# Cervical Spinal Fusion

## Order of Scheduled Presentations

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<tr>
<th>Name</th>
<th>Presentation Details</th>
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| 1    | Joseph Cheng, MD  
       American Association of Neurological Surgeons/  Congress of Neurological Surgeons |
| 2    | Jason Lerner, Director Marketing Access  
       DePuys Synthes |
| 3    | David Flum, MD /  
       Neal Shonnard, MD  
       Spine Surgical Care and Outcomes Assessment Program (SCOAP) |
| 4    | Deana Searce, JD  
       Medtronic, Inc  
       **Note:** Letter received after deadline for submitting comment materials for public meeting. Submitted in lieu of a scheduled presentation. |
Disclosure

Any unmarked topic will be considered a "Yes"

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American Association of Neurological Surgeons  
Congress of Neurological Surgeons

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

Signature:  
Date: 2/19/2013  
Print Name: Joseph Chen, MD

For questions contact: Christine Masters  
Health Technology Assessment  
PO Box 42712  
Olympia, WA 98504-2712  
360-725-5126
COMMENTS ON DRAFT EVIDENCE REPORT FOR CERVICAL SPINAL FUSION FOR DEGENERATIVE DISC DISEASE

Washington State Health Care Authority Health Technology Clinical Committee
March 22, 2013
Presented by: Joseph S. Cheng, MD, MS, Chair
AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves

Presenting Organizations

American Association of Neurological Surgeons
Congress of Neurological Surgeons
AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves
American Association of Orthopaedic Surgeons
AOSpine North America
Cervical Spine Research Society
North American Spine Society
Washington State Association of Neurological Surgeons
Washington State Orthopaedic Association
Presenter Disclosures

- J.S. Cheng has no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services.

Summary

- We appreciate the Washington State HCA HTA attempt to summarize the literature on cervical spine fusion for degenerative disc disease.
- Unfortunately, the assessment makes a number of critical errors that undermine the validity of the report’s analysis and strongly question the quality of the assessment’s final conclusions.
Heterogenous Patient Groups

- Lack of granularity in ICD-9 for cervical DDD
  - Model does not differentiate young patient with a small disc and mild radiculopathy vs. wheelchair bound elderly patient with OPLL and myelopathy
- Report mixes distinct patient populations of axial neck pain, myelopathy and radiculopathy
  - Indication and goals of surgery clearly distinct
  - Most studies focus upon one of these patient populations
  - Lump single level discectomy and multi-level laminectomy and fusion
- Admixing of distinct clinical entities limits the value of the report’s conclusions

Recommendations

- Risk adjustment based on age, co-morbidities, causes of mortality, or multi-level disease
- Clarify patients categories of cervical symptomatology: axial neck pain, cervical radiculopathy, and cervical myelopathy.
- Avoid using outcomes from one distinct clinical entity to construct value-of-care model on a completely different clinical entity
  - Remedied in final report
  - Other issues with Key Question #4 in its final version
Does Not Provide Answers to the Four Key Questions

- Appraisal of the document is missing key elements
  - Of the 15 RCT’s, only 6 within last 10 years and 3 from US
- Cervical arthroplasty literature not reviewed
  - Only a single arthroplasty article incorporated in the final version (Sasso 2011)
- Rigorous assessment of article quality not applied to non-operative treatments
  - Uncommon conservative interventions with limited support in the literature (chemonucleolysis, coblation nucleoplasty) placed on equal footing with ACDF which has over 60 years of clinical experience

Mortality Presented Out of Relevant Context

- Report includes mortality as a potential harm in the Decision Analytic Model and a key model assumption
- Mortality is an infrequent occurrence in cervical fusions
- Risk related to general surgical risks and patient conditions
- Long-term mortality is not a relevant outcome.
Inappropriate Comparators Used in Analysis

- Selection bias in comparing cervical fusion of those who have failed conservative care to those who had improved with conservative care.
- Suggest relevant comparator to cervical fusion would be other procedures or surgical intervention:
  - Did not include recent cervical arthroplasty versus cervical fusion RCT IDE studies.
  - Due to previously review in 2008 HCA report.
  - Many articles published in the last 5 years.
- Confirmation bias with deficiencies not in the extant literature but in the choice of articles summarized.

Limited Decision Analytic Model

- Concerns regarding the robustness of the Markov decision model and its inputs.
  - Estimated downstream values based on treatment with symptoms present, absent, or patient death.
- In the initial version of the report, radiculopathy model based on the assumption that the percentage of patients getting worse, better, or same after surgery will be similar to the Kadanka (2002) paper:
  - Kadanka reported on myelopathy patients.
  - This concern is partially remedied in the final report.
Key Question #4 Model Assumptions Flawed

- The report assumes benefit of surgery will diminish over time, and be equivalent to conservative therapy at four years.
  - Foundation for this assessment is based upon a single report (Persson, 2001), a prospective study randomizing between surgery and conservative therapy for cervical radiculopathy
  - Also cite a study of cervical arthroplasty (Sasso 2011)
- This assumption is not supported by the literature

Assumptions

- Perrson (2001) described similar clinical outcomes at 12 months follow-up in patients randomized between cervical fusion and conservative therapy
  - Patients and procedures not relevant to Washington State in 2013
    - High rate of smoking (65%) which correlated with poor operative outcomes
    - Surgery used cow bone xenograft
    - Number of re-operations extremely high: 8 of 24 operative cases underwent re-operation within 12 months (Perrson 1997)
- This patient population and operative results are not representative and not generalizable
Inaccurate ICERs, QALY

- QALY health state for pre-treatment based on population norms for "neck pain" patients from general population surveys
  - "Neck strain", and not surgically relevant patients
  - No evidence that these patients have DDD or radiculopathy
- QALY-gain or loss based on Van der Velde study
  - General neck pain patients in a pain clinic and "no troublesome neck pain" (0.80) "yes, troublesome neck pain" (0.71 QALY)
  - Regardless of presence or type of medical treatment and not applied in patients with DDD associated neck pain
  - Neck pain is a symptom, not a disease, and utility of treatment of neck pain is not a valid proxy for utility of treatment for cervical stenosis

Incorrect Estimate in Value of a Treatment

- Value of a treatment is most dependent on the effectiveness of that therapy versus that of an alternative
- Definition of effectiveness likelihood (Sasso), comparison to conservative treatment (Persson) and assignment of utility values (Van der Velde) are flawed in this analysis
- Model does not accurately estimate the parameters of benefit in the [benefit/cost] value equation
- Flaws in the benefit estimation are insurmountable and produce extremely misleading results
Summary

- Report highlights the need to have meaningful inclusion of subject matter experts on your writing panels, and the AANS/CNS would be happy to discuss collaboration in this.
- We understand the concern regarding the overutilization of cervical fusions in the hands of certain individual practitioners.
- We applaud the goal of improving patient care through the application of scientifically grounded therapies.
- We have concerns regarding the current draft document as noted, and the adverse effect on patients’ access to beneficial and appropriate surgical care that would improve their quality of life.

THANK YOU!
Joseph S. Cheng, MD, MS
Vanderbilt Univ. Med. Ctr.
T-4224 MCN/Neurosurgery
Nashville, TN 37232-2380
(615)322-1883
joseph.cheng@vanderbilt.edu
Disclosure

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DePuy Synthes Spine

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3/1/2013
Jason Lerner

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126
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I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

Signature: [Signature]
Date: 3/4/13
Print Name: DAVID R. FLUM, MD, MPH

For questions contact:
Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA  98504-2712
360-725-5126
Dave Flum Conflict of Interest Sheet:

**Salary, consulting fees, honoraria in excess of $10,000:**

- Patient Centered Outcomes Research Institute (PCORI) – Methodology Committee (MC) Member – paid salary and travel expenses covered for MC mtgs.

**Status or position as an officer, board member, trustee, owner:**

- Benchmark, LLC – co-owner and leadership for company – money paid currently goes back into the company
- American College of Surgeons – Chair for the Surgical Research Committee and Chair for bi-annual Outcomes Research Course – travel expenses covered

**Research funding:**

- Nestle Health Sciences – funding received for Strong for Surgery Initiative

**Any other relationship, including travel arrangements:**

- Covidien – business class travel expenses covered for international trip to present at various surgical symposiums
- American Academy of Orthopaedic Surgeons – honorarium and travel expenses covered for presenting at Board of Director’s workshop & Safety and Quality Summit
- Nestle – honorarium and travel expenses covered to present at N. American Surgical Nutrition Summit
- Nestle – honorarium and business class travel expenses covered for international trip to present at International Surgical Conference
- Australia New Zealand Hepato-Biliary Association – business class travel expenses covered for international trip to present at annual meeting on Quality in HPB Surgery
- Kenes International – business class travel expenses covered for international trip to present at International Conference on Advanced Technologies and Treatments for Diabetes
Disclosure
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I am Director Spine SCOAP FHCOG

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[X] ___________________________  2/12/13  ___________________________
Signature                              Date                              Print Name

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126
Washington State Spine Surgery Surveillance and the HTA

David R. Flum, MD MPH
Professor of Surgery, Public Health and Pharmacy
University of Washington

Surgical Care and Outcomes Assessment Program
Bending the Cost Curve

Kwon et al. SCOAP at 5 years. Surgery 2012

SPINE SCOAP-

- Developed through the UW CERTAIN program
  - Collaboration with FHCQ
  - Pilot 2011
- Launch 2012
  - 100% Fusion, 30% other cases
  - PROs through the UW Survey center
  - CERTAIN Spine Forum-transparency and engagement
- ~4,000 cases at 18 hospitals
Types of Metrics

- Focus on safety, quality, outcomes that matter and appropriateness of surgery
  - Ability to compare to non-surgical approaches
- Data source-medical record and patient survey
- Function, pain and demographic/clinical variables
- Intraoperative decision making
- Index hospitalization clinical outcomes
- Functional outcomes and clinical events through 2 years

Demographics

- **Total Spine Procedures to date** – 4356
  - Cervical – 1467
  - Lumbar – 2889
- **Median Age** – 57
- **Gender**
  - Male – 48.8%
  - Female – 51.2%
- **Median BMI** – 29
- **Mean Comorbidity Index** – 0.9
- **Prior Spine Surgery** – 36.4%

*to date through 3/4/2013*
Cervical Procedures (N=1467)

- Discectomy without Fusion – 4.9%
  - Anterior – 55.6%
  - Posterior – 44.4%
- Discectomy with Fusion – 78.7%
  - Anterior – 99.6%
  - Posterior – 0.4%
- Fusion alone – 9.3%
  - Anterior – 11%
  - Posterior – 89%
- Artificial Disc Replacement – 1.2%

Cervical Fusion (N = 1291)

Neurologic Symptoms

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<td>SiteC</td>
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SCOAP Average ▲ Hosp Rate
Cervical Fusion Procedures (N=171): Change in Pain Scale

Neck Disability Index

Cervical Spine Procedures: Average Change in NDI
Focus for Improvement:
Cigarette Smoking Pre-Surgery

2013 SPINE SCOAP Activities

- Bree Collaborative-statewide standard
- Deploy interventions to drive improvement
  - Strong for Surgery and cigarette cessation
  - Evaluate BMP use and outcomes
  - Assess fusion outcomes in patients without neurological findings
- HTA collaboration
Opportunity for HTA

- Use SPINE SCOAP data for a view of real world safety, quality and outcomes that matter
- Helps with a "reality check" compared to research data
- Helps re-evaluate safety and outcomes of procedures once launched by HTA
  - Coverage with evidence development
- Encourages participation by all hospitals and clinicians
Dear Mr. Morse,

Thank you for reviewing our comments dated February 14, 2013 and for providing an overview of all the public comments received during the public comment period. We submit these follow-up comments in anticipation of the public meeting scheduled for March 22, 2013. As of now, Medtronic is not planning on testifying at that meeting. In lieu of testimony, please accept this correspondence as we want to briefly state our remaining concerns. As you know, Medtronic Spinal and Biologics manufactures products that treat a variety of disorders of the spine, and these products are utilized by spinal and orthopedic surgeons to treat patients and restore their quality of life.

We applaud the extensive changes made to the Final Evidence Report (February 21, 2013). Specifically, we believe that the change to exclude studies conducted in patients with a primary complaint of cervical spine myelopathy (CSM) was essential. As we mentioned in our comments, the disease in these patients is different than radiculopathy and these patients are typically older with significant co-morbidities. Previous inclusion of the CSM studies created a negative bias in the results, which was especially evident in the Decision Analytic Model (DAM). To that end, we appreciate the significant revisions to the DAM, including applying two outcomes versus three, the altering of mortality to a neutral variable, the change of rates included with assumptions for cervical fusion based on Sasso’s 2012 publication, and the additional discussion regarding Carreon’s 2012 study. The resulting significant reduction in the ICER for fusion compared to conservative care and to other procedures from the initial draft to the final document is reflective of the issues with the initial model.

However, even with the significant modifications to the report and changes to the DAM, we remain concerned that the comparison of cervical fusion to conservative care is an invalid one.

Patients who are treated with cervical fusion have already failed six or more weeks of conservative treatment. Additionally, the severity of illness in patients treated conservatively is lower and not comparable to those patients treated with cervical fusion; this results in inappropriate comparisons between groups.
Furthermore, regarding the DAM, the conservative care patients are not comparable to the fusion patients. The assessment of the conservative care patients as failures at the 6-12 week interval demonstrates the heterogeneity of the groups. If the groups of patients were homogeneous, the utilities comparing fusion to conservative care would be even greater, and potentially yield fusion with a favorable cost-effectiveness ratio.

For example, if the target population is patients that failed conservative care, you could reasonably expect that they would not have QALY gains if they continued in conservative care and received no other treatments. However, the incremental difference in QALYs could be enough to make fusion a cost-effective therapy compared to conservative care. In addition, neither the DAM or the sensitivity analysis should allow for conservative care patients to cross over to fusion, as the analysis should be strictly based on the cost-effectiveness of fusion compared to conservative care in comparable patient populations.

Additionally, further clarification is required with the DAM regarding fusion costs. The added data in section 1.2 of the report is very helpful; however, from these data it seems that costs are derived from a heterogeneous group of patients. According to the data on page 41, patients with cervical degenerative disc disease do not represent a majority of the patients. For example, the cost data includes patients with more serious conditions (and likely higher costs) than cervical DDD/radiculopathy (e.g., stenosis, myelopathy, non-union of fracture).

We are also concerned about the lack of adequate distinction between types of procedures (e.g., anterior and posterior procedures, as well as single and multi-level procedures), and the choice of articles (e.g., excluded comparison of various fusion methods, as well as arthroplasty studies with fusion as a control). These exclusions result in a bias in the results with either some patients having more serious disease and consequently worse results and the exclusion of more contemporary studies.

We would also like to reiterate our comment that the executive summary of the report does not include mention that cervical fusion for DDD is supported by guidelines from the various medical societies, and is covered by various insurance carriers. Input from practitioners is a significant aspect of evidence development relative to state-of-the-art practice.

We thank you again for the opportunity to submit correspondence in anticipation of the upcoming public meeting regarding Cervical Spinal Fusion for Degenerative Disc Disease. Should you have questions, please do not hesitate to contact me for additional information.

Sincerely,

Dena Scearce, JD
Director, State Government Affairs
Medtronic, Inc.
Spinal and Biologics Division
2600 Pyramid Place
Memphis, TN 38132
Cell: 901.428.3516
dena.l.scearce@medtronic.com
Disclosure

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Signature: [Signature] Date: 2/14/13

For questions contact: Christine Masters
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PO Box 42712
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Trent L. Tredway, M.D.
Associate Professor
Director, Minimally Invasive Spine Surgery
Fellowship Director, Spinal Neurosurgery
Department of Neurological Surgery
University of Washington School of Medicine

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Telephone: 206-543-3570  Fax: 206-543-8315
Email: trentt2@u.washington.edu

Home Address:
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Seattle, WA  98101

Education
1985 -1989
Southwest Missouri State University, Springfield, Missouri
B.S. - Biology (Microbiology emphasis), Minor, Chemistry

1991 –1992
Saint Louis University, St. Louis, Missouri
Graduate coursework, cellular and molecular regulation, immunology and biochemistry

1993-1997
M.D. - Rush Medical College, Chicago, Illinois

Postgraduate Training
Internship in General Surgery
Rush University Hospital Medical Center
Chicago, Illinois

July 1997 – June 2003
Resident in Neurological Surgery
Rush University Medical Center
Chicago, Illinois

July 2003 - June 2004
Fellow in Spinal Neurosurgery
Section of Neurosurgery
University of Chicago
Chicago, Illinois
Current Faculty Positions
July 1, 2011 to present
Associate Professor
Department of Neurological Surgery
University of Washington School of Medicine

July 1, 2004 to June 30, 2011
Assistant Professor
Department of Neurological Surgery
University of Washington School of Medicine

July 1, 2011 to present
Joint Associate Professor
Department of Orthopaedics and Sports Medicine
University of Washington School of Medicine

September 1, 2010 to June 30, 2011
Joint Assistant Professor
Department of Orthopaedics and Sports Medicine
University of Washington School of Medicine

Current School and Department Positions
2004 - Present
Attending Neurosurgeon
Department of Neurological Surgery
University of Washington School of Medicine

2006 – Present
Director, Minimally Invasive Spine Surgery
Department of Neurological Surgery
University of Washington School of Medicine

2006 – Present
Fellowship Director, Spinal Neurosurgery
Department of Neurological Surgery
University of Washington School of Medicine

2004 – Present
Neurosurgical Consultant
Northwest Regional Spinal Cord Injury System (NWRSCIS)

2006
Member, Admissions Committee
University of Washington
School of Medicine

Honors
Alpha Omega Alpha (AOA)
**Board Certification**
American Board of Neurological Surgery (ABNS)
Part II (Oral Exam): May 2010

**Current Licensure**
Washington: MD00043699 (6/16/2013)
Illinois: 36-106-538 (7/31/2011)
DEA: BT8059645 (11/30/2014)

**Professional Organizations**
American Association of Neurological Surgeons
Congress of Neurological Surgeons
Washington State Association of Neurological Surgeons
AANS/CNS Spine and Peripheral Nerve Joint Section member
AANS/CNS Trauma Joint Section member
Spinal Arthroplasty Society (SAS) member
Society for Minimally Invasive Spine Surgery – Charter Member
North American Spine Society
World Federation of Neurosurgical Society

**Teaching Responsibilities/CME/Trainees/Courses:**


Breakthroughs in Spine Surgery, 9th Annual Harborview Medical Center Spine Symposium, Seattle, WA, October 1-2, 2010


Evaluation and Management of Cervical Spondylosis, Neurology Grand Rounds, Department of Neurology, University of Washington, Seattle, WA, April 21, 2011.


Seminars in Pain Medicine, Resident Didactics, Department of Anesthesiology, University of Washington, Seattle, WA, May 15, 2012.


TRAINEEES:
Postdoctoral Neurosurgery Spine Fellows:
2005-2006  Fangyi Zhang, MD  
2007-2008  Delmore Morsette, MD  
2008-2009  W. Bradley Jacobs, MD  
2008-2009  Chong Lee, MD  
2009-2010  Nguyen Do, DO  
2010-2011  Nicholas Qandah, DO  
2010-2011  Gareth Adams, MD, PhD  
2011-2012  Tarek Radwan, MD  
2011-2012  Noojan Kazemi, MD  
2012-2013  Jorge Gonzalez-Cruz, MD  

Postdoctoral Orthopaedic Spine Fellows:
2004-2005  Gavin Button, MD/Arturo Gomez, MD  
           Jason Thompson, MD/David Weiss, MD  
2005-2006  Hossein Elgafy, MD/ David Stevens, MD  
2006-2007  Troy Caron, MD/Josh Pratt, MD  
2007-2008  Paul Kraemer, MD/Anthony Russo, MD  
2008-2009  Christopher Howe, MD/Mark Freeborne, MD  
2009-2010  Ablio Reis, MD/Max Reinhold, MD/Roland Kent, MD  
2010-2011  Myles Luszczyz, DO/Jeremiah Maddox, MD/Anuj Varshney, MD  
2011-2012  Amit Patel, MD/Harsha Malempati, MD  

Chief Residents – Trainees:
2004-2005  Farrokh Farrokhi, MD/Daniel Lazar, MD  
           Fangyi Zhang, MD/Andrew Nemecek, MD  
2005-2006  Alex Mohit, MD, PhD/David Lundin, MD  
2006-2007  Thomas Manning, MD, PhD  
2007-2008  Chong Lee, MD  
2008-2009  Mikhail Gelfenbeyn, MD  
2009-2010  Patrik Gabikian, MD  
2009-2010  Leila Khorasani, MD  
2009-2010  Abhineet Chowdhary, MD  
2010-2011  Timothy Lucas, II, MD, PhD.  
2010-2011  Jeffrey Mai, MD, PhD  
2011-2012  Eric Peterson, MD  
2011-2012  Andrew Ko, MD  

COURSE INSTRUCTOR:


Jump Start Resident Program, Faculty, Medtronic Training Program, Denver, Colorado,


Minimally Invasive Resection of Spinal Tumors, Faculty, Cedar-Sinai Medical Center Spine Symposium, Las Vegas, NV, February 4-6, 2010.

Early Career- Handling Complications, Faculty, Medtronic training program, Memphis, TN, March 26-27, 2010


ProDisc-C Implantation Technique, Advanced Cervical Solutions with ProDisc-C, Surgeon Training Program, Dallas, Texas, March 6, 2011.


ProDisc-C, Faculty, Cervical Surgeon Forum, Denver, Colorado, June 5, 2011

ProDisc-C Implantation Technique, Faculty, ProDisc-C Surgeon Forum, Los Angeles, June 11, 2011.

ProDisc-C Implantation Technique, Faculty, ProDisc-C Surgeon Forum, Chicago, April 22, 2012.

ProDisc-C Implantation Technique, Faculty, ProDisc-C Surgeon Training Forum, Cincinnati, Ohio, May 19, 2012.
ProDisc-C Implantation Technique, Faculty, ProDisc-C Surgeon Forum, Frisco, Texas, June 9, 2012

**PRO-DISC-C TRAINING COURSES – CERTIFIED INSTRUCTOR:**

2008  12 courses  
2009  5 courses  
2010  5 courses  
2011  9 courses  
2012  2 (to date 7/1/2012)

**EDITORIAL RESPONSIBILITIES:**

Ad Hoc review:  

**NATIONAL RESPONSIBILITIES:**

CNS (Congress of Neurological Surgeons) Committee Member, Luncheon Seminars, Chicago, Illinois, October 2006


AANS (American Association of Neurological Surgeons) – Faculty Member, Practical Clinic *Surgical Anatomy of the Thoracic and Lumbar Spine*, Chicago, Illinois, April 2008.

AANS, Member, Consensus Committee, Chicago, Illinois, April 2008.


AANS, Faculty, *Current Surgical Techniques and Approaches to Minimally Invasive Surgery*, Denver, Colorado, April 8, 2011


Texas Back Institute Grand Rounds, Invited Speaker, *Reoperation for Vertebral Column Tumors: Salvage Strategy, Technique & Outcome*, Dallas, Texas, September 21, 2012,


**LOCAL RESPONSIBILITIES:**
Washington State Association of Neurological Surgeons,
   Secretary 2009-2011
   Vice President 2011-present

**RESEARCH AND SUPPORT:**
2005-2007
Medtronic Spine Fellowship Research Fund
$75,000/year: Trent L. Tredway, MD and Richard G. Ellenbogen, MD

2011-2012
Neurosurgery Research and Education Foundation (NREF)
$37,000: Tarek Radwan, MD, Neurological Surgery Spine Fellow

**RESEARCH:**

   Project: In vivo evaluation of the glioma-associated gene, dek, utilizing adenoviral and liposomal vectors in a SCID mouse model
   Project: SNP analysis of the glioma-associated gene, dek, in glioma cell lines and clinical specimens
   Project: In vivo evaluation of α2,6 sialyltransferase gene utilizing an adenoviral vector in an intracranial SCID mouse model
   Project: Development of a glioma intracranial SCID mouse model
Sponsor: Drs. Joseph Moskal and Roger Kroes

**June 1994-** Hines VA Research Center, Department of Pathology, Hines, Illinois

**Sept. 1994**  
Project: Expression of PCNA and EPAG in a Hodgkin’s Disease cell line (L428) utilizing immunocytochemistry  
Sponsor: Drs. John F. Nawrocki and George J. Dizikes

**Sept. 1992- Sept. 1993**  
Loyola University-Stritch School of Medicine, Department of Pathology, Department of Microbiology & Immunology, Maywood, Illinois  
Project: Isolation of cDNA clones overexpressed in a Hodgkin’s Disease cell line (L428)  
Project: Characterization of alternatively-spliced mRNAs arising from a novel gene, epag  
Project: Protein expression of a novel gene, epag, in bacterial expression vector systems  
Project: Engineer an antibody towards a protein expressed by the novel gene, epag  
Sponsor: Drs. John F. Nawrocki and George J. Dizikes

**June 1992- Sept. 1992**  
Loyola University-Stritch School of Medicine, Department of Microbiology & Immunology, Maywood, Illinois  
Project: Isolation and characterization of alternatively spliced mRNAs arising from the CD5 gene in rabbits  
Sponsor: Drs. Katherine L. Knight and Chander Raman

**Nov. 1989- May 1992**  
The Monsanto Corporation, Chesterfield, Missouri  
Research Analyst  
Project: Physical and biochemical analysis of genetically engineered recombinant bovine and porcine somatotropins (rBST and rPST)  
Project: Research and development of drug delivery systems in animal models  
Sponsor: Philip B. Larbi

**July 1987- May 1989**  
Dayco Technical Center, Springfield, Missouri  
Laboratory Technician and Raw Materials Coordinator  
Project: Responsible for the computer-aided experimental design and analytical testing of new rubber compounds  
Sponsor: Dr. Leonard Outz and Wes McFall

**Clinical Investigations:**
Prodisc-C  
Investigator for FDA-approved IDE Study (July 2004 – ongoing)

Stabilimax-NZ  
Principal Investigator for FDA-approved IDE Study (July 2006 – discontinued)

**Publications:**


BOOK CHAPTERS


**ABSTRACTS AND PRESENTATIONS:**

1. Heat Shock Protein 60 (HSP-60) overexpression in cells adjacent to glioblastomas. Abe, Yamamoto, **Tredway**, Cerullo, Mkrdichian, Leestma, Kroes, and Moskal. American Association for Cancer Research (AACR); March 24-28, 2001 in New Orleans, Louisiana


8. Two level minimally-invasive transforaminal lumbar interbody fusion (MI-TLIF) with three arm Sextant instrumentation. Tredway, Santiago, Kim, Rice, and Fessler. AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, March 17-20, 2004 in San Diego, California


Chronic neck pain is prevalent and costly
Degenerative disc disease (DDD) a common cause
Management options:
  o Conservative treatment
  o Spinal injections
  o Surgical procedures
    • Decompressive procedures for radiculopathy (discectomy, foraminotomy, and laminectomy/laminoplasty)
      +/- fusion as an add on
    • Cervical fusion for chronic neck pain, related to “instability”
Background, cont.

- CSF most common surgical procedure in U.S. for patients with symptomatic cervical DDD

- 1990-2004: Eight-fold increase in CSF

- Utilization is increasing disproportionately in older populations

- Cost is high

- Safety and effectiveness of the procedure are of concern

Agency Medical Directors’ Perspective

Safety

- Reoperation rates are high at same / adjacent segments

- Adding fusion to cervical decompression procedures may do more harm than good
Agency Medical Directors’ Perspective

Efficacy

- Chronic neck pain is not necessarily caused by DDD - even with radiographic evidence of DDD
  - CSF may be performed on patients without radiculopathy or myelopathy - an unnecessary surgical procedure for those patients
- Adding fusion to other decompression procedures (i.e. discectomy) does not appear to provide additional benefits

Cost-Effectiveness

- Average cost per procedure: $24,000
  Can be as high as $230,000
- More than $63M paid for CSF between 2008 - 2011
Agency Medical Directors’ Concerns

Primary Criteria Ranking

Safety = Medium (Now High)
Efficacy = High
Cost = High

Cervical Spinal Fusion for DDD
State Agency Utilization

Current State Policy

**Labor and Industries**
- Prior authorization (through Qualis), for entrapment of single nerve root
- Completion of conservative care and specific clinical findings
- Non-covered for chronic neck pain without evidence of radiculopathy or myelopathy

**Medicaid**
- Prior authorization (through Qualis), with same guidelines as for LNI.

**Department of Corrections**
- Prior authorization required, but no specific criteria identified

**Regence**
- Prior authorization
### Overview

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>4-Yr²</th>
<th>Avg Chg</th>
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<tbody>
<tr>
<td><strong>Agency Population</strong></td>
<td>205K</td>
<td>211K</td>
<td>213K</td>
<td>213K</td>
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<td>1.3%</td>
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<td><strong>Patient Count</strong></td>
<td>141</td>
<td>167</td>
<td>196</td>
<td>165</td>
<td>648</td>
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<td><strong>Procedure Count</strong></td>
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<td>186</td>
<td>193</td>
<td>163</td>
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<tr>
<td><strong>Total Paid</strong></td>
<td>$3.2M</td>
<td>$5.6M</td>
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<td><strong>Avg. Paid/ Procedure</strong></td>
<td>$21,727</td>
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<table>
<thead>
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<tr>
<td><strong>Agency Population</strong></td>
<td>393K</td>
<td>417K</td>
<td>424K</td>
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<td><strong>Patient Count</strong></td>
<td>313</td>
<td>335</td>
<td>295</td>
<td>326</td>
<td>1269</td>
<td>-1.6%</td>
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<tr>
<td><strong>Procedure Count</strong></td>
<td>313</td>
<td>335</td>
<td>299</td>
<td>331</td>
<td>1278</td>
<td>-1.2%</td>
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<tr>
<td><strong>Total Paid</strong></td>
<td>$3.8M</td>
<td>$3.9M</td>
<td>$1.5M</td>
<td>$1.1M</td>
<td>$10.3M</td>
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<td><strong>Avg. Paid/ Procedure</strong></td>
<td>$11,989</td>
<td>$11,659</td>
<td>$5166</td>
<td>$3294</td>
<td>$8054</td>
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<table>
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<th>2010</th>
<th>2011</th>
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<tr>
<td><strong>Agency Population</strong></td>
<td>147K</td>
<td>126K</td>
<td>122K</td>
<td>121K</td>
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<td>-6.2%</td>
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<tr>
<td><strong>Patient Count</strong></td>
<td>347</td>
<td>370</td>
<td>381</td>
<td>344</td>
<td>1341</td>
<td>7.4%</td>
</tr>
<tr>
<td><strong>Procedure Count</strong></td>
<td>361</td>
<td>381</td>
<td>393</td>
<td>351</td>
<td>1486</td>
<td>6.7%</td>
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<tr>
<td><strong>Total Paid</strong></td>
<td>$8.3M</td>
<td>$9.1M</td>
<td>$9.8M</td>
<td>$8.8M</td>
<td>$36.0M</td>
<td>9.9%</td>
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<td><strong>Avg. Paid/Procedure</strong></td>
<td>$23,007</td>
<td>$23,869</td>
<td>$24,938</td>
<td>$25,031</td>
<td>$24,217</td>
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</table>

### Cervical Spinal Fusion for DDD

#### Average Allowed Amount Per Fusion

<table>
<thead>
<tr>
<th></th>
<th>PEB Primary (No Medicare)</th>
<th>PEB Medicare</th>
<th>L&amp;I</th>
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<tbody>
<tr>
<td><strong>Breakdown 1</strong></td>
<td></td>
<td></td>
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<tr>
<td>Professional Services</td>
<td>$8,006</td>
<td>$3,207</td>
<td>$9,262</td>
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<tr>
<td>Facility</td>
<td>$26,006</td>
<td>$41,016</td>
<td>$14,955</td>
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<td><strong>Breakdown 2</strong></td>
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<tr>
<td>Pre-Op Charges</td>
<td>$62</td>
<td>$141</td>
<td>$1,094</td>
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<tr>
<td>Imaging</td>
<td>$533</td>
<td>$613</td>
<td>$320</td>
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<tr>
<td>Fusion</td>
<td>$33,387</td>
<td>$43,461</td>
<td>$20,427</td>
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<tr>
<td>Post-Op Charges</td>
<td>$30</td>
<td>$56</td>
<td>$2375</td>
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<tr>
<td><strong>Average Allowed Amount Per Fusion</strong></td>
<td>$34,011</td>
<td>$44,270</td>
<td>$24,217</td>
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</table>
Cervical Spinal Fusion for DDD
State Agency Utilization

Costs

<table>
<thead>
<tr>
<th></th>
<th>Total Allowed¹</th>
<th>Total Paid</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEB</td>
<td>$26,441,157</td>
<td>$16,294,859</td>
</tr>
<tr>
<td>Medicaid</td>
<td>$13,018,813</td>
<td>$10,293,260</td>
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<tr>
<td>L &amp; I</td>
<td>$35,985,774</td>
<td>$35,985,774</td>
</tr>
<tr>
<td>All Agencies</td>
<td>$75,445,744</td>
<td>$62,573,893</td>
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</table>

¹ Payments by other primary and secondary payers and patients, as well as state payers.

² Procedures for CPT 22554 were under-reported for years 2008 – 2010, reducing both allowed and paid amounts.

Cervical Spinal Fusion for DDD
State Agency Utilization

PEB Patients
By Age Gender, 2008-2011

Age Groups

<table>
<thead>
<tr>
<th>Age Groups</th>
<th>0-20</th>
<th>21-35</th>
<th>36-50</th>
<th>51-65</th>
<th>66-80</th>
<th>80+</th>
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<tbody>
<tr>
<td>Female</td>
<td>0</td>
<td>12</td>
<td>97</td>
<td>172</td>
<td>86</td>
<td>2</td>
</tr>
<tr>
<td>Male</td>
<td>2</td>
<td>6</td>
<td>66</td>
<td>133</td>
<td>71</td>
<td>8</td>
</tr>
</tbody>
</table>
Cervical Spinal Fusion for DDD
State Agency Utilization

L & I Patients
By Age / Gender, 2008 - 2011

- Female: 0, 33, 222, 164, 6
- Male: 1, 78, 478, 341, 16

Cervical Spinal Fusion for DDD
State Agency Utilization

Medicaid Patients
By Age / Gender, 2008 - 2011

- Female: 5, 37, 299, 293, 26, 1
- Male: 8, 30, 278, 269, 29, 0
Cervical Spinal Fusion for DDD State Agency Utilization

Medicaid Radiculopathy and Myelopathy Diagnosis

Cervical Spinal Fusions by Year

- Other Diagnoses: 52, 59, 71, 92
- Myelopathy CF: 108, 117, 109, 107
- Radiculopathy CF: 153, 159, 119, 132
- Total Procedures: 313, 335, 299, 331

L&I Patient Event Rate - First Cervical Spinal Fusion Hospital Type, 2008-2011

- Reoperations: 18.3% ASC, 11.4% Inpatient, 35.7% Outpatient
- ER Visits within 30 days: 12.2% ASC, 14.5% Inpatient, 48.8% Outpatient
- ER visits within 90 days: 14.6% ASC, 18.3% Inpatient, 56.0% Outpatient
- Readmissions (non-fusion): 1.2% ASC, 2.7% Inpatient, 10.7% Outpatient
- Total Patient Counts: 82, 1320, 84

Health Technology Clinical Committee
ER Visits Within 90 Days of CSF Procedures

**PEB**
- 11.6% of patients
- 108 visits / 75 patients

**Top 10 Diagnosis for ER visits**

<table>
<thead>
<tr>
<th>Diagnosis Category</th>
<th>Patient Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back/Skeletal</td>
<td>13</td>
</tr>
<tr>
<td>Neurologic Symptoms</td>
<td>11</td>
</tr>
<tr>
<td>Respiratory Symptoms</td>
<td>9</td>
</tr>
<tr>
<td>Urinary Tract Symptoms</td>
<td>8</td>
</tr>
<tr>
<td>Abdominal Symptoms</td>
<td>8</td>
</tr>
<tr>
<td>Cardiac Symptoms</td>
<td>8</td>
</tr>
<tr>
<td>Esophageal Symptoms</td>
<td>6</td>
</tr>
<tr>
<td>Complication</td>
<td>5</td>
</tr>
<tr>
<td>Infection</td>
<td>3</td>
</tr>
<tr>
<td>Allergic Reaction</td>
<td>3</td>
</tr>
</tbody>
</table>

**L&I**
- 13.7% of patients
- 365 visits / 184 patients

**Top 10 Diagnosis for ER visits**

<table>
<thead>
<tr>
<th>Diagnosis Category</th>
<th>Patient Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back/Skeletal</td>
<td>76</td>
</tr>
<tr>
<td>Acute Pain</td>
<td>32</td>
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<tr>
<td>Musculoskeletal</td>
<td>30</td>
</tr>
<tr>
<td>Respiratory</td>
<td>29</td>
</tr>
<tr>
<td>Neurologic Symptoms</td>
<td>27</td>
</tr>
<tr>
<td>Head &amp; Neck</td>
<td>26</td>
</tr>
<tr>
<td>Abdominal Symptoms</td>
<td>25</td>
</tr>
<tr>
<td>Wound Disruption</td>
<td>21</td>
</tr>
<tr>
<td>Cardiac Symptoms</td>
<td>20</td>
</tr>
<tr>
<td>Infection</td>
<td>19</td>
</tr>
</tbody>
</table>

Cervical Spinal Fusion for DDD
State Agency Utilization

**More Than One ER Visit Within 90 Days**

Average number of ER visits per patient within 90 days of Cervical Spinal Fusion:

- PEB: 1.4 (108 visits/75 patients)
- L&I: 2.0 (365 visits/184 patients)
- Medicaid: 1.9 (704 visits/360 patients)
Cervical Spinal Fusion for DDD
State Agency Utilization

Cervical Fusion Reoperations

<table>
<thead>
<tr>
<th>Number Reoperations</th>
<th>Number Patients</th>
<th>Avg. Days From Previous Fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>35</td>
<td>352</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>185</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>432</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>511</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>L&amp;I</th>
<th>12.2% of patients</th>
<th>196 reoperations / 163 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number Reoperations</td>
<td>Number Patients</td>
<td>Avg. Days From Previous Fusion</td>
</tr>
<tr>
<td>1</td>
<td>138</td>
<td>447</td>
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<tr>
<td>2</td>
<td>19</td>
<td>398</td>
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<td>3</td>
<td>4</td>
<td>156</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>257</td>
</tr>
</tbody>
</table>

New Evidence in 2013

ACDF + physiotherapy did not result in additional improvement in functional outcomes vs. physiotherapy alone.¹

Study Design
- RCT with two-year follow-up
- Physiotherapy vs. ACDF + physiotherapy
- 63 subjects with radiculopathy and nerve root compression

Functional Outcome
(Neck ROM, muscle endurance, hand-related functioning)
- Both groups showed improvement compared to baseline
- No difference between the groups

Evidence for cervical fusion vs. other forms of surgery for radiculopathy

- **Treatment success:** No difference was found in 6 higher-quality RCTs, except from one RCT (Barlöcher, 2002).
  
  Meta-analysis using two RCTs on treatment success showed no difference

- **Pain and function:** No significant effects of treatment on pain were observed in 4/5 RCTs.

- **Quality of life:** No difference

- **Return to work:** ICER Meta-analysis directionally favored discectomy at 12-24 months, though difference was not statistically significant

**Nov. 2012 systematic review of 10 RCTs using pooled risk differences (Middelkoop et al, Pain 2012: 153: 2167-73):** No additional benefit of fusion with anterior discectomy on pain, recovery and RTW.

**Evidence for cervical fusion for chronic neck pain - No RCTs**

---

**Summary**

**Efficacy of Cervical Fusion**

- There is little or no difference in patient-centered outcomes between cervical fusion and conservative therapy in the long-term
- There is little or no difference in patient-centered outcomes between decompressive procedures +/- fusion in patients with radiculopathy

**Safety**

- The risk of adverse events is much higher for patients with cervical fusion than with conservative treatment
- The risk of reoperation at the same or adjacent levels is substantial

**Cost-Effectiveness**

- Spinal fusion is not superior to conservative treatment in terms of outcomes, but is substantially more expensive
- Discectomy with add-on fusion does not increase clinical effectiveness compared to discectomy alone, but increases the cost significantly
Recommendations:

- Cervical fusion as an add-on procedure to a decompressive procedure for cervical radiculopathy
  - Not covered
- Cervical fusion for chronic neck pain in the absence of radiculopathy
  - Not covered

Note:
Agencies will continue to cover decompressive procedures for cervical radiculopathy, and fusion +/- decompression for myelopathy.

Questions?

More Information:

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Cervical Spinal Fusion

An Assessment of Comparative Clinical Effectiveness and Comparative Value

Presented to the Washington State Health Care Authority by
Daniel A. Ollendorf, MPH, ARM
March 22, 2013

Structure of the presentation

- Project Scope, Comparators, Outcomes of Interest
- Systematic Review of published evidence
  - Quality of evidence
  - Findings on comparative clinical effectiveness
  - Potential harms
- Comparative Value
  - Decision analytic model
  - Costs, outcomes, and cost-effectiveness
- Summary
Scope

- Spinal fusion vs. alternatives in patients with cervical degenerative disc disease (DDD)
  - Comparisons to surgical and nonsurgical alternatives
    - Exception: artificial discs (previously evaluated by HCA)
  - Focus on adults w/ or w/o radiculopathy and/or spondylosis
    - Excluded populations w/urgent neurologic conditions (e.g., myelopathy, acute trauma)
  - Excluded comparisons of fusion variants (e.g., graft type, instrumentation)

Comparators

- Continued conservative management
  - Physical therapy
  - Cervical collar immobilization
  - Interdisciplinary rehabilitation
- Minimally-invasive procedures
  - Radiofrequency denervation
  - Spinal injections
- Other surgical approaches
  - Discectomy alone
  - Foraminotomy
Outcomes

- Measures of effectiveness
  - “Treatment success” (e.g., Odom’s criteria)
  - Pain (e.g., VAS, McGill)
  - Function (e.g., DRI)
  - Quality of life
  - Return to work

- Potential harms
  - “Peri-procedure” (within 30 days) mortality and complications (e.g., hardware failure, nerve damage)
  - Longer-term mortality and adverse events (e.g., pseudarthrosis, adjacent segment degeneration)

Study Types

- Randomized controlled trials (RCTs)
- Comparative cohort studies
- Fusion case series:
  - Sample size >50
  - Follow-up 12+ months
  - Data on outcomes and/or subgroups of interest
Description of Included Studies

- **RCTs**
  - 14 studies met criteria (N=1,209)
  - Nearly all conducted in patients with radiculopathic symptoms
  - 1 comparison to conservative care; others primarily to discectomy alone or foraminotomy
  - Relatively small (10-50 patients per treatment arm)

- **Comparative cohorts**
  - 7 studies met criteria; 929 patients from 6 studies + 1 large database analysis (N=~100,000)
  - 6 of 7 were retrospective

Description of Included Studies

- **RCTs conducted in single centers**
- No studies comparing fusion to minimally-invasive nonsurgical techniques
- No studies in patients with generalized neck pain
- Variability in:
  - Procedures performed by same or different surgeons
  - Post-surgery protocol
- Little published data on training standards and relationship to outcomes
Clinical Benefits (KQ1): Fusion vs. Conservative Management

- 1 RCT, 1 comparative cohort study
- Statistically and clinically-significant improvement in pain/function with fusion vs. cervical collar at 3-4 months (radiculopathy population)
- Differences no longer statistically-significant after 12+ months of follow-up
- No statistical differences vs. physical therapy
- No statistically-significant differences in quality-of-life or return-to-work measures

Fusion vs. Conservative Management: VAS Pain

*: p<.01, fusion vs. collar; all other comparisons not statistically significant
Source: Persson et al., Disability & Rehabilitation; 2001:23:325-35
Clinical Benefits (KQ1): Fusion vs. Discectomy Alone/Foraminotomy

- 13 RCTs, 1 comparative cohort study
- Rates of “treatment success” did not statistically differ by type of surgery in 5 of 6 higher-quality RCTs
- Similar levels of improvement in pain and function for fusion and surgical comparators
- Limited data on quality of life

Fusion vs. Discectomy Alone: Return to Work

Meta-Analysis: Return to Work at 12-24 Months

<table>
<thead>
<tr>
<th>Study/Subgroup</th>
<th>Fusion Events</th>
<th>Total Events</th>
<th>Total Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bartlocher 2002</td>
<td>25</td>
<td>30</td>
<td>29</td>
<td>33</td>
<td>41.8%</td>
</tr>
<tr>
<td></td>
<td>0.95 [0.77, 1.16]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hauersberg 2007</td>
<td>11</td>
<td>36</td>
<td>20</td>
<td>43</td>
<td>5.9%</td>
</tr>
<tr>
<td></td>
<td>0.66 [0.37, 1.16]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rosenem 1983</td>
<td>24</td>
<td>31</td>
<td>30</td>
<td>32</td>
<td>39.5%</td>
</tr>
<tr>
<td></td>
<td>0.83 [0.67, 1.02]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Xie 2007</td>
<td>12</td>
<td>15</td>
<td>10</td>
<td>12</td>
<td>13.6%</td>
</tr>
<tr>
<td></td>
<td>0.96 [0.67, 1.37]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>112</td>
<td>120</td>
<td>100.0%</td>
<td>0.88 [0.77, 1.01]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 72 Favor [discectomy] vs. 89 Favor [fusion]

Heterogeneity: Tau^2 = 0.00; Chi^2 = 2.43, df = 3 (P = 0.49); I^2 = 0%

Test for overall effect: Z = 1.85 (P = 0.06)

• Anterior discectomy and fusion

NOTE: Ratios <1 favor discectomy alone, >1 favor fusion
Fusion vs. Discectomy Alone: Return to Work

Meta-Analysis: Return to Work at 6 Months

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Fusion* Events</th>
<th>Discectomy Events</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barthécher 2002</td>
<td>22</td>
<td>30</td>
<td>69.7%</td>
<td>0.61 [0.18, 2.03]</td>
</tr>
<tr>
<td>Xie 2007</td>
<td>15</td>
<td>9</td>
<td>30.9%</td>
<td>1.33 [0.22, 8.22]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>34</td>
<td>45</td>
<td>100.0%</td>
<td>0.77 [0.28, 2.11]</td>
</tr>
<tr>
<td>Total events</td>
<td>45</td>
<td>45</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

•Anterior discectomy and fusion

NOTE: Ratios <1 favor discectomy alone, >1 favor fusion

Harms (KQ2)

- Estimates ranged widely across studies
- Peri-operative mortality and serious complications were rare (<1%)
- Most frequent peri-procedure complications: dysphagia (range: 3-18%), hoarseness (5-20%)
- Most frequent long-term adverse outcomes (per year): adjacent segment degeneration (7-17%), neurological decline (3-23%), reoperation (1-22%)
Benefits/Harms in Key Subgroups (KQ3)

- Limited subgroup data available from RCTs
- Key findings from comparative cohort studies and case series:
  - Inpatient vs. outpatient fusion: no differences in measures of benefit or harm
  - Anterior vs. posterior fusion: posterior procedures have higher rates of mortality and complications
  - Single vs. multi-level fusion: higher rates of dysphagia w/greater numbers of operative levels
  - Older age and symptom duration >12 months associated w/poorer fusion outcomes

Comparative Value (KQ4)

- Limited prior data examining economic impact and cost-effectiveness of cervical fusion
- Carreon 2012: cost per quality-adjusted life year (QALY) gained of ~$25,000 at 5 years
  - Comparison vs. baseline, NOT alternative treatments
  - Assumed relatively low cost of fusion (~$15,000)
- Other economic comparisons limited to fusion variants only (e.g., autograft vs. allograft with plating)
Comparative Value (KQ4)

- Simulation model focusing on patients with persistent cervical DDD symptoms after 6-12 week trial of conservative care
  - Moderate-severe neck/radicular pain (NDI = ~50)
- Primary comparison: anterior cervical discectomy w/fusion (ACDF) vs. continued conservative care
  - Comparisons to other surgical and nonsurgical options made in secondary analyses
- 1-3 year time horizon
- Public payer perspective

Model Structure

SAE=serious adverse event
Key Model Inputs

- Gap in clinical improvement between fusion and conservative care narrows over time
- Patients with unresolved neck/radicular pain have decreased quality of life and incur costs (continued PT)
- Fewer lost work days with fusion in first year
- No reoperation or mortality differences assumed in primary analysis
- Treatment cost estimates obtained from Washington HCA

Key Model Outputs

- Measures of effectiveness:
  - Treatment response: % with resolution of neck/radicular pain
  - QALYs: time in particular state of health X “utility” (quality of life) associated with state
- Costs of initial treatment, adverse effects, and continuing treatment for unresolved pain
- Cost-effectiveness:
  - Cost per additional treatment responder
  - Cost per QALY gained
Results: Resolution of Neck Pain

![Graph showing resolution of neck pain over time for Spinal Fusion and Conservative Treatment]

Results: Cost-Effectiveness (3 yrs)

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Incremental Fusion $</th>
<th>Incremental Fusion Response</th>
<th>Incremental Fusion QALYs</th>
<th>Cost per Responder</th>
<th>Cost per QALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conservative care</td>
<td>$24,693</td>
<td>3.6%</td>
<td>0.0711</td>
<td>$677,917</td>
<td>$347,473</td>
</tr>
<tr>
<td>Foraminotomy</td>
<td>-$328</td>
<td>2.2%</td>
<td>0.0115</td>
<td>Slightly ↓ $, slightly ↑ effective</td>
<td>Slightly ↓ $, slightly ↑ effective</td>
</tr>
<tr>
<td>Discectomy alone</td>
<td>$6,945</td>
<td>2.2%</td>
<td>0.0115</td>
<td>$317,757</td>
<td>$603,558</td>
</tr>
<tr>
<td>Epidural steroid injections</td>
<td>$18,831</td>
<td>44.4%</td>
<td>0.2340</td>
<td>$42,375</td>
<td>$80,488</td>
</tr>
</tbody>
</table>

Cost-effectiveness ratios of $200,000 - $870,000 per QALY gained across a variety of sensitivity and variability analyses.
Summary

- No evidence supporting use of cervical spinal fusion in patients with cervical DDD with only generalized neck pain
- No evidence comparing fusion to minimally-invasive nonsurgical alternatives
- In patients with radiculopathy, limited data comparing fusion to conservative therapy suggests early clinical benefits for fusion vs. some conservative options, but relative benefits diminish over time
- Fusion's clinical performance similar to alternative surgical approaches (discectomy alone and foraminotomy)
- Based on HCA payment data, modeling suggests:
  - Benefits of fusion vs. conservative care come at relatively high cost across a range of assumptions and alternative scenarios
  - Effectiveness and costs similar for fusion and foraminotomy
  - Fusion is also clinically comparable to discectomy alone but at higher cost
Thank you

Daniel A. Ollendorf, MPH, ARM
Jennifer A. Colby, PharmD
Christopher Cameron, MSc
Swetha Sitaram, MS
Steven D. Pearson, MD, MSc, FRCP
Chief Review Officer
Sr. Research Associate
Decision Scientist
Research Associate
President
## Harms: RCTs & Comparative Cohorts

<table>
<thead>
<tr>
<th>Type of Harm</th>
<th>Factors</th>
<th>Conservative Rx</th>
<th>Surgical Approaches</th>
<th>No. of studies reporting harms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Surgical Events</strong></td>
<td>RCT</td>
<td>CC</td>
<td>RCT</td>
<td>CC</td>
</tr>
<tr>
<td>Malignancy</td>
<td>0</td>
<td>0.01</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Herpes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Herniation</td>
<td>2.6</td>
<td>0.03</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Nerve Damage</td>
<td>2.6</td>
<td>0.6</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>0.13</td>
<td>0.05</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>0.13</td>
<td>0.13</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Dystrophy</td>
<td>3.3</td>
<td>0.1</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Thromboembol</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C/E Leak</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Return to CR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Long term Events**

<table>
<thead>
<tr>
<th>Complications</th>
<th>RCT</th>
<th>CC</th>
<th>RCT</th>
<th>CC</th>
<th>Retinectomy</th>
<th>Facetectomy</th>
<th>Lumbarplasty</th>
<th>Facetectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pain</td>
<td>4.8</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>2.6</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>NID</td>
<td>65.9</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>74.5</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Paediatrican</td>
<td>0.0</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>0</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Neurological</td>
<td>3.23</td>
<td>0</td>
<td>14.2</td>
<td>NR</td>
<td>27.2</td>
<td>NR</td>
<td>0</td>
<td>NR</td>
</tr>
<tr>
<td>Myelopathy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle weakness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rupture</td>
<td>11.2</td>
<td>3</td>
<td>6.2</td>
<td>NR</td>
<td>NR</td>
<td>0</td>
<td>NR</td>
<td>1</td>
</tr>
</tbody>
</table>

Subsequent Rx

<table>
<thead>
<tr>
<th></th>
<th>RCT</th>
<th>CC</th>
<th>RCT</th>
<th>CC</th>
<th>Retinectomy</th>
<th>Facetectomy</th>
<th>Lumbarplasty</th>
<th>Facetectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5-15.7</td>
<td>0.22</td>
<td>31.8</td>
<td>11.9</td>
<td>3.1</td>
<td>NR</td>
<td>1</td>
<td>10</td>
<td>4</td>
</tr>
</tbody>
</table>
To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

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

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

**Principle One: Determinations are Evidence-Based**

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective\(^1\) as expressed by the following standards\(^2\):

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

**Principle Two: Determinations Result in Health Benefits**

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms\(^3\):

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population’s value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

\(^1\) Based on legislative mandate: See RCW 70.14.100(2).
\(^2\) The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm
\(^3\) The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm
Using Evidence as the Basis for a Coverage Decision

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

1. **Availability of Evidence:**

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

2. **Sufficiency of the Evidence:**

   Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence using characteristics such as:
   
   - Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
   - The amount of evidence (sparse to many number of evidence or events or individuals studied);
   - Consistency of evidence (results vary or largely similar);
   - Recency (timeliness of information);
   - Directness of evidence (link between technology and outcome);
   - Relevance of evidence (applicability to agency program and clients);
   - Bias (likelihood of conflict of interest or lack of safeguards).

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

<table>
<thead>
<tr>
<th>Not Confident</th>
<th>Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.</td>
<td>Very certain of evidentiary support. Further information is unlikely to change confidence.</td>
</tr>
</tbody>
</table>

3. **Factors for Consideration - Importance**

   At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology’s safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:
   
   - Risk of event occurring;
   - The degree of harm associated with risk;
   - The number of risks; the burden of the condition;
   - Burden untreated or treated with alternatives;
   - The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
   - The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
   - Value variation based on patient preference.

---

4 Based on GRADE recommendation: [http://www.gradeworkinggroup.org/FAQ/index.htm](http://www.gradeworkinggroup.org/FAQ/index.htm)
Medicare Coverage *(page 57 of evidence report)*

Centers for Medicare and Medicaid Services (CMS): Medicare does not have a National Coverage Determination (NCD) for any form of fusion surgery. Local coverage decisions (LCDs) are limited to the use of spinal fusion for *lumbar* degenerative disc disease only.

Guidelines *(page 55 of evidence report)*

- **North American Spine Society (NASS, 2010)**
  
  
  Anterior cervical discectomy with fusion (ACDF) is recommended in the treatment of 1-level cervical radiculopathy from degenerative disorders and is considered a comparable treatment strategy to anterior cervical discectomy (ACD) based on long-term follow-up. ACDF or posterior laminoforaminotomy (PLF) are recommended for the treatment of 1-level cervical radiculopathy secondary to foraminal soft disc herniation, while ACDF is recommended over PLF in patients with 1-level disease from central and paracentral nerve root compression and spondylotic disease. Evidence suggests that ACDF results in comparable short-term success relative to ACD, PLF, and reconstruction with total disc replacement.

- **American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves (AANS/CNS 2009)**
  
  
  For patients with cervical spondylotic myelopathy (CSM) or ossification of the posterior longitudinal ligament (OPLL), cervical laminectomy with fusion is recommended as an equivalent strategy to laminectomy or laminoplasty and is associated with postoperative neurological improvement. Laminectomy and fusion consistently results in ventral and dorsal cord decompression.

  
  ACD and ACDF produce equivalent clinical outcomes for patients with 1-level cervical disc degeneration. ACDF is recommended over ACD to reduce risk of kyphosis and increase fusion rate for patients with 1-level disease. ACDF is also considered superior to ACD in achieving quicker relief of neck or arm pain, though functional outcomes may be similar.

  Anterior cervical plating (ACDFI) does not improve long-term outcomes in patients with level-1 disease but is considered superior to ACDF in improving arm pain for patients with 2-level cervical disc degeneration. Plating does not improve other clinical outcomes with respect to 2-level disease. For patients with 1-level cervical degeneration, plating is recommended to reduce risk of pseudarthrosis, incidence of graft-related complications, and improve cervical lordosis, but not to improve clinical outcomes alone. Plating may increase surgical blood loss.

Anterior surgical nerve root decompression via ACDF is recommended with patients with cervical radiculopathy for fast relief (3–4 months) of arm or neck pain and/or sensory loss over physical therapy (PT) or immobilization with a cervical collar. Anterior surgical nerve root decompression may also improve long-term functional outcomes relative to PT, including wrist extension, elbow extension, shoulder abduction, and internal rotation. However, recurrent symptoms are common.

- **American College of Occupational and Environmental Medicine (ACOEM, 2011)**
  [http://guideline.gov/content.aspx?id=35207&search=fusion#Section442](http://guideline.gov/content.aspx?id=35207&search=fusion#Section442)
  Cervical discectomy and fusion is recommended to speed recovery in patients with chronic cervical radiculopathy or symptomatic spinal stenosis who continue to have significant functional limitations after 6 weeks of appropriate non-operative therapy. All forms of decompressive surgery, with or without fusion, are recommended in patients with symptoms of cervical myelopathy. Cervical fusion is recommended in patients with degenerative spondylolisthesis or in patients undergoing discectomy for this condition if during the same operative episode as the discectomy.

  Cervical fusion is not recommended for chronic non-specific cervical pain.

- **Work Loss Data Institute (WLDI, 2011)**
  Anterior cervical fusion procedures are considered an option for a variety of chronic neck conditions. Posterior fusion remains under study and is not specifically recommended. Multi-level corpectomy with fusion is considered equivalent to other procedures in patients with cervical myelopathy, although the complication rate with fusion may be somewhat higher. Patients undergoing fusion at the C1-C2 level should refrain from returning to any activity with a risk of reinjury.

- **UpToDate (2012)**
  ACDF and other decompressive procedures should be considered in patients with (1) signs and symptoms of radiculopathy; (2) MRI or CT myelographic evidence of nerve root compression; and (3) persistence of radicular pain despite conservative management of at least 6-12 weeks’ duration. There is little convincing evidence that any one surgical option is superior to another, or that any improve upon the natural history of the condition.

  Surgical consultation is warranted in patients presenting with cervical myelopathy and disabling neurologic deficits, or in patients with mild symptoms who are at risk of neurologic deterioration. There is no evidence to distinguish the relative benefits and risks of fusion techniques, laminoplasty, laminectomy, or corpectomy in patients with cervical myelopathy.
## HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

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

<table>
<thead>
<tr>
<th>Safety Outcomes</th>
<th>Safety Evidence</th>
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<tbody>
<tr>
<td>Mortality</td>
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<tr>
<td>Complications</td>
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<tr>
<td>Hemorrhage</td>
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<td>Nerve Damage</td>
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<td>Paralysis</td>
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<td>Infection</td>
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<td>Hoarseness</td>
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<tr>
<td>Dysphagia</td>
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<td>Thrombosis</td>
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<tr>
<td>CSF Leak</td>
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<tr>
<td>Reoperation</td>
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<tr>
<td>Chronic pain</td>
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<tr>
<td>Adjacent Segment Disease</td>
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<tr>
<td>Pseudarthrosis</td>
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<td>Neurological decline</td>
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<td>Myelopathy</td>
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<td>Muscle weakness</td>
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<td>Paresthesia</td>
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<tr>
<td>Subsequent Rx</td>
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<table>
<thead>
<tr>
<th>Efficacy – Effectiveness Outcomes</th>
<th>Efficacy / Effectiveness Evidence</th>
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<tbody>
<tr>
<td>Treatment success</td>
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<tr>
<td>Special Population / Considerations</td>
<td>Special Population Evidence</td>
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<tr>
<td>------------------------------------</td>
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<tr>
<td>Outcomes</td>
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<td>Age</td>
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<td>Sex</td>
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<td>Race</td>
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<td>Ethnicity</td>
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<td>Disability</td>
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<td>Comorbidities</td>
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<td>Single vs 2-level surgery</td>
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<td>Smoking status</td>
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<td>Treatment setting</td>
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<tr>
<td>Anterior vs Posterior</td>
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<tr>
<th>Cost</th>
<th>Cost Evidence</th>
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<tbody>
<tr>
<td>Cost-effectiveness</td>
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<tr>
<td>Direct cost</td>
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</table>
First Voting Question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

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

<table>
<thead>
<tr>
<th></th>
<th>Unproven (no)</th>
<th>Equivalent (yes)</th>
<th>Less (yes)</th>
<th>More (yes)</th>
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<tbody>
<tr>
<td>Effective</td>
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<tr>
<td>Safe</td>
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<tr>
<td>Cost-effective</td>
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Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

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

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

Second Vote
Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, it is

_____ Not Covered _____ Covered Unconditionally _____ Covered Under Certain Conditions

Discussion Item
Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.
Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

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

Efficacy Considerations:
- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests’ accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?
**Safety**

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

**Cost Impact**

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

**Overall**

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