


Washington State
Health Care Authority

Program updates

Josh Morse, HTA Program Director
WA – Health Care Authority
March 17, 2017



Washington State
Health Care Authority


Today's agenda

- 1) Extracorporeal shock wave therapy



2017 Committee calendar

- **May 19**
 - Treatment of chronic migraine and chronic tension-type headache
 - Varicose veins
- **July 14**
 - Meeting by webinar: Final action on May 19, findings and decisions
- **November 17**
 - Skin Substitutes
 - Mammogram: Computer-aided detection (CAD)



Update on 2016 technology selections

- ✓ Artificial disc replacement (Re-review)
- ✓ Extracorporeal shock wave therapy for musculoskeletal conditions
- ✓ Interventions for treatment of migraines/ headaches
- ✓ Varicose veins
- ✓ Skin substitutes
- ✓ Mammogram: Computer-aided detection mammography

Health Technology Clinical Committee

Date: January 20, 2017

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted:

Meeting materials and transcript are available on the HTA website at:
www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials

Draft HTCC Minutes

Members present: John Bramhall, MD, PhD; Gregory Brown, MD, PhD; Joann Elmore, MD, MPH; Chris Hearne, RN, DNP, MPH; Laurie Mischley, ND, PhD, MPH; Carson Odegard, DC, MPH; Seth Schwartz, MD, MPH; Christopher Standaert, MD; Kevin Walsh, MD; Tony Yen, MD
Clinical experts: Jon Montgomery McClellan, MD; Rod J. Oskouian, Jr., MD.

HTCC Formal Action

- 1. Call to order:** Dr. Standaert, chair, called the meeting to order; members present constituted a quorum.
- 2. HTA program updates:** Josh Morse, program director, presented upcoming topics for committee meetings.
- 3. November 18, 2016 meeting minutes:** Draft minutes reviewed; no changes or updates suggested. Motion made to approve November 18, 2016 minutes as written, seconded. Committee voted to accept the minutes.

Action: Nine committee members approved the November 18, 2016 meeting minutes.

- 4. Negative pressure wound therapy for home use – Draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. One comment was received on the draft decision. The committee reviewed and discussed the comment which included recommended changes to clarify the intent of the determination. The committee modified the draft. Staff was directed to change the final determination per the approved comments.

Action: Ten committee members voted to approve the negative pressure wound therapy findings and decision as amended.

- 5. Fecal microbiota transplantation draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. No comments were received on the draft decision.

Action: Ten committee members voted to approve the fecal microbiota therapy findings and decision.

Draft

6. Pharmacogenomic testing for selected conditions:

The chair introduced Jon (Jack) McClellan, MD, Professor, Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle.

Agency utilization and outcomes: Charissa Fotinos, MD, MSc, Deputy Chief Medical Officer, Health Care Authority, presented the state agency perspective for Pharmacogenomics Testing for Selected Conditions. The full presentation is published with the [January 20, meeting materials](#).

Scheduled and open public comments: The chair called for public comments. Comments provided by:

- Nathan Roe, PhD, Medical Science Liaison, Assurex Health
- Jim Pollard, National Account Manager, Government Accounts, Assurex Health

Public presentations are published with the [January 20, meeting materials](#).

Vendor report / HTCC question and answer:

Margaret A. Piper, PhD, MPH, Hayes, Inc. presented the evidence review of *Pharmacogenomic testing for selected conditions*. The full presentation is published with the [January 20, meeting materials](#).

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee evaluated the available evidence. The committee discussed and voted on the evidence for use of pharmacogenomic testing compared to current alternative strategies. A majority of committee members found the technology unproven for safety, efficacy and cost-effectiveness based on the quality of available evidence. The committee considered and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover pharmacogenomic testing for selected conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Pharmacogenomic testing for selected conditions	7	3	0

Discussion

The committee reviewed and discussed the available studies of pharmacogenomics. Details of study design, inclusion criteria and other factors affecting or potentially affecting study quality were discussed.

Limitations

Not applicable.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for pharmacogenomic testing.

The committee discussed clinical guidelines identified for pharmacogenomic testing for select conditions from the following organizations:

- Clinical practice guidelines: Depression in adolescents and young adults (2010)
- Position Statement : The value of antidepressants in the treatment of unipolar depression (2011) European Psychiatric Association
- Adult Depression in Primary Care (2016) ICIS
- Clinical Practice Guidelines for the Management of Major Depressive Disorders (2016) VA/DoD
- World Federation of Societies for Biological Treatment of Unipolar Depressive Disorders (2013)
- Practice Guidelines for the treatment of Patients with Panic Disorders (2009) American Psychiatric Association (APA)
- Practice Guidelines for the Treatment of Patients with Substance Use Disorders (2006) APA
- Guidelines: Pharmacological management of substance abuse, harmful use, addiction and comorbidity (2005) BAP
- Expert Group Consensus Guidelines: Focus on the therapeutic monitoring of antidepressants (2005) AGNP

The committee chair directed HTA staff to prepare a findings and decision document for pharmacogenomic testing for selected conditions reflective of the majority vote for public comment, followed by consideration for final approval at the next public meeting.

7. Updates: HTA reviews in progress- Josh Morse, HTA program director.

8. Artificial disc replacement – Re-review

The chair introduced Rod J. Oskouian Jr, MD, Chief of Spine and Co-Director, Complex and Minimally Invasive Spine Fellowship Program at the Swedish Neuroscience Institute.

Agency utilization and outcomes: Gary Franklin, MD, MPH, Medical Director for the Washington State Department of Labor and Industries, presented the state agency perspective and utilization and cost data to the committee. The presentation is published with the [January 20, meeting materials](#).

Draft

Scheduled and open public comments: The chair called for public comments. Comments provided by:

- Jens Chapman, MD, Washington State Association of Neurological Surgeons, American Association of Neurological Surgeons, North American Spine Society, Congress of Neurological Surgeons
- Daniel Elskens, MD, Washington State Association of Neurological Surgeons, American Association of Neurological Surgeons, North American Spine Society, Congress of Neurological Surgeons

Public presentations are published with the [January 20, meeting materials](#).

Vendor report and HTCC Q & A:

Andrea C. Skelly, PhD, MPH, Spectrum Research, Inc. presented the evidence review addressing artificial disc replacement. Find the full presentation published with the [January 20, meeting materials](#).

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on lumbar and cervical artificial disc replacement should be considered and voted on separately. The committee also determined that current evidence is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of artificial disc for these conditions compared to current alternative strategies. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover lumbar artificial disc replacement and separately voted to cover with conditions cervical artificial disc replacement.

	Not covered	Covered under certain conditions	Covered unconditionally
Lumbar artificial disc replacement	10	0	0
Cervical artificial disc replacement	0	10	0

Discussion

The committee reviewed and discussed the available studies of lumbar artificial disc replacement. Details of study design, inclusion criteria and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that lumbar artificial discs replacements were unproven for safety and unproven for

effectiveness compared to alternatives for some conditions, and unproven for cost-effectiveness. A majority of the committee voted to not cover lumbar artificial disc replacement.

The committee reviewed and discussed the available studies of cervical artificial disc replacement. Details of study design, inclusion criteria and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that cervical artificial discs replacements were at least equivalent for safety and effectiveness compared to alternatives for some conditions, and unproven for cost-effectiveness. A majority of the committee voted to cover with conditions, cervical artificial disc replacement

Limitations

Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:

- Skeletal mature patients
- Disc replacement following one- or two-level discectomy for intractable symptomatic radiculopathy or myelopathy confirmed by patient findings and imaging.

Patient must have advanced imaging or clinical evidence of corresponding nerve root or spinal cord compression and have failed or be inappropriate for non-operative care. For two-level procedures, objective evidence of radiculopathy, myelopathy, or spinal cord compression at two consecutive levels is required.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does have a NCD for lumbar artificial disc replacement.

The committee discussed clinical guidelines identified for cervical artificial disc replacement from the following organizations:

- Diagnosis and treatment of Cervical Radiculopathy from Degenerative Disorders (2010) North American Spine Society
- Cervical spine injury medical treatment guidelines (2014) State of Colorado Department of Labor and Employment, Division of Workers' Compensation
- Cervical and Thoracic spine disorders (2011) American College of Occupational and Environmental Medicine

The committee's cover with conditions determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on cervical artificial disc replacement for public comment; followed by consideration for final approval at the next public meeting.

6. Meeting adjourned.

**Health Technology Clinical Committee
Draft Findings and Decision**

Topic: Pharmacogenomic testing for selected conditions

Meeting date: January 20, 2017

Final adoption:

Meeting materials and transcript are available on the HTA website:
www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials

Number and coverage topic:

20170120A - Pharmacogenomic testing for select conditions

HTCC coverage determination:

Pharmacogenomic testing for selected conditions is **not covered**.

HTCC reimbursement determination:

Limitations of coverage: N/A

Non-covered indicators: N/A

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

Draft

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee evaluated the available evidence. The committee discussed and voted on the evidence for use of pharmacogenomic testing compared to current alternative strategies. A majority of committee members found the technology unproven for safety, efficacy and cost-effectiveness based on the quality of available evidence. The committee considered and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings the committee voted to not cover pharmacogenomic testing for selected conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Pharmacogenomic testing for selected conditions	7	3	0

Discussion

The committee reviewed and discussed the available studies of pharmacogenomics. Details of study design, inclusion criteria and other factors affecting or potentially affecting study quality were discussed.

Limitations

Not applicable.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for pharmacogenomic testing.

The committee discussed clinical guidelines identified for pharmacogenomic testing for select conditions from the following organizations:

- Clinical practice guidelines: Depression in adolescents and young adults (2010)
- Position Statement : The value of antidepressants in the treatment of unipolar depression (2011) European Psychiatric Association
- Adult Depression in Primary Care (2016) ICIS
- Clinical Practice Guidelines for the Management of Major Depressive Disorders (2016) VA/DoD:
- World Federation of Societies for Biological Treatment of Unipolar Depressive Disorders (2013)
- Practice Guidelines for the treatment of Patients with Panic Disorders (2009) American Psychiatric Association (APA)

- Practice Guidelines for the Treatment of Patients with Substance Use Disorders (2006) APA
- Guidelines: Pharmacological management of substance abuse, harmful use, addiction and comorbidity (2005) BAP
- Expert Group Consensus Guidelines: Focus on the therapeutic monitoring of antidepressants (2005) AGNP

The committee chair directed HTA staff to prepare a findings and decision document for pharmacogenomic testing for selected conditions reflective of the majority vote for public comment, followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Pharmacogenomic testing for selected conditions

Findings and decision
Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Pharmacogenomic testing for selected conditions.

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	February 26, 2016	
Public comments	February 26, to March 11, 2016	14
Selected technologies published	April 18, 2016	
Public comments	April 18, to May 19, 2016	32
Draft key questions published	July 14, 2016	
Public comments	July 15, to 29, 2016	15
Final key questions published	August 10, 2016	
Draft report published	October 21, 2016	
Public comments	October 21, to November 21, 2016	33
Final report published	December 16, 2016	
Public meeting	January 20, 2017	
Draft findings & decision published	February 16, 2017	
Public comments	February 16, to March 1, 2017	14

Overview

Category	Comment Period	
	February 16, to March 1, 2017	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	2	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
Total	2	0

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. Robert Hilt, MD	Associate Medical Director for Behavioral Health Consultative and Community-Based Programs Associate Professor of Psychiatry University of Washington/ Seattle Children's	No
<input type="checkbox"/>	2. Shana Johnson, MD	Medical Officer, Clinical Quality and Care Transformation, WA Health Care Authority	No

From: Hilt, Robert <Robert.Hilt@seattlechildrens.org>
Sent: Thursday, February 16, 2017 1:33 PM
To: HCA ST Health Tech Assessment Prog
Subject: Comment on Pharmacogenomic testing for selected conditions

I am writing to provide a public comment on: 20170120A - Pharmacogenomic testing for select conditions

I want to say that I support the January 20th 2017 draft decision to not cover pharmacogenomics testing. I have personally found it shameful that many genetic testing companies are directly marketing this test to patients and to treatment providers with the promise that their testing will tell them which psychiatric medications will be effective for treatment and which will be ineffective for treatment. I view this as false advertising, because clinical correlations between test results and clinical response in psychiatry has not been demonstrated.

What the testing actually delivers is a report on P450 metabolic pathways, and whether someone based on their genes would be predicted to be a slow or fast metabolizer of different medications based on their variants of different P450 metabolic enzyme pathways. What the testing does NOT say is whether a given psychiatric medication will be clinically efficacious for a patient.

Child psychiatrists operate with a prescribing mantra to “start low and go slow” with medication doses. Someone who happens to be a slow metabolizer of a medication (which pharmacogenomics testing may reveal) would be expected to show a response at lower dosages than most other patients—clinically one would not advance to administering a high dose which would carry a higher than usual risk of side effects because if the medication is efficacious there is no reason to increase doses. If someone is a slow metabolizer I would not alter my usual starting dose, and I would clinically still choose to advance the starting dose higher if there were no side effects and there had been insufficient benefit. In other words, I would make the same evidence based clinical treatment choices whether or not the patient is recognized to be a slow metabolizer of a particular psychiatric medication.

I have seen patients come in with long printed pharmacogenomics test reports telling them that their child should not use any medications that have been shown to be effective for their child’s treatment indication, and requesting to receive medications that are not shown with research to be effective. So the testing right now is not only an unnecessary expense, but it is also steering families to more often give their children ineffective medication treatments.

I do hope in the future that there is more clinically helpful information obtainable from such tests, but that is not our current state.

Bob Hilt

Robert Hilt, MD
Associate Medical Director for Behavioral Health Consultative and Community-Based Programs
Associate Professor of Psychiatry
University of Washington/ Seattle Children’s
206-987-3073 (office)
206-987-2753 (fax)

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Pharmacogenomic testing for selected conditions

Presented by Dr. Shana Johnson, Clinical Quality and Care Transformation, Health Care Authority

Please add more specificity to the decision by defining what the selected conditions are that are not covered for pharmacogenomics testing.

The selected conditions are: depression, mood disorders, psychosis, anxiety, ADHD, and substance use disorder.

**Health Technology Clinical Committee
Draft Findings and Decision**

Topic: Artificial disc replacement – Re-review

Meeting date: January 20, 2017

Final adoption:

Meeting materials and transcript are available on the HTA website:
www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials

Number and coverage topic:

20170120B – Artificial disc replacement – Re-review

HTCC coverage determination:

Lumbar artificial disc replacement is **not a covered benefit**.

Cervical artificial disc replacement is a **covered benefit with conditions**, consistent with the criteria identified in the reimbursement determination.

HTCC reimbursement determination:

Limitations of coverage:

Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:

- Skeletally mature patients
- Disc replacement following one- or two-level discectomy for intractable symptomatic radiculopathy or myelopathy confirmed by patient findings and imaging.

Patients must have advanced imaging or clinical evidence of corresponding nerve root or spinal cord compression and have failed or be inappropriate for non-operative care. For two-level procedures, objective evidence of radiculopathy, myelopathy or spinal cord compression at two consecutive levels is required.

Non-covered indicators: NA

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

Draft

HTCC coverage vote and formal action:***Committee decision***

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on lumbar and cervical artificial disc replacement should be considered and voted on separately. The committee also determined that current evidence is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of artificial disc for these conditions compared to current alternative strategies. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover lumbar artificial disc replacement and separately voted to cover with conditions cervical artificial disc replacement.

	Not covered	Covered under certain conditions	Covered unconditionally
Lumbar artificial disc replacement	10	0	0
Cervical artificial disc replacement	0	10	0

Discussion

The committee reviewed and discussed the available studies of lumbar artificial disc replacement. Details of study design, inclusion criteria and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that lumbar artificial discs replacements were unproven for safety and unproven for effectiveness compared to alternatives for some conditions, and unproven for cost-effectiveness. A majority of the committee voted to not cover lumbar artificial disc replacement.

The committee reviewed and discussed the available studies of cervical artificial disc replacement. Details of study design, inclusion criteria and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that cervical artificial discs replacements were at least equivalent for safety and effectiveness compared to alternatives for some conditions, and unproven for cost-effectiveness. A majority of the committee voted to cover with conditions, cervical artificial disc replacement.

Limitations

Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:

- Skeletal mature patients
- Disc replacement following one- or two-level discectomy for intractable symptomatic radiculopathy or myelopathy confirmed by patient findings and imaging.

Patient must have advanced imaging or clinical evidence of corresponding nerve root or spinal cord compression and have failed or be inappropriate for non-operative care. For two-level procedures, objective evidence of radiculopathy, myelopathy, or spinal cord compression at two consecutive levels is required.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does have a NCD for lumbar artificial disc replacement.

The committee discussed clinical guidelines identified for cervical artificial disc replacement from the following organizations:

- Diagnosis and treatment of Cervical Radiculopathy from Degenerative Disorders (2010) North American Spine Society
- Cervical spine injury medical treatment guidelines (2014) State of Colorado Department of Labor and Employment, Division of Workers' Compensation
- Cervical and Thoracic spine disorders (2011) American College of Occupational and Environmental Medicine

The committee's cover with conditions determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on cervical artificial disc replacement for public comment; followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Artificial disc replacement – Re-review

Findings and decision Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on artificial disc replacement – re-review.

Timeline

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Technology recommendations published	February 26, 2016	
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Public comments	February 16, to March 1, 2017	14

Overview

Category	Comment period	
	February 16, to March 1, 2017	Cited evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	2	0
Industry & manufacturer	0	0
Professional society & advocacy organization	1	0
Total	3	0

Comments

	Respondents	Representing	Cited evidence
<input type="checkbox"/>	1. Clyde T. Carpenter, ME	Olympia Orthopaedic Associates	No
<input type="checkbox"/>	2. Frederick A. Boop, MD Alan M. Scarrow, MD John J. Knightly, MD Hee Kit Wong, President F. Todd Wetzel, MD Farrokh Farrokhi, MD Jens R. Chapman, MD	American Association of Neurological Surgeons (AANS) Congress of Neurological Surgeons (CNS) AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves International Society for the Advancement of Spine Surgery North American Spine Society (NASS) Washington State Association of Neurological Surgeons Board member-at-large Washington State Orthopaedic Association	No
<input type="checkbox"/>	3. Dr. Gary Franklin, MD	Medical Director, WA State Department of Labor and Industries	No

[REDACTED]

From: Clyde and Patti Carpenter <carpx5@msn.com>
Sent: Saturday, February 18, 2017 2:54 PM
To: HCA ST Health Tech Assessment Prog
Subject: Comment on ADR

To whom it may concern:

As a spinal surgeon in the state of Washington who has done artificial disk replacements in the lumbar spine as well as the cervical spine, I would like to comment on the artificial disks. I will keep my comments brief.

First, ADR is a valuable technology available to surgeons who are treating the spine. It may be an alternative to a fusion with all the attendant risks.

Second, we are in the infant stages of disk replacement just as we were with total joint replacements in the 1960's, so we still have some things to iron out. There will be complications, as with all procedures, but it's very clear from all the research, including the most rigorous, prospective, randomized controlled trials (some of whom I was a part) ever done in medicine with 5 year follow-up, that disk replacement is at least as good, if not better, than fusion procedures.

Third, there are very narrow indications for artificial disk in the lumbar spine. As the only surgeon in 5 Southwestern Washington counties who performs lumbar disk replacement, I can tell you that I only do about 2 to 4 of these procedures per year. I use stringent criteria applying all the indications and contraindications that were used in the prospective randomized trials. Because of this, I have good results.

Fourth, cervical spine disk replacement is a great tool to treat disk herniations in the cervical spine in younger patients. There is less stress on the adjacent segments when this is done. It doesn't mean that all cervical disk protrusions should be treated with an artificial disk, but it does mean that it is an important tool in the hands of skilled surgeons using the study criteria.

Finally, as an inventor, surgeon and researcher, I am working on developing a higher quality artificial disk that will be more anatomic and physiologic. Please see my patent; US 8,353,964- Anatomic Total Disk Replacement.

Thank you for your consideration and please continue to allow us to use this technology to relieve suffering in a most safe and physiologic manner in our patients.

Clyde T. Carpenter, MD



American
Association of
Neurological
Surgeons



CNS



INTERNATIONAL
SOCIETY for the ADVANCEMENT of
SPINE SURGERY



March 1, 2017

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 ADR: 20170120B.

Dear Mr. Morse:

We, the American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, Washington State Association of Neurological Surgeons (WSANS), International Society for the Advancement of Spine Surgery and North American Spine Society (NASS), herewith express our resolute disagreement with the January 20, 2017, decision of the Washington State Healthcare Authority (HCA) Health Technology Assessment (HTA) program Health Technology Clinical Committee (HTCC) not to cover lumbar artificial disc replacement (ADR) surgery for all FDA approved indications. We concur with the decision to expand coverage to two level for cervical ADR as stated in the draft decision.

For the record, our combined societies express our concerns on behalf of our patients that we as medical professionals are entrusted to care for. Moreover, we are deeply concerned about the flawed process for re-review of the ADR lumbar policy, as well as the content of the draft findings and decision for ADR lumbar rendered by the HTCC on January 20, 2017. The member physicians of our professional societies wish it to be known 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 with the more recent January 20, 2017 decision. To be clear, we support the 2008 ADR lumbar decision, which permitted coverage under certain conditions following a period of nonoperative care. However, this recent decision is not compatible with the latest scientific evidence or reasonable methodology, nor does it reflect our professional experience of caring for our patients in the United States, nor was this re-review of lumbar disc replacement even necessary by the HTA/HTCC's own standards.

We believe the findings posted for ADR lumbar, as well as the process leading up to this decision, ignore sound fundamental scientific principles. The HTCC disregarded constructively rendered public comments voiced by true expert physicians in the field, the invited clinical panel expert and the

Director of the Washington State Surgical Care and Outcomes Assessment Program (SCOAP) for Spine, all of whom provided valid reasons not to change the ADR lumbar policy at this time.

Specific concerns with the non-coverage decision process

No need for re-review of ADR lumbar at this time

The call for a re-review of a previous HTCC decision should have been prompted by available ***new*** research data. The review of ADR cervical policy is appropriate, as new evidence strongly supports the safety and efficacy of additional level procedures. We commend the HTCC for this. However, the contracted review organization (CRO) failed to present any significant new studies that would support a change in the 2008 policy for ADR lumbar, or for that matter even a re-review.

Disregard for available registry data

Since the 2008 HTCC decision, several large-scale spine registries have become available. These provide high-quality prospective data. Due to its artificially narrowed allegedly scientific 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 chose to ignore this valuable real-time safety data from its own state. The Director of the SCOAP program testified at the meeting that current analysis of data for ADR lumber shows strong safety and effectiveness with relatively low utilization and that the adverse events found in the European study do not appear to be of concern in Washington State.

Lack of Nonoperative Outcomes data

We continue to be concerned that the HTCC discusses nonoperative spine care without clear definitions or evidence that such care is available to patients in Washington State. The HTCC often uses 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 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. In reality, nonoperative care is expensive, frequently not available and usually not covered in the amount described in studies from Europe. The actual efficiency of nonoperative care – as nonstandardized as it is - very much remains in question.

As far as the AANS, CNS, WSANS and its observers were able to tell, the contracted review organization (CRO) and HTCC rested their findings mainly on a single PRCT from Norway. This study is flawed and not relevant to patient care in Washington State. Specifically the surgeons in this study did multilevel procedures in a third of patients – a procedure that is not FDA approved in the United States. In a third of patients, they did not utilize a general surgeon for access, which is a standard of care in the United States and they were not required to undergo formalized pre-training as is the case in our country. Sadly, the HTCC and its CRO ignored these important variables completely.

Moreover the lumbar ADR procedure numbers presented by the Director of Labor and Industries show a very low utilization rate and reflect a rare and prudent application of this device technology. Neither is there any discernible safety concern in Washington State, as presented by the Agency director, nor is there an abuse in procedure frequency.

Disregard of Professional Society Recommendations

Organized medicine 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 chronic low back pain. 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, as well as that of the Washington State SCOAP Director, and the invited panel expert is very difficult to align with the statutory mission of the HCA and the HTCC.

Conclusion

In light of the above, the AANS, CNS, WSANS, ISASS and NASS, hereby request that the HTCC Decision **20170120B, Non-coverage for ADR Lumbar** be **suspended** for the following reasons:

- Lack of relevant new data to warrant re-review of this topic.
- Useful Data from the Washington State Spine SCOAP Registry is available now. Furthermore, more detailed data will soon be available and should be reviewed before a new policy is implemented for ADR lumbar spine. This data is likely much more useful for real time safety and utilization review and will offer more relevant insights than studies from other continents performed under artificial study premises.
- Flaws in the European study reviewed by the HTCC should be highlighted and the differences in practice, patient population and procedures should be thoroughly considered and weighed.
- In its present form, the HTCC decision is not credibly based on a fair and scientific process. In fact, it falls far short of this premise, thus calling into question its mission to provide appropriate health care to the patients under its purview.
- Lack of available appeals process for affected patients under the present HTCC decision process.

We are deeply concerned that the January 2017, HTCC decision not to cover ADR lumbar and the November 2015 decision not to cover lumbar fusion for patients with degenerative disc disease with low back pain, discriminate against injured workers and the poor in the state of Washington. These decisions subject many patients covered under the Washington State Health Care programs to only conservative therapy and opioid dependency without any chance of a surgical solution. Furthermore, we believe that the November 2015 non-coverage decision for lumbar fusion was inappropriately cited as a reason for non-coverage for ADR lumbar. We are also enclosing our letter regarding the November 2015 with this letter, as many of our concerns about the process are the same for both issues.

Thank you for the opportunity to provide our comments.

Sincerely,



Frederick A. Boop, MD, President
American Association of Neurological Surgeons



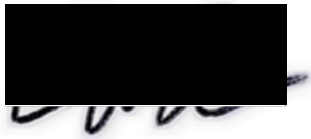
Alan M. Scarrow, MD, President
Congress of Neurological Surgeons



John J. Knightly, MD, Chairman
AANS/CNS Joint Section on Disorders of the
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Farrokh Farrokhi, MD, President
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Jens R. Chapman, MD, Board Member at Large
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American
Association of
Neurological
Surgeons



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N
S



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 fusion⁷⁻⁸). 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 (N²QOD). 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}

¹⁹Eck JC et al, JNS Spine 21, 2014

²⁰NICE 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. (See *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-unconstitutional>

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.

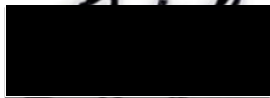
Sincerely,



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



Praveen Mummaneni, Chairman
AANS/CNS Joint Section on Disorders of the
Spine and Peripheral Nerves



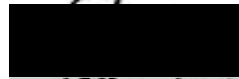
Jens R. Chapman, MD, Board Member at Large
Washington State Orthopaedic Association

Enclosures:

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

Staff Contact:

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Farrokh Farrokhi, MD, President
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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

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)

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Washington State
Health Care Authority

Lumbar Fusion - Re-Review

Agency Medical Directors' Concerns

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

3

Washington State Health Care Authority

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

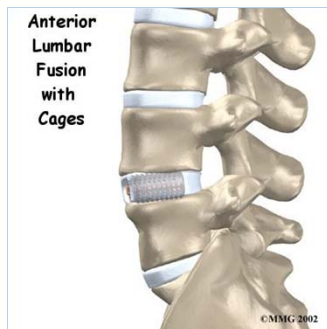
Washington State Health Care Authority

Background

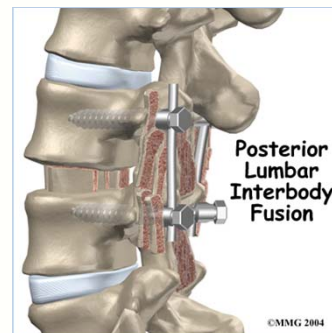
- Lumbar fusion may have a clear role for treating traumatic injuries, patients with significant and measurable instability, congenital defects, or central canal stenosis with neurological impairment
- Significant proportion of the fusion procedures are done in patients with chronic low back pain and 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

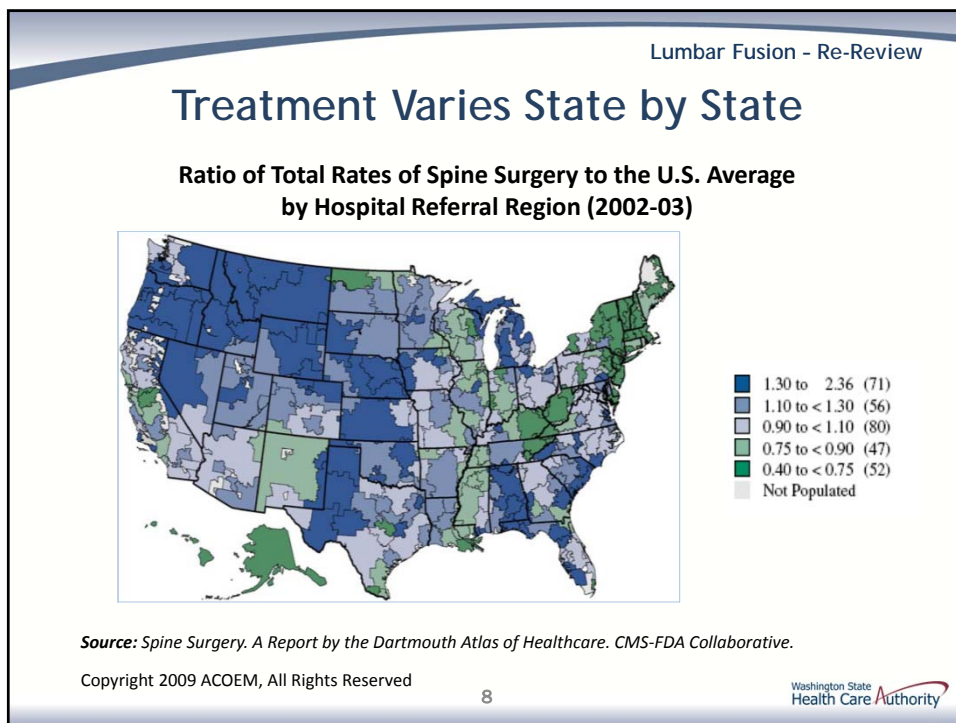
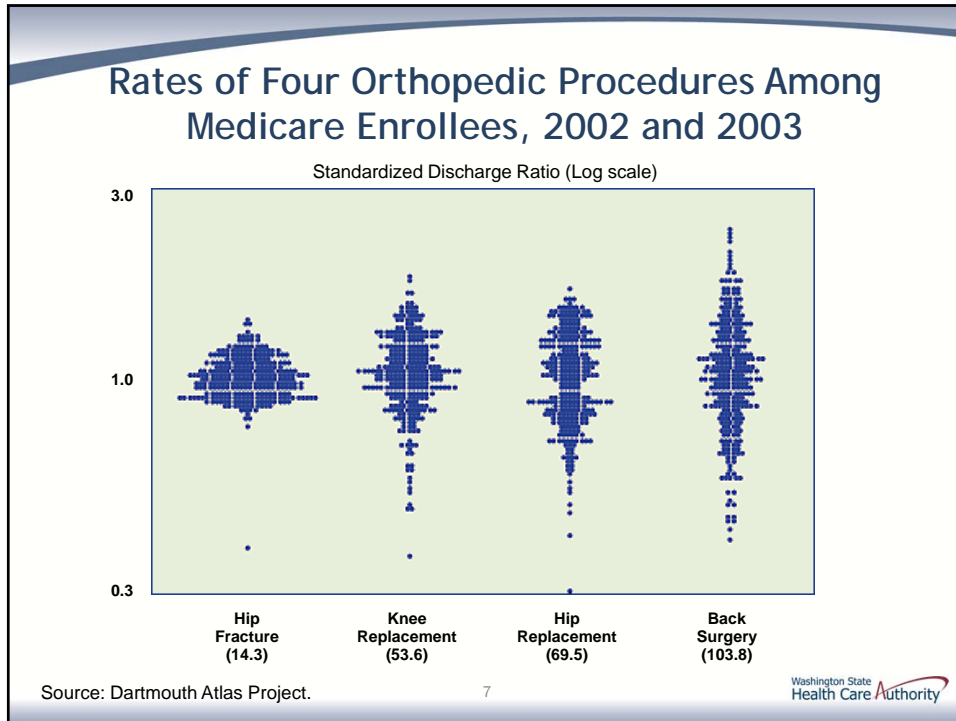


Anterior



Posterior

6



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

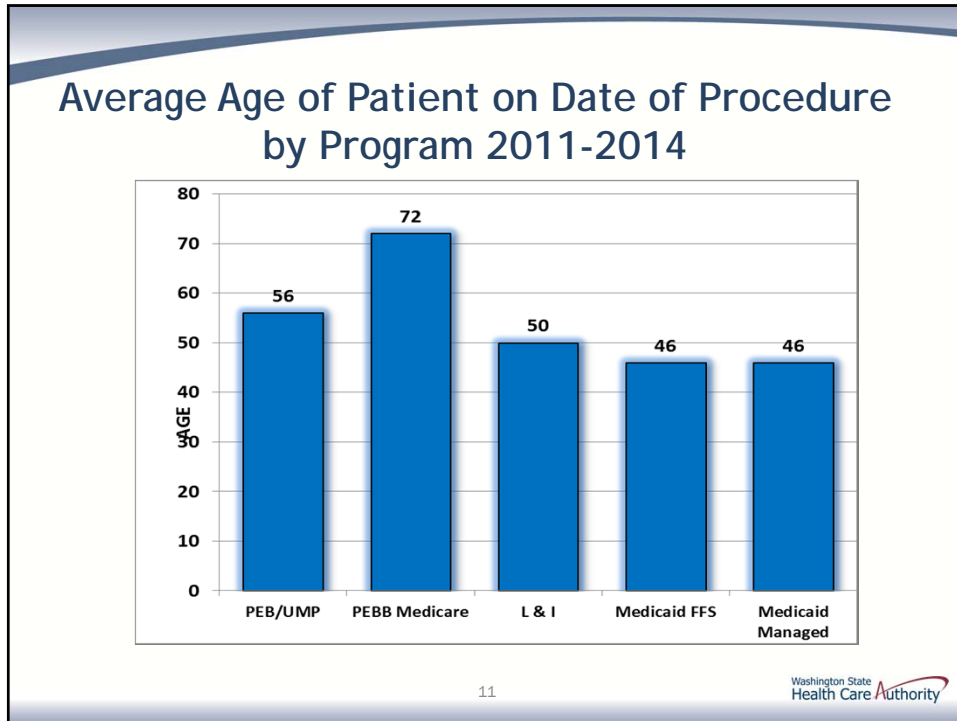
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Utilization & Cost of Lumbar Fusion, 2012-2014 - Dollars in millions -

	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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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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Washington State Health Care Authority


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.

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.

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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

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Lumbar Fusion - Re-Review

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.

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Washington State Health Care Authority

Lumbar Fusion - Re-Review

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

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Washington State Health Care Authority

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)

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Lumbar Fusion - Re-Review

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

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Washington State Health Care Authority

Lumbar Fusion - Re-Review

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

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Washington State Health Care Authority

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

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State Agency Recommendation

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

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Lumbar Fusion - Re-Review

Questions?

More Information:

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Washington State
Health Care Authority



**WASHINGTON
HEALTH TECHNOLOGY
ASSESSMENT PROGRAM**

November 20, 2015

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WASHINGTON STATE ASSOCIATION OF NEUROLOGICAL SURGEONS

American Association of Neurological Surgeons

SSFS SEATTLE SCIENCE FOUNDATION

Congress of Neurological Surgeons
The Official Meeting of the Neurological Surgeons

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 JJ et al Spine 2003

³ Brox JJ 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 trials⁶⁻⁷
 - Cost effectiveness data⁸
 - PRCT's ⁹⁻¹⁰
 - Specialty Society Guidelines ¹²
 - SCOAP (Washington State Spine Registry)
 - N2QOD (National Neurosurgery Quality and Outcomes Database)

¹Blumenthal S et al: Spine 30, 2005

²Zigler J, et al: Spine 32, 2007

³Delamarter R et al: JBJS 93, 2011

⁴Zigler J and Delamarter R: J NS Spine 17, 2012

⁵Aghayev E et al, ESJ 23, 2014

⁶Weinstein JN et al, NEJM 356, 2007

⁷Weinstein JN et al, JBJS 91, 2009

⁸Ghogawala Z et al: J NS, 21, 2014

⁹Burkus JK, et al Spine 27, 2002

¹⁰Sasso RC, et al Spine 29, 2004

¹¹Mirza et al The Spine Journal 13/2013

¹²Eck 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 CLBP¹
- 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.

Artificial Disc Replacement – Re-review

Presented by Dr. Gary Franklin, Medical Director, WA State Department of Labor and Industries

We would like the committee to clarify the wording in the last paragraph under “Limitations of coverage” (Please see below).

1. We believe that both criteria, advanced imaging and clinical evidence of corresponding nerve root or spinal cord compression, should be met for diagnosis of radiculopathy or myelopathy, and either one of them alone would be insufficient.
2. In the context of two-level procedures, “spinal cord compression” seems redundant in the sentence if it refers to myelopathy.

Proposed changes

Limitations of coverage:

Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:

- Skeletally mature patients
- Disc replacement following one- or two-level discectomy for intractable symptomatic radiculopathy or myelopathy confirmed by patient findings and imaging.

Patients must have advanced imaging ~~or~~and clinical evidence of corresponding nerve root or spinal cord compression, and have failed or be inappropriate for non-operative care. For two-level procedures, objective evidence of radiculopathy ~~,or~~ myelopathy ~~or spinal cord compression~~ at two consecutive levels is required.