
  - Complications: 9-18% for fusion in RCTs and comparative studies, including dural tears, bleeding, and wound infection; none reported for conservative groups
  - Mortality: No deaths reported that were deemed related to surgery or conservative treatment in primary evidence base

25



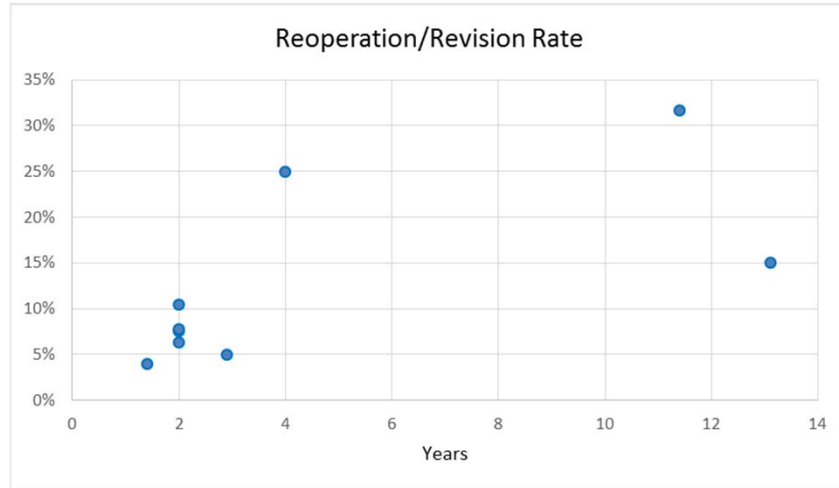
## KQ3: Adverse Events and other Harms

- Subsequent treatment
  - Reoperations
    - 12.5% across included studies over a mean of 5 years of f/u
    - Studies of shorter duration (i.e., up to two years) had a lower reported rate of reoperation (4%-11%) compared to the limited number of studies with longer follow-up periods (15%-32%)
  - Adjacent segment degeneration (ASD)
    - Considered a major harm associated with fusion surgery\*
    - Only one case series meeting our criteria associated repeat surgery with ASD (Lamlli 2014) and found that 1/3 of subsequent procedures were performed due to degeneration adjacent to the primary fusion level

26 \*Miyagi *Eur Spine J.* 2013;22(8):1877-83.



### KQ3: Subsequent Surgery



27



### KQ4: Differential Effectiveness/Safety

Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
<b>KQ4: Differential Effectiveness and Safety According to Patient, Procedure, or Other Factors</b>								
Intensity of Fusion	Single-level vs. multi-level High vs. low levels of instrumentation	High	Inconsistent	Direct	Imprecise	++ Low	No discernible differences in effectiveness Higher complication rates w/more intensity	Variable estimates by study and procedure
Type of Fusion	Anterior, posterior, transforaminal, combined approaches	High	Inconsistent	Direct	Imprecise	++ Low	Evidence mixed, some studies suggest higher complication rates w/anterior approaches	Variable estimates by study and procedure
Conservative Management Intensity	Varying levels of intensity and components	High	Inconsistent	Direct	Imprecise	++ Low	Performance vs. surgery better for more intense programs Evidence mixed for interdisciplinary programs vs. less intense interventions	No discernible patterns of individual program component association with outcome


28



## KQ4: Differential Effectiveness/Safety (2)

Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
<b>KQ4: Differential Effectiveness and Safety According to Patient, Procedure, or Other Factors</b>								
Age		High	Inconsistent	Direct	Imprecise	++ Low	Some evidence for greater RTW but also higher disability claims in younger age categories	
Gender		High	Inconsistent	Direct	Imprecise	++ Low	No clear patterns of gender impact	
Workers' Compensation		Medium	Consistent	Direct	Precise	+++ Moderate	Evidence suggesting WC status associated with poorer clinical outcome, lower RTW, and higher costs	WC a predictor in surgical but not non-surgical patients
Psychological Factors		High	Inconsistent	Direct	Imprecise	++ Low	Mixed evidence on effects of depression  Presence of neuroses or personality disorder associated with poor surgical outcome	

29




## KQ4: Differential Effectiveness/Safety (3)

Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
<b>KQ4: Differential Effectiveness and Safety According to Patient, Procedure, or Other Factors</b>								
Lifestyle Factors	Smoking, BMI	High	Consistent	Indirect	Imprecise	++ Low	No association with any surgical outcome of interest	

***No studies identified of differential impact of fusion vs. conservative management by race/ethnicity or surgical setting***

30



## KQ4: Differential Effectiveness

- Surgical intensity/approach
  - One cohort study evaluated primary vs. revision surgery but found no statistically-significant differences for any outcome
  - An RCT compared different fusion procedures with and without instrumentation and did not find any significant differences
  - Broad systematic reviews have generally reported higher complication rates with complex vs. simple fusion
- Conservative management intensity/approach
  - Available studies suggest interdisciplinary programs may provide better outcomes than unstructured/less-intensive approaches
  - Current data do not support identification of specific components of interdisciplinary programs necessary for success

31



## KQ4: Differential Effectiveness

- Surgical setting: no studies identified
- Sociodemographic factors
  - Age: mixed results
  - Gender: no discernible effects
  - Race/ethnicity: no studies identified
- Psychological factors: differential effect on patient global assessment
  - Neurotic personality was statistically-significantly negatively associated with improvement in the surgical group *but not* in the conservative group
  - Effects of depressive symptoms were in the opposite direction (negative impact in conservative group but not for surgery)

32





## KQ4: Differential Effectiveness

- Workers' Compensation (WC)
  - WC status was negatively associated with work status following fusion, but not for conservatively-treated patients
  - Pre-surgery work status (i.e., working vs. not working) rather than WC status may influence this outcome after fusion, but had no effect among conservatively-treated patients
- Lifestyle factors
  - Smoking: did not have an effect on work status or 30% improvement on the RDQ
    - One poor-quality retrospective study (Smith 2014) found that smoking negatively influences treatment outcomes regardless of intervention
  - BMI: no studies identified

33



## KQ5: Cost and Cost-effectiveness

Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
<i>KQ5: Costs and Cost-Effectiveness of Lumbar Spinal Fusion</i>								
Surgery	Conservative Mgmt	High	Inconsistent	Direct	Imprecise	++ Low	>\$100,000 per QALY over 2 years; other studies had unusual measures or inappropriate comparators	Variable data sources and assumptions; surgical costs high in the US and willingness to pay for fusion lower than for other procedures

34



## KQ5: Cost and Cost-effectiveness

- Economic evaluations of lumbar fusion in patients with uncomplicated DDD are limited both in number and in quality
- Hospital costs alone can approach \$100,000 in the U.S., particularly for more complex forms of surgery (less for more simple forms)
- Results of two RCT-based economic evaluations mirrored findings for clinical outcomes:
  - Comparison of fusion to multidisciplinary programs yielded a 2-year cost-effectiveness estimate of >\$100,000 per QALY gained
  - Comparison of fusion to variable approaches for physical therapy did not assess traditional cost-effectiveness measures

35



## KQ5: Cost and Cost-effectiveness

- Willingness-To-Pay (WTP)
  - Survey-based study indicated a WTP threshold greater than the actual observed costs of surgery for discectomy and decompression alone, but this was not the case for lumbar fusion
- Other Evaluations
  - Two additional cost-effectiveness evaluations included ratios calculated *in relation to a pre-surgical state* rather than to the costs and outcomes associated with an alternative treatment


36



## Evidence Ratings

<i>Comparative Clinical Effectiveness</i>	Superior: A	Aa	Ab	Ac
	Incremental: B <sup>+</sup> /B	B <sup>+</sup> a Ba	B <sup>+</sup> b Bb	B <sup>+</sup> c Bc
	Comparable: C <sup>+</sup> /C	C <sup>+</sup> a Ca	C <sup>+</sup> b Cb	C <sup>+</sup> c Cc
	Inferior: D	Da	Db	Dc
	Promising but Inconclusive: P/I	Pa	Pb	Pc
	Insufficient: I	I	I	I
		a High	b Reasonable/Comp	c Low


*Comparative Value*



37

## Evidence Ratings

- Lumbar Fusion vs. Intensive/Interdisciplinary Rehabilitation
  - Dc (“Inferior/Low Value”)
    - No evidence of incremental clinical benefit for surgery in uncomplicated DDD, but greater potential for harm vs. conservative treatment
    - Limited economic evidence, but fusion appears to represent a very high-cost intervention in the U.S.
- Lumbar Fusion vs. Less Intensive Conservative Management
  - Cc (“Comparable/Low Value”)
    - Short-term incremental benefit for fusion weighed against long-term mitigation of effects and greater potential for harm



38

## Practice Guidelines

- AANS, APS, Bree Collaborative, ISASS, NICE, NASS, WA DLI
- AANS and NASS support fusion for uncomplicated DDD after attempts at general conservative management
- APS, NICE, and ISASS recommend intensive interdisciplinary rehab after failure of general conservative measures and prior to considering surgery
- Lumbar fusion not recommended in the absence of spinal instability by Bree and WA DLI
  - Even in presence of instability, structured rehabilitation efforts are recommended before surgery considered

39



## Coverage Policies

- CMS
  - No NCDs or LCDs covering WA state
- Private payers
  - Most national payers do not cover lumbar fusion for uncomplicated DDD or cover with restrictions (e.g., 12+ months of structured conservative management)
  - Regence and Premera do not consider fusion medically necessary for uncomplicated DDD
  - Health Net provides coverage after 6+ months of conservative management, and for 1- or 2-level fusion only

40



## Appendix: Quality Criteria

41



## Quality Ratings: USPSTF criteria

### Outcome Studies:

- **“Good”:**
  - Comparable groups with no or low attrition; intent-to-treat analysis used in RCTs
  - Reliable and valid measurement instruments used
  - Clear description of intervention and comparator(s)
  - All important outcomes considered
  - Attention to confounders in design and analysis
- **“Fair”:**
  - Generally comparable groups, some differential follow-up may occur; intent-to-treat analysis used in RCTs
  - Acceptable measurement instruments used
  - Some but not all important outcomes considered
  - Some but not all potential confounders are accounted for
- **“Poor”:**
  - Noncomparable groups and/or differential follow-up; lack of intent-to-treat analysis for RCTs
  - Unreliable or invalid measurement instruments used (including not masking outcome assessment)
  - Key confounders given little or no attention

42





## **Health Technology Clinical Committee**

### **Findings and Coverage Decision**

**Date:** 11/16/07

**Topic:** Lumbar Fusion

#### **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**

- Patients must first meet the conditions of a structured, intensive multi-disciplinary program as established by the agency (if covered).

##### ➤ **Non-Covered Indicators**

- Not applicable.

<b>Agency</b>	<b>Contact Phone Number</b>
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, interdisciplinary 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



## **FINAL Key Questions and Background**

### **Lumbar Fusion – Re-Review**

#### **Background**

Low back pain is an exceedingly common complaint, with a lifetime prevalence ranging from 60-70% (WHO, 2013). Chronic low back pain may be seen in as many as one-quarter of patients six months after an initial episode (Johannes, 2010). The economic impact of low back pain is also substantial. It is the second most common reason for all physician visits in the U.S. (Licciardone, 2008), and is responsible for approximately \$30 billion in direct medical costs annually, of which \$18.3 billion is related to ambulatory care (Soni, 2010). In addition, low back pain is a major cause of lost productivity; it is estimated that over 3% of the U.S. work force is compensated for back pain or injury each year (Stewart, 2003), with approximately 187 million missed work days and wage losses accounting for an additional \$22.4 billion in indirect costs (AAOS, 2009).

Low back pain can be caused by various specific and nonspecific conditions, which differ in prevalence and affect different age groups. Degenerative disc disease (DDD) is a common condition associated with low back pain in many individuals. Use of the term “disease” to describe this condition is something of a misnomer, however, as disc degeneration (dehydration and shrinkage) is a natural consequence of aging, and many individuals never develop overt symptoms of DDD. Diagnosis and subsequent treatment typically involves an initial history and physical examination by a clinician. Depending on the presentation, the clinician might prescribe various self-care therapies or will perform a diagnostic exam to check the patient’s pain tolerance, functional capabilities, and reflexes (Pengel, 2003). An MRI and/or CT scan may be used to identify other potential causes of the patient’s symptoms, including other co-occurring conditions such as radiculopathy (compression of the root nerve), spondylolisthesis (displacement of the vertebral disc), or spinal stenosis (narrowing of the spinal canal) (Ullrich, 2013).

Multiple treatment options are available for symptoms associated with DDD of the lower back, including so-called “conservative” measures such as physical and exercise therapy, spinal manipulation, alternative therapies (e.g., acupuncture), and medication; minimally-invasive treatments such as spinal injections and radiofrequency ablation; and surgical intervention. Lumbar fusion surgery, which involves the creation of a permanent connection across the vertebral space by means of a graft, is often considered when conservative treatments fail to relieve the patient’s pain (Eck, 2014). However, many patients may be at risk of persistent low back pain, as initial surgery is subject to high rates of reoperation with declining success rates after each consecutive surgery. It is estimated that as many as 80,000 cases of so-called “failed back surgery syndrome” are seen in the U.S. each year (Ragab, 2008).

***Policy Context***

Due to the prevalence of low back pain and the varying nature of the conditions that underlie it, numerous management options are available. These options vary substantially in their intensity, degree of invasiveness, and most importantly, level of evidence regarding their effectiveness. Although there is lack of consensus on when lumbar fusion surgery is indicated, how the surgery should be performed, and long-term prognosis after surgery (Christensen, 2004), the number of lumbar fusion surgeries performed in the U.S. has nevertheless increased more than two-fold between 2000 and 2009 (Yoshihara, 2014). In particular, some studies have shown poor success rates for lumbar fusion when used to treat low back pain caused by disk degeneration alone (Herkowitz, 1995). Not surprisingly, there is significant interest on the part of patients, clinicians, policymakers, and other stakeholders in evaluating the clinical and economic impact of lumbar fusion for patients with chronic low back pain and DDD.

**Scope**

The Washington State Health Care Authority has commissioned ICER to update a prior assessment on lumbar fusion in patients with chronic low back pain and “uncomplicated” degenerative disk disease (i.e., no confounding spinal injuries or disorders) (ECRI, 2007). Evidence will be culled from RCTs, systematic reviews, and high-quality observational studies. Unlike the original review, we will not assess the role of discography prior to lumbar fusion, as its use in diagnosing and staging DDD has largely been displaced by more recent innovations in imaging (Saboeiro, 2009). In addition, because chronic low back pain is often an occupational concern, the workers’/disability compensation literature will be evaluated along with traditional electronic literature databases.

***Population***

The target population for this review will be adults (age >17 years) with chronic (≥3 months) lumbar pain and uncomplicated degenerative disk disease. As in the original review, patients with conditions such as radiculopathy, spondylolisthesis (> Grade 1) or severe spinal stenosis, as well as acute trauma or systemic disease affecting the lumbar spine (e.g., malignancy) will be excluded. We recognize that some studies of lumbar fusion will involve mixed patient populations; we will abstract data from these studies only if outcomes are reported separately for individuals with chronic low back pain and otherwise uncomplicated DDD. Note that some surgical studies will include patients who have attempted conservative management for varying lengths of time; these will be included regardless of the duration and/or intensity of prior conservative management. Studies that include patients with a history of prior back surgery for any indication will be analyzed separately from patients undergoing lumbar fusion surgery for the first time.

***Intervention***

The intervention of interest will be the major technical approaches to lumbar fusion surgery, regardless of surgical technique (e.g., anatomic approach, laparoscopic vs. open) or type of hardware utilized.

**Comparators**

Given the questions that currently exist regarding the benefits of lumbar fusion versus nonsurgical management, the primary comparator of interest will be conservative approaches, alone or in combination, including physical therapy, intensive exercise/rehabilitation, cognitive behavioral therapy, and medication management. We will also include any comparisons of lumbar fusion to minimally-invasive treatments (e.g., radiofrequency ablation, electrothermal therapy) where available. Studies comparing lumbar fusion to artificial disc replacement will be excluded, as artificial discs represent a separate review topic for the HCA.

**Outcomes**

Outcomes of interest will include: 1) patient- and clinician-reported measures of pain, function, and disability; 2) opioid medication use; 3) requirements for repeat surgery or other retreatment according to type of initial surgery; 4) return to work and/or resumption of normal activities; 5) mortality, stratified according to cause of death where available; 6) other complications and adverse events; 7) measures of “treatment success” or “successful clinical outcome” (e.g., return to work and/or functional goals, cessation of pain medication, available composite measures); and 7) the total costs and cost-effectiveness associated with fusion in comparison to alternative treatment approaches. Functional status will be recorded as measured by standard indices (e.g., Oswestry Disability Index [ODI], Roland-Morris Disability Questionnaire [RDQ]), back pain will be recorded as measured by a visual analog scale (VAS), and quality of life will be abstracted based on validated instruments (e.g., short-form [SF]-36 questionnaire). Of particular interest in this evaluation will be measurement of treatment effects in comparison to varying intensities of conservative management (e.g., interdisciplinary rehabilitation vs. physical and/or behavioral therapy alone).

Recommendations from influential clinical societies and other authoritative sources will be used to inform discussions on the magnitude of improvement as reported on validated measures for pain and/or function. For example, a mean 10-20 point change on a 100-point visual analog pain scale or 5-10 points on the RDQ are generally considered moderate improvements (Chou, 2007). Other published thresholds for clinically-meaningful improvement include at a 30% decrease from baseline on a chronic pain scale or an improvement of at least 20 points on the ODI (Ostelo, 2008). Importantly, while we will seek data on these specific thresholds as reported in clinical studies, we will abstract all measures of clinically-meaningful change as defined in each study, even if they differ from published guidance.

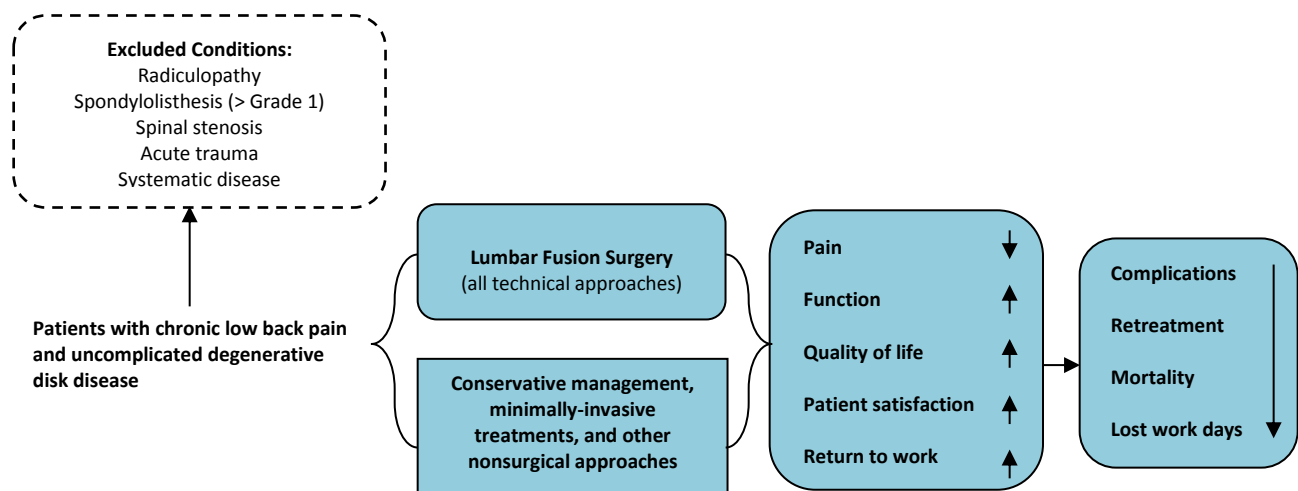
Information on the costs and cost-effectiveness of lumbar fusion procedures compared to alternative treatment will also be assessed from the available economic literature, including treatment-related costs, costs of care over the long-term (e.g., treatment switching, repeat surgery, complications, etc.), and indirect costs (e.g., productivity loss, caregiver burden).

**Analytic Framework**

The proposed analytic framework for this project is depicted on the following page. It is expected that studies will vary substantially in terms of their entry criteria, as there is no agreed-upon standard of

what constitutes uncomplicated lower back DDD. In addition, the fusion technique and intensity of the nonsurgical intervention may have differential effects on the outcomes of primary interest in low back pain studies, including pain, function, quality of life, patient satisfaction, and work status. Finally, RCTs of fundamentally different interventions (e.g., surgery for pain relief vs. rehabilitation for functional restoration) may have difficulty enrolling and randomizing patients, resulting in many studies with inadequate statistical power or other quality concerns (e.g., high dropout and/or crossover rates). It is therefore important to keep these challenges in mind during the evaluation of different management options for uncomplicated DDD.

**Analytical Framework: Lumbar Fusion**



**Methodology**

**Evidence Synthesis**

We propose a systematic review of all RCTs, higher-quality comparative cohort studies, and prior higher-quality systematic reviews of the effectiveness of lumbar fusion for chronic low back pain with uncomplicated DDD as compared to alternative treatment approaches. Information on safety will also be abstracted from these studies as well as from selected case series focusing on lumbar fusion.

In order to identify high-quality observational studies not incorporated in the original review, the timeframe of the literature search will span from January 2000 to the most recent data available. We will also include any RCTs published since the 2007 ECRI review. We will include randomized controlled trials and comparative cohorts without restrictions on study design parameters. Case series data describing at least 100 patients with a minimum of two years of follow-up (i.e., to adequately capture longer-term outcomes) will also be evaluated. Case series will also be restricted according to certain quality criteria (e.g., sample retention, clearly-described entry criteria, consecutive samples).

The full search strategy will include articles in MEDLINE, EMBASE, the Cochrane Register of Controlled Trials, and the Databases of Abstracts of Reviews of Effects (DARE) maintained by the University of York. We will also conduct a supplementary search with a focus on lumbar fusion in the workers'/disability compensation literature in several databases, including OT Seeker, PEDro, ABI Inform, EconLit, and Health and Psychosocial Instruments. Electronic searches will be supplemented by manual review of retrieved references.

Data on relevant outcomes will be synthesized quantitatively if feasible. Random-effects models will be specified, and will focus on weighted mean differences in "change score" variables such as pain, function, and quality of life as well as rate ratios for binary measures such as treatment success and retreatment. Qualitative evidence tables will also be generated for each key question.

### **Quality Assessment**

Assessment of the quality of clinical trial reports and systematic reviews will follow methods adapted specifically for studies of low back pain from the Cochrane Back Review Group (Chou, 2007). For observational studies, we will follow the approach of the U.S. Preventive Services Task Force (USPSTF) (AHRQ, 2008). Overall strength of evidence for each key question will be described as "high", "moderate", or "low", and will utilize the evidence domains employed in the AHRQ approach (AHRQ, 2012). In keeping with standards set by the Washington HCA, however, assignment of strength of evidence will focus primarily on study quality, quantity of available studies, and consistency of findings.

In addition, summary ratings of the comparative clinical effectiveness and comparative value of the procedures of interest (i.e., *across* multiple key questions) will be assigned using ICER's integrated evidence rating matrix (Ollendorf, 2010). The matrix has been employed in previous Washington HCA assessments of virtual colonoscopy, coronary CT angiography, proton beam therapy, and breast imaging in special populations. The matrix can be found in the Appendix to this document.

### **Key Questions**

We suggest a number of key questions as central to this review. Each question is listed below, along with the source for the evidence necessary to address it.

1. What is the comparative clinical effectiveness of lumbar fusion surgery for patients with chronic low back pain and uncomplicated DDD relative to that of conservative management, minimally-invasive treatments, and other nonsurgical approaches?
  - Sources: RCTs, high-quality comparative cohort studies, and high-quality systematic reviews of lumbar fusion vs. the comparators of primary interest
2. What are the rates of "treatment success" or "successful clinical outcome" of lumbar fusion as defined by measures of clinically-meaningful improvement in pain, function, quality of life, patient satisfaction, and/or work status?

- Sources: RCTs, high-quality comparative cohort studies, and high-quality systematic reviews of lumbar fusion vs. the comparators of primary interest
3. What are the rates of adverse events and other potential harms (perioperative, long-term adverse events, and reoperations) associated with lumbar fusion surgery compared to alternative treatment approaches?
    - Sources: RCTs, high-quality comparative cohort studies, and high-quality systematic reviews of lumbar fusion vs. the comparators of primary interest; selected non-comparative case series
  4. What is the differential effectiveness and safety of lumbar fusion according to factors such as age, sex, race or ethnicity, pre-existing conditions (e.g., smoking history), intensity of conservative management (e.g., interdisciplinary rehabilitation vs. physical and/or behavioral therapy alone) technical approach to fusion (e.g., posterolateral vs. interbody, minimally-invasive vs. open procedures), initial vs. repeat surgery, insurance status (e.g., worker's compensation vs. other), and treatment setting (e.g., inpatient vs. ambulatory surgery)?
    - Sources: RCTs, high-quality comparative cohort studies, and high-quality systematic reviews of lumbar fusion vs. the comparators of primary interest; selected non-comparative case series
  5. What are the costs and potential cost-effectiveness of lumbar fusion relative to alternative treatment approaches?
    - Sources: Published economic evaluations, agency data



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**APPENDIX: ICER INTEGRATED EVIDENCE RATING™**  
**(Compares an intervention of interest to a reference comparator)**

<i>Comparative Clinical Effectiveness</i>	Superior: A	<b>Aa</b>	<b>Ab</b>	<b>Ac</b>
	Incremental: B <sup>+</sup> /B	<b>B<sup>+</sup> a</b>	<b>B<sup>+</sup> b</b>	<b>B<sup>+</sup> c</b>
		<b>Ba</b>	<b>Bb</b>	<b>Bc</b>
	Comparable: C <sup>+</sup> /C	<b>C<sup>+</sup> a</b>	<b>C<sup>+</sup> b</b>	<b>C<sup>+</sup> c</b>
		<b>Ca</b>	<b>Cb</b>	<b>Cc</b>
	Inferior: D	<b>Da</b>	<b>Db</b>	<b>Dc</b>
Promising but Inconclusive: P/I	<b>Pa</b>	<b>Pb</b>	<b>Pc</b>	
Insufficient: I	<b>I</b>	<b>I</b>	<b>I</b>	
		<b>a</b>	<b>b</b>	<b>c</b>
		High	Reasonable/Comp	Low
		<i>Comparative Value</i>		

**For more information** about this technology review and the Washington State Health Technology Assessment program, Visit [www.hca.wa.gov/hta](http://www.hca.wa.gov/hta).

# HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

## Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective<sup>1</sup> as expressed by the following standards<sup>2</sup>:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

## Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms<sup>3</sup>:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

<sup>1</sup> Based on Legislative mandate: See RCW 70.14.100(2).

<sup>2</sup> The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

<sup>3</sup> The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

## Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

### **1. Availability of Evidence:**

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

### **2. Sufficiency of the Evidence:**

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence<sup>4</sup> using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

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<sup>4</sup> Based on GRADE recommendation: <http://www.gradeworkinggroup.org/FAQ/index.htm>

Not Confident	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

### 3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology’s safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

## Health Technology Evidence Identification

### Discussion Document:

What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	Safety Evidence
Mortality- perioperative, long-term	
Complications	
Adverse events- other	
Repeat surgery	
Efficacy – Effectiveness Outcomes	Efficacy / Effectiveness Evidence
Pain	
Function	

Disability	
Treatment outcome (e.g. "success")	
Opioid medication use	
Return to work or normal activities	
<b>Special Population / Considerations Outcomes</b>	<b>Special Populations/ Considerations Evidence</b>
Surgical intensity/approach	
Conservative mgmt intensity/approach	
Age	
Gender	
Psychological status	
Workers' compensation status	
<b>Cost Outcomes</b>	<b>Cost Evidence</b>
Direct cost	
Cost-effectiveness	

## Medicare Coverage and Guidelines

[From page 17, Evidence Report]

### 5.1 Centers for Medicare and Medicaid Services (CMS)

There are currently no national or local coverage determinations (LCDs) for lumbar fusion that pertain to Washington State.



[From page 14, Evidence Report]

#### **4. Clinical Guidelines and Training Standards**

##### ***American Association of Neurological Surgeons (AANS) (2014)***

<http://thejns.org/doi/pdf/10.3171/2014.4.SPINE14270>

Lumbar fusion is recommended for patients with one- or two- level DDD without stenosis or spondylolisthesis if CLBP persists after conservative treatment, which may include physical therapy and other non-operative measures.

##### ***American Pain Society (APS) (2009)***

[http://journals.lww.com/spinejournal/Abstract/2009/05010/Interventional\\_Therapies,\\_Surgery,\\_and.14.aspx](http://journals.lww.com/spinejournal/Abstract/2009/05010/Interventional_Therapies,_Surgery,_and.14.aspx)

For patients with non-radicular LBP who have not responded to usual care, APS advises clinicians to consider intensive interdisciplinary rehabilitation that combines physical rehabilitation with a psychological and social or occupational component.

For patients with non-radicular LBP, common degenerative spinal changes, and persistent and disabling symptoms, APS recommends that clinicians use a shared-decision making approach in deciding whether or not to pursue fusion surgery. Physicians should discuss with patients the similar efficacy of interdisciplinary rehabilitation, and the small to moderate average benefit of surgery over interdisciplinary rehab. If the patient and clinician together decide that surgery is the best option, instrumented fusion is associated with enhanced fusion rates over non-instrumented fusion, though the evidence is not sufficient to suggest better outcomes. No specific fusion method is recommended over another.

For patients with persistent non-radicular LBP, APS found evidence to be insufficient to evaluate long-term benefits and harms of vertebral disc replacement, local injections, botulinum toxin injection, epidural steroid injection, intradiscal electrothermal therapy, therapeutic medical branch block, radiofrequency denervation, sacroiliac joint steroid injection, or intrathecal therapy with opioids or other medications. Facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injection are not recommended.

##### ***Dr. Robert Bree Collaborative (2014)***

<http://www.breecollaborative.org/wp-content/uploads/Lumbar-Fusion-Bundle-Final-14-09.pdf>

The Bree Collaborative does not endorse the use of single- or multi-level lumbar fusion to treat back pain associated with degenerative joint disease in the presence or absence of structural instability, and recommends a structured, conservative, non-surgical approach for patients without neurologic symptoms or signs. Failure of other therapies is also not an indication for lumbar fusion, and decompression should be considered before fusion, where appropriate. For patients with continuing disability despite nonsurgical therapy, a four-cycle model is recommended as a guide to providers, purchasers, and payers; this model requires documentation of persistent disability, meeting fitness requirements for patients prior to surgery, adherence of standards for best practice surgery, and implementation of a structured plan to rapidly return patients to function.

## ***International Society for the Advancement of Spine Surgery (ISASS) (2015)***

[https://www.isass.org/public\\_policy/2011-07-15\\_policy\\_statement\\_lumbar\\_surgery.html](https://www.isass.org/public_policy/2011-07-15_policy_statement_lumbar_surgery.html)

DDD is considered to be a medically necessary indication for fusion—at a maximum of two levels—when the following criteria are met:

- The patient is experiencing clinically significant pain and disability consistent with discogenic pain;
- Imaging studies suggest morphological disc degeneration;
- The patient has tried 6 consecutive months of structured conservative management, including pain medication, activity modification, and daily exercise, with demonstrated compliance, and has not shown sufficient improvement;
- Following 6 months of conservative management, the patient has tried intensive multidisciplinary rehabilitation if available and covered by the patient's insurance. The program must include a cognitive/behavioral component, with at least 80 hours of on-site treatment during a 2-4 week period;
- The patient has been screened for possible mental illness or substance abuse issues and has undergone professional treatment if a condition is identified;
- The patient is not currently involved in an ongoing litigation case related to his or her back;
- The patient is between the ages of 25 and 65;
- The patient is not pregnant; and
- Provocative discography or magnetic resonance spectroscopy has been used to confirm that pain is likely due to disc degeneration observed on imaging.

## ***National Institute for Health and Care Excellence (NICE) (2009)***

<http://www.nice.org.uk/guidance/cg88/chapter/1-guidance>

For first line therapy, NICE advises clinicians to promote self-management and provide patients with strategies to manage their LBP. Patients may also be offered medication, including NSAIDs, opioids, or antidepressants, as well as one of the following treatment options, depending on patient preference: a structured exercise program, a course of manual therapy, or a course of acupuncture, each lasting 12 weeks. If these therapies do not provide sufficient improvement, physicians may consider a combined physical and psychological treatment program that includes at least 100 hours of treatment over an eight-week period. If the patient has completed these steps and continues to have pain, referral to a specialist for spinal surgery may be considered.

Prior to surgery, any patient with psychological distress should receive treatment. Patients should be referred to a specialist, and physicians should consider all possible risks for the patient. Patients should not be referred for other procedures, including intradiscal electrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation, or radiofrequency facet joint denervation.

These guidelines were current as of 2009 and an update is currently in development for 2016.

## **North American Spine Society (2014)**

<https://www.spine.org/Documents/PolicyPractice/CoverageRecommendations/LumbarFusion.pdf>

Lumbar fusion is indicated for discogenic LBP secondary to a degenerated disc when the following criteria are met:

- Single level disease confirmed by MRI with moderate to severe degeneration of the disc with Modic changes;
- Patient has had symptoms for at least one year that have not responded to nonsurgical options, which at minimum must include physical therapy. Other nonsurgical options may include pain management, injections, CBT, and exercise programs;
- Patient does not have an active psychological disorder that requires pharmacologic management;
- Patient has not smoked for at least three months prior to surgery; and
- The primary complaint is axial pain, with a possible secondary complaint of pain in lower extremities.

## **Washington State Department of Labor and Industries (2009)**

<http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/LumbarFusion.pdf>

For patients with no prior lumbar surgery, fusion should only be recommended if the patient has non-radicular LBP with at least Grade 2 spondylolisthesis and: 1) objective signs/symptoms of neurogenic claudication, 2) objective signs/symptoms of unilateral or bilateral radiculopathy, which are corroborated by neurologic examination and by MRI or CT (with or without myelography), or 3) instability of the lumbar segment. For patients with prior lumbar surgery, fusion may be recommended depending on the location and type of previous surgery, but only if three months of conservative care failed to relieve symptoms. Per the Washington State Health Technology Clinical Committee decision made in November 2007, for patients with single-level uncomplicated DDD, lumbar fusion could be a covered service if treatment by a Structured Intensive Multidisciplinary Program (SIMP) for chronic pain management was completed first and pain was still unresolved.

## **Clinical Committee Findings and Decisions**

### **Efficacy Considerations**

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?

- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

### **Safety**

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

### **Cost Impact**

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

### **Overall**

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

### **Next Step: Cover or No Cover**

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

### **Next Step: Cover with Conditions**

If covered with conditions, the Committee will continue discussion.

- 1) Does the committee have enough information to identify conditions or criteria?
  - Refer to evidence identification document and discussion.
  - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.

- Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:

- What are the known conditions/criteria and evidence state
- What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

## Clinical Committee Evidence Votes

### First Voting Question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

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

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
<b>Effective</b>				
<b>Safe</b>				
<b>Cost-effective</b>				

### Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;

- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

**Second Vote**

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

Not Covered  Covered Unconditionally  Covered Under Certain Conditions

**Discussion Item**

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

**Next Step: Proposed Findings and Decision and Public Comment**

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

- 1) Based on public comment was evidence overlooked in the process that should be considered?
- 2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

**Next Step: Final Determination**

Following review of the proposed findings and decision document and public comments:

**Final Vote**

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.