December 18, 2015

Josiah Morse, MPH
Program Director
Washington State Healthcare Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

SUBJECT: Non-coverage Decision for Washington State HTA Re-review of Lumbar Spinal Fusion for Degenerative Disc Disease: 20151120A

Dear Mr. Morse:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and the Washington State Association of Neurological Surgeons (WSANS), we would like to express our disappointment with the decision of the Washington State Healthcare Authority (HCA) Health Technology Assessment (HTA) program Health Technology Clinical Committee (HTCC) not to cover lumbar spinal fusion for degenerative disc disease (DDD).

We strongly disagree with the process, as well as the content of the draft findings and decision rendered by the HTCC on Nov. 20, 2015. Our professional societies are seriously concerned that patients experiencing certain forms of severe life-altering low back pain, which has been shown to be refractory to all appropriate forms of nonoperative care, will be denied access to effective surgical treatment. To be clear, we support the 2007 Lumbar Fusion for DDD decision, which permitted coverage under certain conditions following a period of nonoperative care. However, the recent decision is not compatible with the latest scientific evidence, nor does it reflect our professional experience of caring for our patients.

We believe the findings posted, as well as the process leading up to this decision, ignore fundamental scientific principles. The selected key questions were biased, the clinical research organization (CRO) utilized was conflicted, and the HTCC continued to disregard constructively rendered public comments voiced by true experts in the field at all stages of the narrowly permitted public comment periods. By assigning the power of law to all affected state agencies (RCW 70.14.080-14), the HTCC and the HCA assume absolute medical decision-making powers over many Washington state citizens — without affording a mechanism for appeal. We believe that this inappropriately interferes with the doctor-patient relationship and will lead to undue hardship, despair, and unintended negative consequences for those individuals who have failed all appropriate nonoperative care.

Specific concerns with the non-coverage decision process

Terms Used are Unclear

We are concerned about the lack of meaningful definition of the targeted healthcare problem to be addressed by the HTA program. The HTCC uses various terms in their transcript and throughout their discussions. Few of these terms are used by the scientific community, nor are clinicians in the field communicating in this fashion. In fact, as transcribed, these terms are vague, indistinct, intrinsically contradictory and can be interpreted as offensive to long-term sufferers of severe low back pain. Below are some of the terms used in the decision and the discussions of the HTCC on Nov. 20,

2015:

- Lumbar degenerative disc disease without complicating comorbidities
- Uncomplicated degenerative disc disease
- Discogenic back pain

The use of the term ”uncomplicated degenerative disc disease” shows a lack of understanding of the profound adverse life altering experiences patients who have failed appropriate low back pain have experienced. Many of these patients have resorted to life-threatening regular opiate use and fallen into significant dysfunction as other nonoperative forms of treatment have failed. There is truly nothing “uncomplicated” about chronic low back pain for patients who have failed nonoperative care. This phrasing chosen by the HTCC reveals the remoteness of most of the committee members from clinical care for patients with back pain.

Lack of precise definitions of included and excluded conditions

The HTCC has chosen to ignore conditions for which fusion surgery is clearly indicated over nonoperative care in case of failed nonoperative care. Such conditions include spinal deformities such as scoliosis, kyphosis or combinations thereof, endstage inflammatory diseases of spinal motion segments, certain congenital spinal conditions and local infections. In addition, the exclusion of Grade 1 spondylolisthesis for fusion is not supported by the literature.

No need for re-review at this time

The call for a re-review of a previous HTCC decision should have been prompted by available ***new*** research data. However, the CRO presented the ***very same*** **studies previously presented in the 2007 decision.** Three European prospective randomized controlled trials (PRCTs) from 2001, 2003, 2005 and 2006 (follow-up study) were again evaluated — at public expense — and presented as major substantive evidence in this re-review. Astoundingly, this was despite multiple clear methodological shortcomings of these studies and the fact that the HTCC committee previously had used these same studies in their original 2007 decision **to support fusion surgery** for low back pain refractory to sustained nonoperative care. The profound limitations of these studies have been repeatedly and clearly spelled out in the peer-reviewed literature, but the findings of these systematic reviews have been ignored by the contracted CRO and the HTCC.[1] There has simply not been a new game-changing study that would cast doubt on this original decision. The studies used have significant limitations and are from European countries with social infrastructure very different than the United States; thus negating any methodological appeal the prospective randomized character that the studies may possess.

[1] Mirza SK, Deyo RA: Systematic Review of Randomized Trials Comparing Lumbar Fusion Surgery to Nonoperative Care for Treatment of Chronic Back Pain. Spine: 1 April 2007 - Volume 32 - Issue 7 - pp 816-823

Selective inclusion of data by the contracted CRO

Sadly, The HTCC missed the opportunity to advance the public’s knowledge base by analyzing more recent peer-reviewed publications with newer statistical and epidemiologic techniques. (*See example,* FDA disc arthroplasty trials with the fusion control groups[2-6,9-10] and SPORT trials using fusion[7-8]). Similarly, the CRO chose to exclude these valuable patient cohorts since they did not fit their artificially narrowed observational window. Moreover, the two more recent prospective randomized studies comparing surgical and nonoperative care, which both favored fusion surgery over nonoperative care, were both minimized as to their findings and impact by the CRO and some members of the HTCC — reflecting what very much looks like a preconceived bias. This is all the more surprising as one of these studies comes from the State of Washington itself and more

accurately reflects the socio-demographic realities of this area compared to a study from a European country.[11]

[2] Blumenthal S et al: Spine 30, 2005

[3] Zigler J, et al: Spine 32, 2007

[4] Delamarter R et al: JBJS 93, 2011

[5] Zigler J and Delamarter R: J NS Spine 17, 2012

[6] Aghayev E et al, ESJ 23, 2014

[7] Weinstein JN et al, NEJM 356, 2007

[8] Weinstein JN et al, JBJS 91, 2009

[9] Ghogawala Z et al: J NS, 21, 2014

[10] Burkus JK, et al Spine 27, 2002

[11] Mirza SK, Deyo RA, Heagerty PJ, Turner JA, Martin BI, Comstock BA. One-year outcomes of surgical versus nonsurgical treatments for discogenic back pain: a community-based prospective cohort study. Spine J. 2013 Nov;13(11):1421-33.

[12] Ohtori S, Koshi T, Yamashita M, Yamauchi K, Inoue G, Suzuki M, Orita S, Eguchi Y, Ochiai N, Kishida S, Takaso M, Kuniyoshi K, Aoki Y, Ishikawa T, Arai G, Miyagi M, Kamoda H, Suzuki M, Nakamura J, Toyone T, Takahashi K.: Surgical versus nonsurgical treatment of selected patients with discogenic low back pain: a small-sized randomized trial. Spine (Phila Pa 1976). 2011

Disregard for available registry data

Since the 2007 HTC decision, several large-scale spine registries have become available. These provide high-quality prospective data. Due to the artificially narrowed focus, the HTCC chose to ignore these data sources, including a Washington State spine surgery database (Spine SCOAP), which includes data from over 30,000 patients, prospectively captured, through hospital databases. With its self-imposed methodologic restrictions, the HTCC also chose to ignore valuable real-time safety data from its own state, and further ignored large scale cost efficiency and outcomes data from other national data sources such as organized neurosurgery's NeuroPoint Alliance National Neurosurgery Quality and Outcomes Database (N^2QOD). Instead, the HTCC elected to take into consideration outdated materials as shown by the Labor and Industries Agency director in his presentation using utilization data from before 2003 (slide 8) and outdated procedure types from 2004 and earlier (Slide 6). The same inaccurate and outdated data can be seen in the display of patient safety and Washington State Labor and Industries outcomes data from 1986-1987 (Slide 16) and 1994-2000 (Slide 17), as well as complications reported by the same department using a pre-2000 cohort in 2006. While it comes as no surprise that any surgical procedure will have higher immediate complications that can be identified more easily than nonoperative modalities, it is difficult to understand why the real time surgical care data, that are available from respected and independently available prospective data registries, is simply ignored. From a scientific perspective, high quality prospectively gathered, patient safety and outcomes data retains a higher evidence level than that of prospectively randomized studies.

Lack of Nonoperative Outcomes data

The HTCC used phrases such as "intensive nonoperative care," "cognitive behavioral back care," "Structured, Intensive, Multi-disciplinary, Program (SIMP)," and similar terms in their discussions as

modalities that are allegedly equivalent to low back pain fusion surgery. Committee members did not attempt to define what such nonoperative care actually consists of, nor did they attempt to factually assess how many care facilities for some form of integrated multimodal nonoperative care programs actually are available to subscribers of HCA insurance products in Washington State — particularly in areas away from its major Western Washington urban centers.

As far as the AANS, CNS, WSANS and its observers were able to tell, the CRO and HTCC rested their findings mainly on a single PRCT from Norway. Again, this study has been heavily criticized for a number of serious methodologic flaws, lack of cogent reporting and overall absence of clarity in describing the actual substance of their nonoperative treatment of choice — which was described as "cognitive behavioral therapy" (CBT). In fact, a recent systematic review, and a Cochrane review, demonstrated that CBT as a single entity does not exist, and there are multiple variations of this therapy concept that still require validation.[13,14] In fact, the cost and futility of nonoperative care for chronic low back pain (CLBP) is well established in the scientific literature[15,16] and was reflected in some of the materials presented by the Labor and Industry agency Director himself (See Slide 13). He described a period of three years or more prior to low back pain fusions being performed in Washington state on average, despite increasing enrollments into a so-called SIMP (structured, intensive multidisciplinary program) nonoperative program of over 550 patients per year. Despite inquiries by members of the HTCC, the presenting agency director had no outcomes, costs and efficiency data, whatsoever, for patients enrolled in the SIMP program. It is telling that the HTCC members did not insist on having some — or any form of outcomes data — from in-state patients treated nonoperatively for CLBP prior to making their decision.

The limitations of nonoperative care are clearly spelled out in a number of high quality studies and also reflect the difficulty in gathering data from nonoperative care compared to surgical patients. The absence of nonoperative care data should not allow it to be held to a much lower standard of accountability compared to surgery, when in fact there are a clear number of patient deaths associated with a long term opiate pain reliever (OPR) use. Indeed, per a 2012 report of the *Seattle Times*, 200-300 deaths related to OPR in the State of Washington were reported annually, and, according to the Centers for Disease Control and Prevention (CDC), in 2008, 14,800 deaths were reported nationally.[17,18]

[13] Henschke N, Ostelo RW, van Tulder MW, Vlaeyen JW, Morley S, Assendelft WJ, Main CJ. Behavioural treatment for chronic low-back pain. Cochrane Database Syst Rev. 2010;(7).

[14]Hanscom D, Brox JO. Global Spine Journal 2015

[15] Fritz JM, Magel JS, McFadden M, Asche C, Thackeray A, Meier W, Brennan G.: Early Physical Therapy vs Usual Care in Patients With Recent-Onset Low Back Pain: A Randomized Clinical Trial. JAMA. 2015 Oct 13;314(14):1459-67.

[16] Niemistö L1, Rissanen P, Sarna S, Lahtinen-Suopanki T, Lindgren KA, Hurri H. Cost-effectiveness of combined manipulation, stabilizing exercises, and physician consultation compared to physician consultation alone for chronic low back pain: a prospective randomized trial with 2-year follow-up. Spine (Phila Pa 1976). 2005 May 15;30(10):1109-15.

[17] Seattle Times, Monday, April 30, 2012, Methadone and The Politics Of Pain.

[18]Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999--2008 *Weekly* November 4, 2011 / 60(43);1487-14921.

Disregard of Professional Society Recommendations

Organized neurosurgery takes its responsibilities for patients very seriously. This includes developing socially responsible management strategies for a wide variety of brain and spine conditions —

including the management of chronic low back pain. We are disappointed that the HTCC and its CRO decided to brush aside the significant efforts of our professional neurosurgical societies, experts in the field of spine and high-quality published guidelines for the management of CLBP. These efforts were undertaken according to the highest scientific standards, were discussed extensively in a discursive opinion forming process, and are published in the peer-reviewed literature. To ignore this scientific and clinical expertise, and place the efforts of 11 other medical professionals — who were bound by the "findings" of a contracted CRO and the highly biased key questions — above the clinical experts and scientific evidence is very difficult to align with the statutory mission of the HCA and the HTCC. With its findings, the HTCC claims to have insights superior to all major professional societies in the field, as well as larger national guidelines recommendations foundations such the National Institute for Health and Care Excellence from the United Kingdom.[19,20]

[19]Eck JC et al, JNS Spine 21, 2014

[20]NICE guidelines [CG88] Published date: May 2009 Low back pain in adults: early management.

Concerns about the Scope of the HCA

Our concerns about the proceedings of the HTCC regarding its re-review of lumbar fusions for low back pain are profound, particularly in light of the adverse effect they may have on patient access to care. These concerns also extend to questions regarding the presentations permitted by stakeholders, with agency directors and the contracted CROs allotted lengthy presentations, while the invited panel experts were only permitted to speak when questioned and specialty society experts were only allotted three minutes of presentation time each. Clearly, the deck was inappropriately stacked against accurate, current clinical information from key surgeons with actual experience performing the procedure under review. We believe this undermines the basics of the intent of the HCA's mandate.

Last year, there was a precedent-setting case in the State of Washington, where the court ruled that the statute empowering HTA (RCW 70.14.120-3) was an unconstitutional delegation of lawmaking power because there were insufficient procedural safeguards to control arbitrary or abusive agency action. (S*ee* Sund v. Regence BlueShield, King County Superior Court No. 13-2-03122-1 SEA).[21,22] The interference with due process and scientific fact finding methodology, in favor of the opinions of a few individuals (many of whom lack clinical subject matter expertise), as well as the absence of an appeals process for affected patients, cause us grave concern about access to appropriate care for our patients.

[21] http://www.kellerrohrback.com/news/keller-rohrback-llp-announces-settlement-state-washington-after-successfully-challenging

[22] http://100percentisaac.com/blog/2014/2/17/washingtons-health-technology-clinical-committee-found-unconsitutional

Conclusion

In light of the above, the AANS, CNS and WSANS, hereby request that the HTCC Decision **20151120A, Non-coverage for Lumbar Fusion for DDD** be **suspended** for the following reasons:

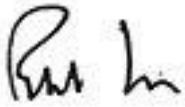
- Lack of relevant new data to warrant re-review of this topic
- Inadequate definitions and unclear terms in the key questions
- Old data and inaccurate statements made during the HTCC meeting discussions and presentations, which underappreciated the limited options for severely disabled patients with LBP.

- Lack of available appeals process for affected patients under the present HTCC decision process

Thank you for the opportunity to provide our comments.

Sincerely,

H. Hunt Batjer, MD, President
American Association of Neurological Surgeons



Russell R. Lonser, MD, President
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Praveen Mummaneni, Chairman
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Farrokh Farrokhi, MD, President
Washington State Association of Neurological Surgeons

Jens R. Chapman, MD, Board Member at Large
Washignton State Orthopaedic Association

Enclosures:

- Presentation of Gary M. Franklin, MPH, Medical Director, Department of Labor and Industries
- WSANS, AANS, CNS and SSF Presentation

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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

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)

Agency Medical Directors' Concerns

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

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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)

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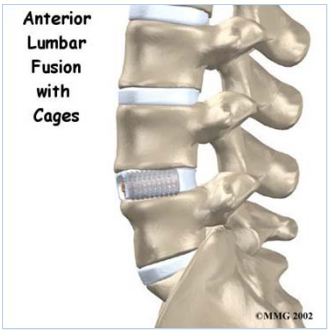
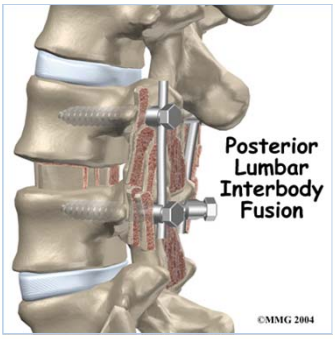
Background

- 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

Lumbar Fusion Procedures

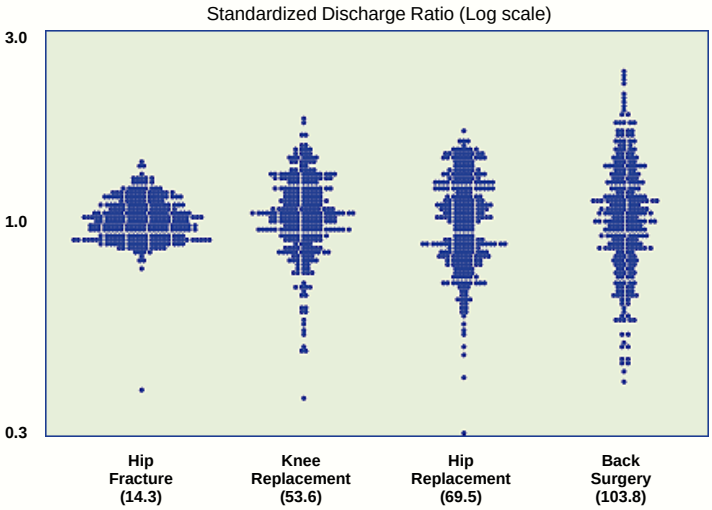


Anterior



Posterior

Rates of Four Orthopedic Procedures Among Medicare Enrollees, 2002 and 2003



Source: Dartmouth Atlas Project.

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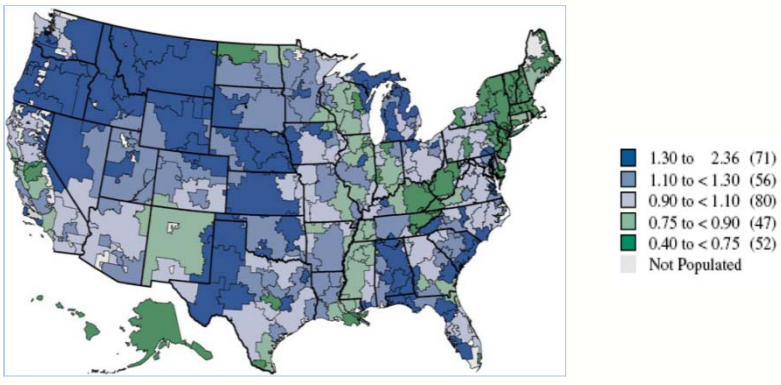
Lumbar Fusion - Re-Review

Treatment Varies State by State

Ratio of Total Rates of Spine Surgery to the U.S. Average by Hospital Referral Region (2002-03)



Source: *Spine Surgery. A Report by the Dartmouth Atlas of Healthcare. CMS-FDA Collaborative.*

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Lumbar Fusion - Re-Review

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

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Utilization & Cost of Lumbar Fusion, 2012-2014

- Dollars in millions -

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

§ Does not include Medicare

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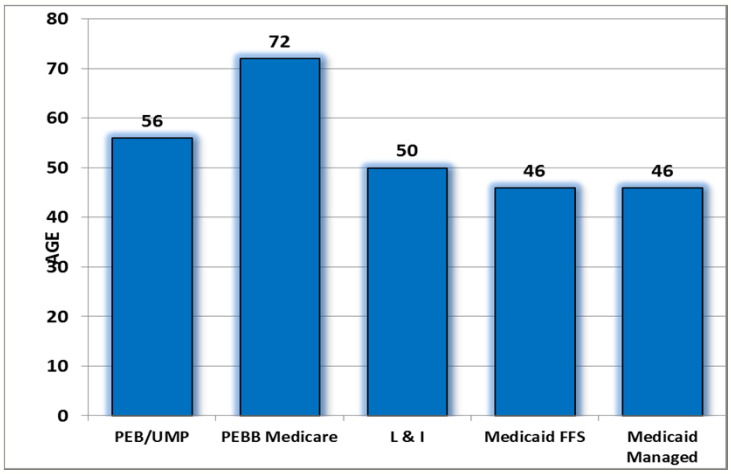
Average Age of Patient on Date of Procedure by Program 2011-2014



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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)

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Lumbar Fusion - Re-Review

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.

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Lumbar Fusion - Re-Review

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)§

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

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

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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.

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

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.

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§

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

§ Juratli et al, 2006; Spine 31:2715–23

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

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)

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

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

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

Blue Cross Blue Shield North Carolina

May 2015

When lumbar spine fusion surgery is not covered:

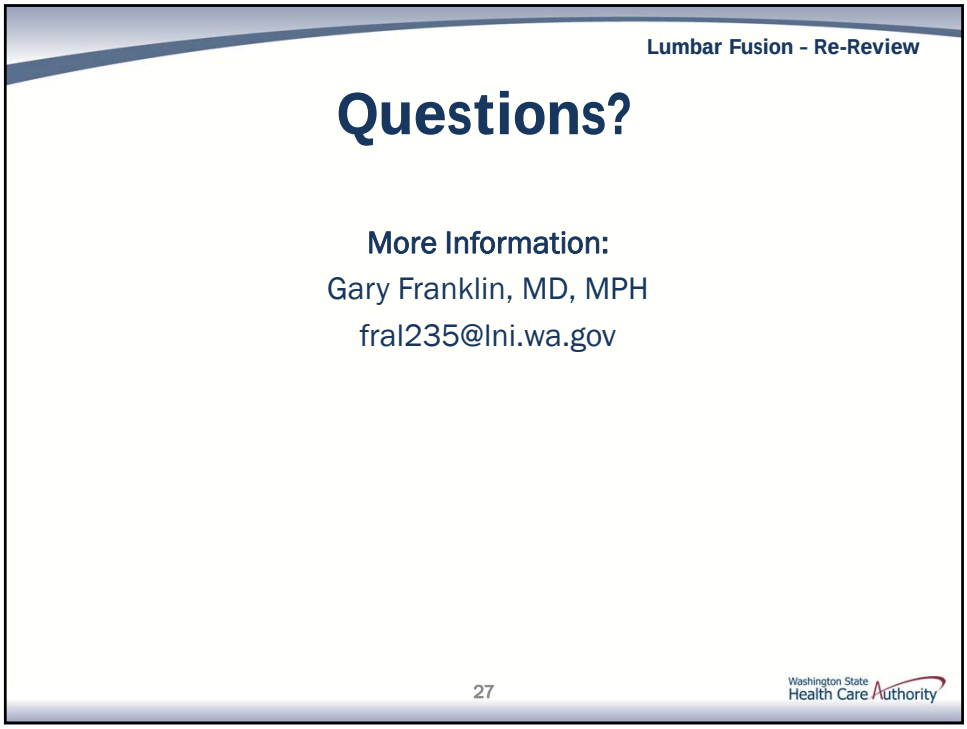
- If not meet an included condition (eg, fracture, stenosis with neuro compromise)
- Not medically necessary if sole condition is any one or more of the following:
  - Disc herniation
  - Degenerative disc disease
  - Initial diskectomy/laminectomy for neural structure decompression
  - Facet syndrome

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

State Agency Recommendation

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


Lumbar Fusion – Re-Review
Questions?
More Information:
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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.[1-4]
    - 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.[1-4]

[1] Fritzell P et al, Spine 2001
[2] Brox JI et al Spine 2003
[3] Brox JI et al Pain 2006
[4] 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[1,2]
- 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 [3,4]
- Question we should be asking:
  - *What non-operative care should be considered for the DDD patient population with LBP, and how effective is it?*

[1] *Radcliff KE et al*, Spine 36, 2011
[2] Rohan MX et al, Spine J 9, 2009
[3] *Hanscom and Brox,* Global Spine J (in print) 2015
[4] *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) [1-5]
  - SPORT trials[6-7]
  - Cost effectiveness data[8]
  - PRCT's [9-10]
  - Specialty Society Guidelines [12]
  - SCOAP (Washington State Spine Registry)
  - N2QOD (National Neurosurgery Quality and Outcomes Database)

[1]Blumenthal S et al: Spine 30, 2005
[2]Zigler J, et al: Spine 32, 2007
[3]Delamarter R et al: JBJS 93, 2011
[4]Zigler J and Delamarter R: J NS Spine 17, 2012
[5]Aghayev E et al, ESJ 23, 2014

[6]Weinstein JN et al, NEJM 356, 2007
[7]Weinstein JN et al, JBJS 91, 2009

[8]Ghogawala Z et al: J NS, 21, 2014

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

[12]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[1]
- Question of nonoperative *versus* surgical care is fundamentally flawed
- Legislating away surgical care options for CLBP will not solve problem
- [1] 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.